Sudan University of Since and Technology

Collage of Graduate Studies

Total Quality and Excellence Center

The Impact of Quality Tools on Improving Intravenous Infusion Quality and Reducing Defect Rate

Case Study: Ain Sudan Company

أثر أدوات ضبط الجودة في تحسين جودة المحاليل الوريدية وتقليل معدل العيوب

دراسة حالة: شركة عين سودان

A Thesis is submitted in Partial Fulfillment of the Requirements for MSc in Total Quality Management and Excellence

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الإستهلال

قال تعالى:

{قَالَ يَا قَوْمِ أَرَأَيْتُمْ إِن كُنتُ عَلَىَ بَيِّنَةٍ مِّن رَّبِّي وَرَزَقَنِي مِنْهُ رِزْقًا حَسَنًا وَمَا أُرِيدُ أَنْ أُخَالِفَكُمْ إِلَى مَا أَنْهَاكُمْ عَنْهُ إِنْ أُرِيدُ إِلاَّ الإِصْلاَحَ مَا اسْتَطَعْتُ وَمَا تَوْفِيقِي إِلاَّ بِاللّهِ عَلَيْهِ تَوَكَّلْتُ وَإِلَيْهِ أُنِيبُ }

صدق الله العظيم

سورة هود (الآية 88)

DEDICATION

Every Challenging work needs Self Efforts as well as guidance of elders specially those who were very close to our hearts.

I dedicate my humble effort to my sweet and loving

Father & mother

Kamal & Amal

Whose affection, love, encouragement and prays of day and night make me able to get such success and honor

I also dedicate this research to my dear brothers

Mohamed & Elfatih

Those who always support and motivate me to reach the top in my life

I dedicate this work & give special thanks to my Pretty sisters ,kind hearted, my inspiration

Nada & Namarig

Nihad and her Sweet, humorous and really amazing Children

Moaz, Mustafa & Nagla

I also dedicate this research to the Soul of my lovely

Sister Nagla

The one who was my bright moon ,my guide when I lost my way

May God bless her with mercy and forgiveness and bring her into Paradise

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ABSTRACT

The main Aims of this Study was to evaluate the role of quality tools on improving intravenous infusion quality and reducing defect rate and identify the seven quality control tools, how they are used to solve problems, their impact on product quality and defect rate and how these tools contribute to continuous improvement, in order to demonstrate this, information has been collected from various sources, Historical data were collected from quality control and quality assurance departments. Data analysis was performed using SPSS ,The product under study was NS due to high rate of defects during production and only physical defects were discussed in this study, Pareto analysis revealed that there were a large number of defects for 20 batches in 2017 equivalent to 6610 defective items, and this quantity decreased by almost half in 2018, when it became 3361 defective items, There were 3 types of defects representing the highest amount in both years (leak, excess plastic and dirty body), so it is recommended to create cause and effect diagram to study each defect separately To identify the root causes and suggest an action plan to avoid it, which means that the use of the seven QC tools has a positive Impact on the defect rate. To study the effect of these tools on quality, a control chart for the batches produced in 2017 was created for both primary and final product samples to monitor the level of product quality in terms of an assay and pH and they were always under control and this means that the use of these tools has a positive impact on quality. According to using the scatter plot to determine the type of relationship between the defect rate and the product yield, it was found that there was a complete inverse relationship between them. finally, to find out whether the use of these tools contributes to continuous improvement, the histogram was used as it clearly showed that there is a gradual increase in the produced quantity from one year to the next in the following years(2014, 2015, 2016, 2017) as an effect of applying Seven Quality control tools, increasing was also gradual "in the four quarters for each year separately.

المستخلص

الأهداف الرئيسية لهذه الدراسة تتمثل في تقييم أثر ادوات ضبط الجودة في تحسين جودة المحاليل الوريدية وتقليل معدل العيوب في معرفة أدوات مراقبة الجودة السبع، وكيفية استخدامها في حل المشكلات، وتأثيرها على جودة المنتج ومعدل العيوب وكيف تساهم هذه الأدوات في التحسين المستمر، من أجل إثبات ذلك، قد تم جمع المعلومات من مصادر مختلفة ، تم جمع البيانات التاريخية من قسم مراقبة الجودة وضمان الجودة، تم إجراء تحليل للبيانات باستخدام.SPSSكان المنتج المستخدم في هذه الدراسة NS بسبب ارتفاع معدل العيوب أثناء الإنتاج وقد تمت مناقشة العيوب الفيزيائية فقط في هذه الدراسة، كشف تحليل باريتو أن هناكعددكًبير ً ا من العيوب ل 20 دفعة في عام 2017 بما يعادل 6610 عنصر معيب وانخفضت هذه الكمية إلى النصف تقريبا في عام 2018 حيث اصبحت 3361 عنصر معيب وقد كان هناك 3 أنواع من العيوب تمثل أعلى كمية في كلتا السنتين وهي (تسرب، فائض من البلاستيك والجسم المتسخ) لذا يوصى بإنشاء مخطط للسبب والنتيجة لدراسة كل عيب علي حدا لتحديد الأسباب الجذرية واقتراح خطة عمل لتجنبه، وذلك يعني أن استخدام أدوات مراقبة الجودة السبعة له تأثير إيجابي في معدل العيوب. ولدر اسة تأثير هذه الأدوات على الجودة ،تم إنشاء مخطط التحكم للدفعات المنتجة في عام 2017 لكل من العينات الاولية وعينات المنتج النهائي لمراقبة مستوي جودة المنتج من حيث التركيز والرقم الهيدروجيني وكانا دائما تحت السيطرة وهذا يعني أن استخدام هذه الأدوات له تأثير إيجابي على الجودة. وبناءعلى استخدام مخطط التبعثر لتحديد نوع العلاقة بين معدل المعيب وعائد المنتج وجد أن هناك علاقة عكسية كاملة بينهما. واخيرا" لمعرفة ما إذا كان استخدام هذه الادوات يساهم في التحسين المستمر تم استخدام المدرج التكراري حيث انه وضح بوضوح أن هناك زيادة تدريجية في كمية العناصر المنتجة من سنة إلى أخرى في السنوات التالية (2017،2016،2015،2014) كأثر لتطبيق أدوات ضبط الجودة السبعة، وكانت الزيادة متدرجة ايضا" في الارباع الاربعة لكل سنةعلى حدا.

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LIST OF ABBREVIATIONS

No.	Abbreviation	Stands for
1	ASQ	American Society for quality world health organization
2	WHO	World health organization
3	QC	Quality control
4	CE	Cause and effect
5	IV	Intravenous infusion
6	BFS	Blowing ,filling ,sealing
7	CL	Control limit
8	UCL	Upper control limit
9	LCL	Lower control limit
10	cGMP	Current good manufacturing practice
11	PDCA	Plan ,do ,check ,act
12	JUSE	Japanese union of scientists and engineers
13	LVP	Large Volume Parenteral
14	SMF	Site Master File
15	BP	British pharmacopeia
16	SPSS	Statistical Package for Social Sciences
17	QPR	Quality Price Ratio
18	NS	Normal Saline
19	QA	Quality assurance
20	pH	Scale Logarithmic and inversely indicates the concentration of hydrogen ions in the solution

CHAPTER ONE
INTRODUCTION

INTRODUCTION

This chapter provides the reader with an overview of the entire thesis. It covers the Background to the Study, Problem Statement, Structure, the Purpose of the Study, Research Questions as well as the Overview of Ain Sudan pvt.co in Sudan.

1.1 RESEARCH BACK GROUND

The need to improve quality performance has been the subject of major discussion due to competitive pressure in manufacturing industries.

In order to achieve higher competitiveness level the organization must be able to identify the current quality performance and realign their strategies operations and processes to improve the quality performance.

Seven quality tools is one of many tools that have been found useful to identify the current quality performance by diagnosing the opportunities for improvement and place for improvement action. 7 QC tools Practical Methods of registration and analysis of data is a systematic and scientific method for problem solving, it is used for solving 90% of shop problems very easily. Check Sheet helps in organizing data by category, Pareto Chart is a graphical tool for ranking causes from most significant to least significant, Flow Chart / Process Map graphical tool that shows the major steps in a process, Ishikawa Diagram (Fish-Bone diagram) is a tool for analyzing and illustrating a process by showing the main causes and sub causes that lead to an effect ,Histogram is a graphic summary of a set of data that reveals the amount of variation that a process has within it ,Scatter Diagram is a graphical technique to analyze the relationship between two variables and Control Chart which is A run chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted.

1.2 STATEMENT OF THE PROBLEM

Using the 7 QC tools to identify, analyze and control the major problems exist in the organizations by good implementation of this tools which leads to

increase product quality to suit the needs and expectations of customers, Generally The QC Tools are not used in Sudan or perhaps it used by some Organizations but not at basic manner and used by certain levels of employee. Failure to use the 7QC tools in an organization has a negative impact on product quality, Quality Cost, processes, Profit and Reputation. From my own observation there were high quantity of defects at Ain Sudan IV production lineThis study will determine how 7 QC tools are used to Increase product quality and yield through defect reduction by Identify, analyze and control the major problems exist in production line and laboratories .

1.3 QUESTIONS OF THE STUDY

1. What are the 7 QC Tools?
2. How to use an appropriately7 quality control (7 QC) tools in problem solving?
3. What is The Role of the 7Quality Tools on Quality?
4. What is The Role of the 7 Quality Tools on Defect Rate?
5. What is The Relation between product yield and Defect Rate?

1.4 OBJECTIVES OF THE STUDY

1.4.1 GENERAL OBJECTIVE OF THE STUDY

To investigate the role of using 7QC tools in Quality and Defect Rate.

1.4.2 SPECIFIC OBJECTIVES OF THE STUDY

The study aimed to achieving the following specific objective:

1. to identify the 7QC Tools.
2. To demonstrate how to use an appropriate 7 quality control (7 QC) tools in problem solving.
3. To examine the Impact on product quality and Defect rate.
4. To evaluate the impact of implementing 7 QC tools in quality improvement of product and decrease defective Items of the production line and defect rate reduction at production line in Ain Sudan through using 7QCtools.

1.5 STUDAY HYPOTHESIS

H1: Using the 7 QC tools has positive Impact on quality.

H2: Using the 7 QC tools has positive Impact on Defective Items Quantity.

H2: There is a significant relationship between defect rate and product Yield.

H3: There is significant relationship between using 7 QC tools and the continuous improvement in the organization.

1.6 SIGNIFICANCE OF THE STUDY:

The importance of this research is derived from the role of the seven quality tools in quality level control and defective items quantity provided by production line at AIN SUDAN pvt .ltd .

1.7 THE LIMITS OF THE STUDY

Physical Boundaries

- AIN SUDAN Pvt. Ltd. Co. production line (BFS) and Laboratories.

Product:

- Large Volume Parenteral (LVP).Specifically NS.

Temporal Boundaries:-

- 2019 م

1.8 TERMINOLOGIES OF THE STUDY

Quality: Quality means meeting customer (agreed) requirements, formal and informal, at the lowest cost, first time every time.

Quality control: the operational techniques and activities used to fulfill requirements for quality.

Defect: A product's or service's non fulfillment of an intended requirement or reasonable expectation for use, including safety considerations.

Defective item: unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.

Defect Rate: the percentage of output that fails to meet a quality target.

Specifications: Document that prescribes the requirements with which the product or service had to conform.

1.9 STRUCTURE OF THE STUDY:

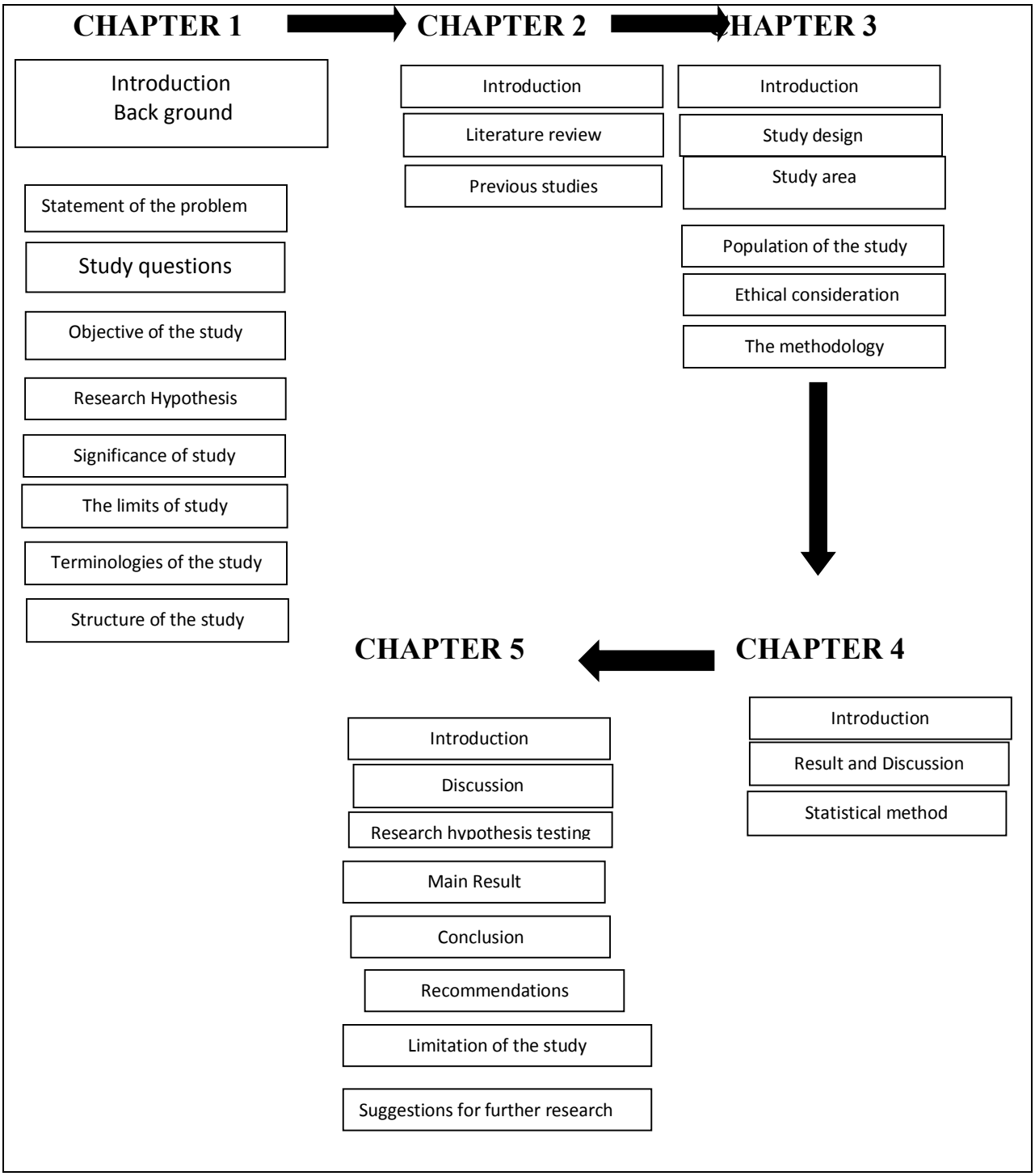


Figure (1.1) Structure of the Study

Source: Researcher

CHAPTER TWO

LITERATURE REVIEW AND PREVIOUS STUDIES

LITERATURE REVIEW AND PREVIOUS STUDIES

2.0 INTRODUCTION

This Chapter Consist of five sections. The first section studies the quality history and definitions; this provides an overview of definition of Quality from different point of views. The second section reviews dimensions of quality. The third section demonstrates quality control definitions.The fourth section reviews the 7QC Tools in details and this could give some ideas on how to use various QC tools and how to use some of them in problem solving and their applications. The fifth section consists of various topics about Ain Sudan Company including brief information about the company, activities at site, types of product, preparation methods, process of production, product dimensions, defective products at production floor and the company quality control system.

2.1 LITERATURE REVIEW

According to Jagdeep and prem(2015)term quality is concerned with the end use of the product. If the finished product meets with the established specifications then the component is said to be of good quality. Quality plays an important role for enhancing productivity. Quality, productivity and cost of operation proportionately rely on each other. To ensure lower rate of rejection, quality of the products need to become better along with the improved productivity. Improvement in quality leads to grow in productivity, which leads to decrease in costs and magnify the market, which helps the company to remain in business.

In addition to that, Pratiket al. (2015) Emphasized that Today industrial area is developing very fast. Every day new concept and ideas are emerging out with their relevance to industry, along with it the problems concerned with the industrial production, quality and customers are also increasing. It is very difficult but also important to maintain the quality of the

product in order to stay in the market and maintain the brand name of the company or firm.

2.1.1Quality definitions

Ibrahim Elshaer(2012) has Concluded that although the term quality is quite widely used by practitioners and academics, there is no generally agreed definition of it, since different definitions of quality are appropriate under different circumstances. (Garvin, 1984; Reeves and Bednar, 1994; Seawright and Young, 1996; Russell and Miles, 1998; Beaumont and Sohal, 1999; Sebastianelli and Tamimi, 2002; Ojasalo, 2006). Indeed, quality has been defined as excellence (Tuchman, 1980), value (Feigenbaum, 1951), conformance to specifications (Shewhart, 1931; Levitt, 1972), conformance to requirements (Crosby, 1979), fitness for use (Juran, 1974; 1988), product desirable attributes (Leffler, 1982), loss avoidance (Taguchi, 1987) and meeting customer expectations (Ryall and Kruithof, 2001; ISO 9000, 2005). Narrow definitions (e.g. conformance to specifications, loss avoidance) are not sufficiently comprehensive to capture the richness and complexity of the concept (Reeves and Bednar, 1995).

In addition to that Ibrahim Elshaer Summarized a number of Quality Definitions as the follow:

1. Quality means “investment of the best skill and effort possible to produce the finest and most admirable results possible....You do it well or you do it half-well....Quality is achieving or reaching for the highest standard as against being satisfied with the sloppy or fraudulent....It does not allow compromise with the second-rate““ Tuchman (1980: 38).
2. Quality is based on the presence or absence of a particular attribute. If an attribute is desirable, greater amounts of that attribute, under this definition, would label that product or service as one of a higher quality, Leffler (1982).

3. Quality is defined as conformance to specifications. Quality of conformance relates to the degree to which a product meets certain design standards Shewhart (1931) and Levitt (1972).
4. Fitness for use. „"the extent to which a product successfully serves the purposes of the user" Juran and Godfrey (1999:2.2).
5. Quality is "best for certain customer conditions". Quality under this definition consists of a product or a service to a customer with certain characteristics at an expectable cost or price. Feigenbaum (1951:10).
6. Quality is „"the loss a product causes to society after being shipped, other than any losses caused by its intrinsic functions. This loss can be caused either by variability in the product's function or by adverse side effects. Taguchi (1987:1).
7. Quality means meeting customer(agreed) requirements, formal and informal, at the lowest cost, first time every time."Customers may be internal or external to the organization. Flood (1993:48).
8. Quality is consistently meeting the continuously negotiated needs and expectations of Customers, in the context of the needs and expectations of other interested parties, in ways that create value and satisfaction for all involved Ryall and Kruithof (2001:20).
9. "Meeting the customer requirements "Oakland(2003: 5).
10. The total features and characteristics of a product or a service made or performed according to specifications to satisfy customers at the time of purchase and during use American society for quality control (2004).
11. All elements of our product that add value for the customer or stakeholders, or are required for our product or service to meet relevant standards and regulations."Kemp (2006:331).
12. "Quality is the extent to which a product or service successfully serves the purposes of the user during usage (not just at the point of sale). Hoyle (2007:10).

13. "Quality has two meanings: 1.the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2. a product or service free of deficiencies". Nelsen and Daniels (2007:54).
14. "A positive attempt by the organizations concerned to improve structural, infrastructural, attitudinal, behavioral and methodological ways of delivering to the end customer, with emphasis on: consistency, improvements in quality, competitive enhancements, all with the aim of satisfying or delighting the end customer. Zairi et al (1994).
15. Degree to which a set of inherent characteristics fulfills requirements UNI EN ISO 9000 (2005:17).
    a. https://asq.org/quality-resources/quality-glossary stated that quality is a subjective term for which each person or sector has its own definition. In technical usage, quality can have two meanings: 1) the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2) a product or service free of deficiencies. According to Joseph Juran, quality means "fitness for use"; according to Philip Crosby, it means "conformance to requirements."

According to Charles S.(1996), Quality Defined as follow :

1. Quality is the search for excellence:
   Quality is a mark of excellence, persistent and maintained over long periods of time. Such excellence is, of course, a function of habits, culture and values, and may thus vary from person to person and from time to time.
2. Anything you can do, I can do better:
   Relative to available alternatives and can be measured and valued by some imputation associated with these alternatives.
3. Quality is in the eye of the beholder:

Quality is then in the eye of the beholden, established over long periods of time by habits, culture and customs which have created 'standards of quality'. In this case, quality is not what we think it is, but what the customer says it is.

It is what our clients think, Peter Drucker, put it in the same terms by stating that it is not what the 'supplier' puts in, but what the consumer takes out and is willing to pay for.

4. Quality is the Proof of the pudding:

   Quality is a variable which can at best be guessed apriority and, perhaps, through successive Experimentation, learning and adaptation, it can be refined and improved.

5. Quality is Value Added

   It is both what the consumer wants and is willing to pay for.

   As a result, quality is not a term that can be defined simply. Rather, itis a composite term, expressed in terms of attributes which define quality by implication. These attributes express:

   The relative desirability of products, items, services

   The potential for substitution and product differentiation, both objective and subjective.

   In this sense, the concept of quality is both objective and subjective, and is based on product and service differentiation, on substitution, as well as on buyer perception and heterogeneity.

6. Quality is not only a cost, it is also a potential benefit, a value added to the manufacturer which can be translated into added sales and profit ability. There are, however, still difficulties in measuring the potential benefits of quality which are essential in inducing managers to take the proper courses of action to improve quality.

7. Quality is not only process-specific, but is a total concept, involving everybody! This is the message of Total Quality Control (TQC). In

other words, the problem is not only the control of statistical variations in a manufacturing process, but the basic question of producing quality in its broadest sense.

In addition to that quality as the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

According to Pratik et al.(2015)Quality means freedom from deficiencies—freedom from errors that require doing work over again (rework) or that result in field failures, customer dissatisfaction, customer claims, and so on. In this sense, the meaning of quality is oriented to costs, and higher quality usually "costs less".

In addition to that Morgen and Malcolm (2013) emphasized that: Today, notions of quality have shifted from producer/provider defined to customer/consumer defined. Producers have an outdated view of 'conformance to requirements', contradicting Deming's heritage. The customer does not care about 'quality' based on a mere removal of non-quality (defects). Customers care about value.

Value = Quality/Price (determined by individual customers)

The notion of quality separated from costs (price) is meaningless to the customer. Either we maximize the value, or we extend quality definition to include the price: Either way we maximize value for the customer. In the end, we have to measure quality and so need its operational definition. Conformance to requirements, norms, standards, or anything else set by bureaucratic auditors directly contradicts the customer's quest for value. The intermediary of bureaucracy mostly adds to the costs and subtracts from the value.

2.1.2Dimensions of quality

Steven et al. (1992) Cleary illustrated The Dimensions of Quality as below: According to Garvin (1984a), "Quality is not a single recognizable characteristic; rather it is multifaceted and appears in many different forms." Consequently, he proposed eight facets or dimensions of product quality.

1. The first dimension, performance, relates to the "primary operating characteristics" of the product. For example, in a sports car speed would be a performance attribute and, there -fore, one of the dimensions used to assess the quality of the sports car .
2. Second, features are secondary characteristic of a product or the "bells and whistles "(Garvin ,1987). Features may be highly visible but not necessarily primary or even important characteristics of the product. A sun roof might be a feature that is used by some customers to assess quality, but it is not instrumental in making performance judgments. Moreover, the distinction between performance and features is ambiguous. As Garvin notes, in many cases the distinction between primary performance characteristics and secondary features is one of relative importance to a particular customer, or user group.
3. Third, reliability indicates the degree to which a product can be counted on to perform as expected and for which the odds of failure are small. Reliability includes such things as mean time to first failure, mean time between failures, and failure rate per unit of time (Garvin, 1987).
4. Fourth, conformance relates to the degree a product's design and operating characteristics match pre-established standards. Does the product conform to standards or do what it is supposed to do? Or, are there frequent disappointments? Examples of conformance failures include lost mail, delays in airline departures, incorrect bank statements, misspelled labels, and shoddy construction (Garvin, 1987).

5. Durability is the fifth dimension and reflects the economic or physical life of the product. It also encompasses concerns over a product's availability: that is, if the product breaks down, can it be brought back into service quickly? Thus, whether or not a product is designed so that repairs can be made simply, and without specialized personnel, should have an impact on perceptions of durability. Durability is also affected by repair costs, the cost of downtime, the relative prices of replacement products, and other economic factors.
6. The sixth dimension, serviceability, is concerned with the ease with which the product can be serviced, the time required for service, the quality of the repair service, and the competence and professionalism of the service personnel.
7. Aesthetics is seventh and refers to attributes that appeal to the senses such as looks, feel, taste, smell, and so on. Aesthetics also recognizes superiority in fit and finish. This dimension is probably the most subjectively evaluated of the eight.
8. Finally, dimension number eight is perceived quality. The perceived quality of a product is concerned more with images originating from advertising, brand identification, and previous experiences than with the actual product characteristics. A product's history and affiliation with superior quality through its market positioning affect its perceived quality. As might be expected, perceived quality is similar to aesthetics in terms of being a very subjective dimension. Both, however, help shape first impressions of product quality and subsequently affect buyer behavior.

   According to Morgen and Malcolm (2013) price is a key dimension of quality (value). QPR increases steadily from lowest to highest as follows:

1. Low quality, high cost: customer's 'world of pain'.

2. Low quality, low cost: ‘paid little, got little’.
3. Good quality, high cost: difficult trade-off, ‘you get what you pay for’.
4. Good quality, low cost: The highest QPR (value), trade-off s-free ‘ideal situation.’

Customers want #4, providers would prefer to deliver #1, and oft en they settle on a compromise of #3, unless . . . Unless customer satisfaction becomes the driving force and purpose of business, and trade-offs-free alternatives become the new norm. So, when people and organizations focus primarily on quality, defined by Deming’s ratio: Quality = Results of work efforts/Total costs, then quality tends to increase and costs fall over time (trade-offs-free). However, when people and organizations focus primarily on costs, costs tend to rise and quality declines over time (trade-off s-based). The New World of Quality relies on new technology, knowledge, and customer sovereignty to move from a trade-offs-based to a trade-offs-free world. In 1990, Marshall Industries CEO, Robert Rodin, trained with the then 90-year-old Deming and achieved a dramatic transformation and growth from $400 million to $1.8 billion. This is chronicled in Deming’s very last book The New Economics, and Rodin’s excellent foresight of trade-off s-free economics in his Free, Perfect, and Now. What is the new definition of quality? Quality of the product or service cannot be satisfactory whenever the customer has to consider and accept trade-offs between four key product dimensions: how designed (fitness), how made (process), how delivered (timing) and how priced (price). So, quality is the process of reducing and removing the trade-offs between fitness, process, timing, and price. The very existence of trade-offs is incompatible with high value. Trade-offs-based quality is only habitual acceptance in a temporary given context. Trade-offs-free quality is the undisputed preference of all consumers. It was W. Edwards Deming who ushered us into the New World of Quality, especially through

his last book. He could not experience it with us and witness its continuing unfolding. But it is on his shoulders that we stand today.

2.1.3 Quality control

As Stated in http://www.businessdictionary.com/definition/quality-control-QC.htmlQuality control is An aspect of the quality assurance process that consists of activities employed in detection and measurement of the variability in the characteristics of output attributable to the production system, and includes corrective responses.

A Concise definition of QC was stated inhttps://asq.org/quality-resources/quality-glossary"Quality Control the operational techniques and activities used to fulfill requirements for quality."

Charles S. (1996) also defined Quality control as: The operational techniques and activities that are used to fulfill requirements for quality.

According to Pratiket.al (2015)QC is more traditional way that businesses have used to manage quality. QC is concerned with checking and reviewing work that has been done. The concept of quality control first originated in Japan after the 2nd world war .Later, the QC concept moved to USA, UK, and other countries and was applied initially in the manufacturing sector. Since then idea of QC has boosted, The 7 QC Tools are simple statistical tools used for problem solving. As Stated inhttps://www.who.int/medicines/areas/quality_safety/quality_assurance/control/en/The term quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical. Such procedures may range from the performance of simple chemical experiments which determine the identity and screening for the presence of particular pharmaceutical substance (thin layer chromatography, infrared spectroscopy, etc.), to more complicated requirements of pharmacopoeial monographs. Activities extend to the area of quality control laboratories

(good laboratory management practices, models, e.g. for certificate of analysis and lists of laboratory equipment, and an external assessment scheme.

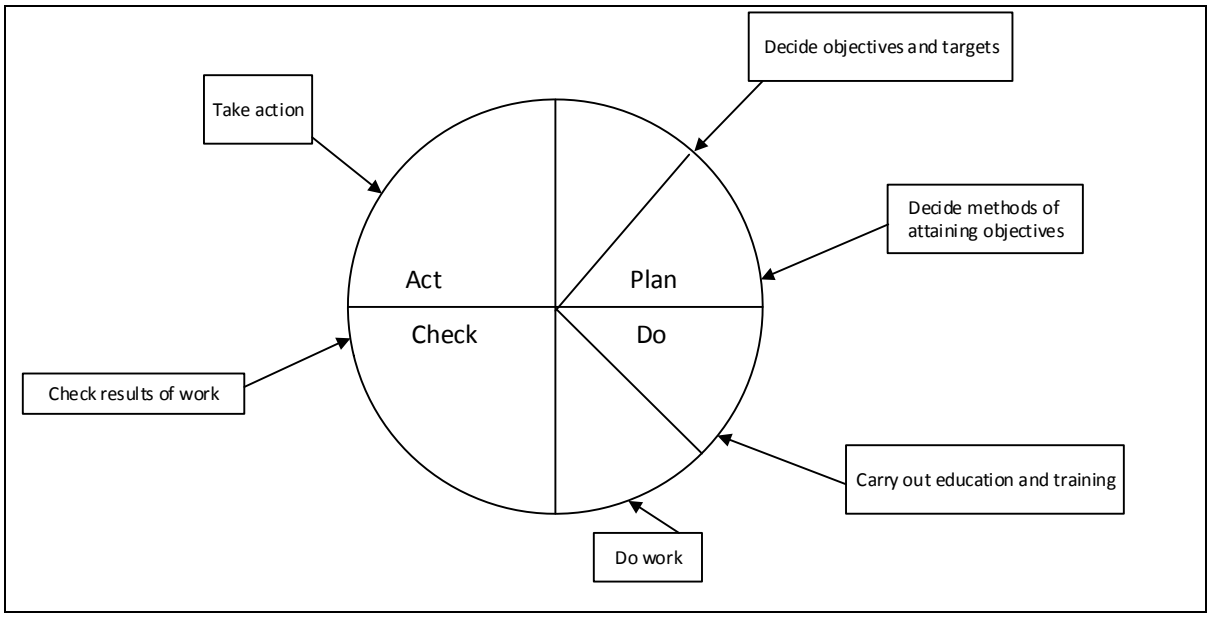


Figure (2.1): the six control steps

Source: Quality Control and Reliability analysis Dr. Brjendra Singh p.5

Plan –do-check-act (PDCA Cycle)

The above is the basic philosophy of control, and control only takes place only when the loops shown in Fig (3) as followed.(Brjendra ,2008).

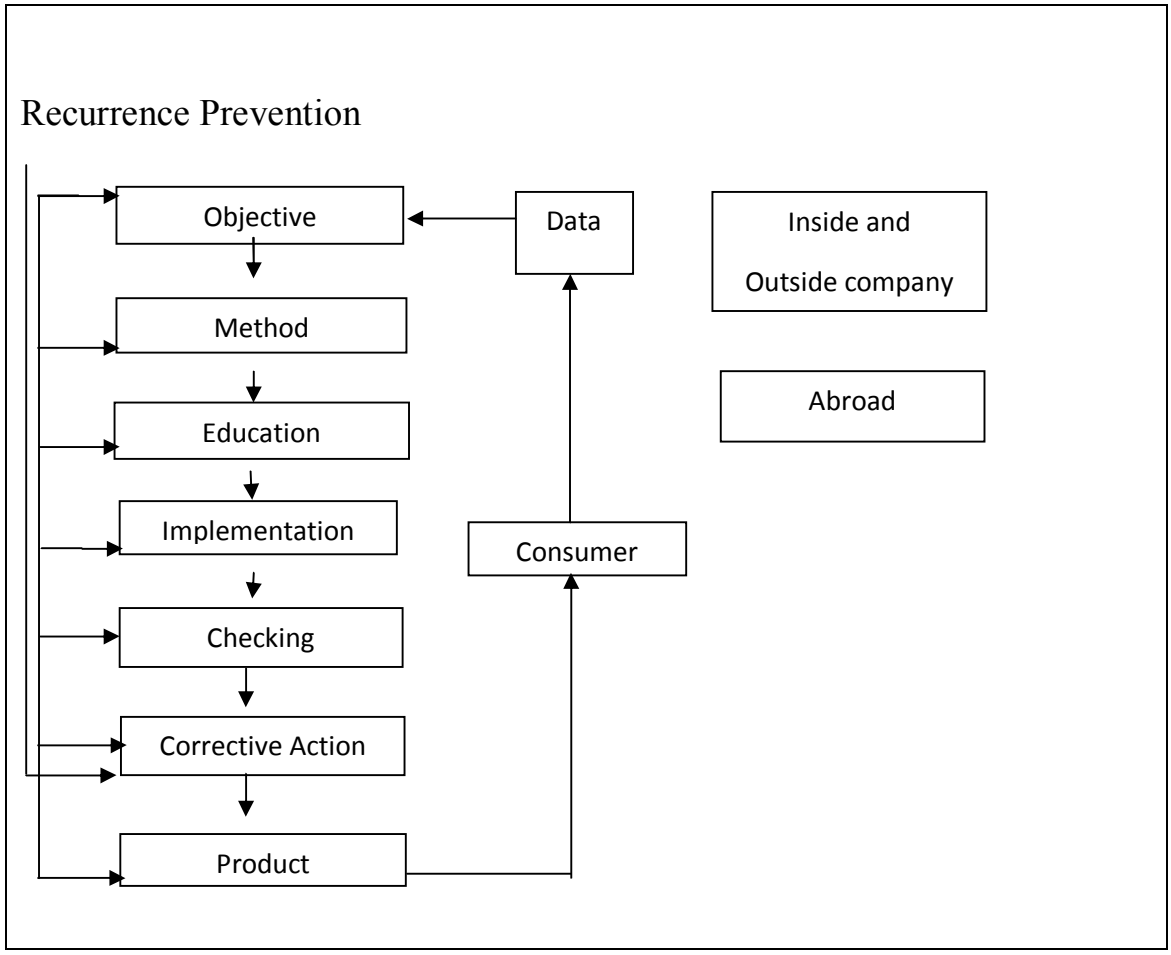


Fig (2.2): cycle of quality control

Source: Quality Control and Reliability analysis Dr. Brjendra Singh p.5

2.1.4 Seven QC Tools:-

2.1.4.1 History

Benjamin(2017)concludes the history of QC ：In 1950, W. Edwards Deming traveled to Tokyo, Japan to deliver a series of lectures to the Japanese Union of Scientists and Engineers (JUSE). Among these was an associate professor, at the University of Tokyo, by the name of Kaoru Ishikawa. Ishikawa took the information and concepts presented by Deming and formalized the Seven Basic Tools of Quality. Control ("Manufacturer's Edge," 2017).Today, the Seven Basic Quality Tools are known as the Seven Quality Concepts (7QC) and are those tools used within the context of the Plan-Do-Check-Act (PDCA) Cycle to solve quality-related problems (PMI, 2013, p. 236).

Also Jagdeep and prem(2015) emphasized that to upgrade the quality of product seven quality control tools (7QC) plays a significant role,these tools are used to recognize, analyze the problem and control the product standards, these tools give the results to avoid the faults which can occur in future. For the successful use of seven quality control tools statistical literacy is necessary. The procedures uses in these Tools are statistical. Seven quality control tools helps to identify any problem in the process, the data arrange in such a way that is easy to analyze and comprehend.

In addition to that Behnam(2017) Introduced that there are seven basic quality tools which can assist an organization for problem solving and process improvements. The first guru who proposed seven basic tools was Dr. Kaoru Ishikawa in 1968, by publishing a book entitled "Gemba no QC Shuho" that was concerned managing quality through techniques and practices for Japanese firms. It was intended to be applied for "self-study, training of employees by foremen or in QC reading groups in Japan. It is in this book that the seven basic quality control tools were first proposed. Valuable resource when applying the seven basic tools(Omachonu and Ross, 2004). These seven basic quality control tools, which introduced byDr. Ishikawa, are:

1) Check sheets.
2) Graphs (Trend Analysis).
3) Histograms.
4) Pareto charts.
5) Cause-and-effect diagrams.
6) Scatter diagrams.
7) Control charts.

According to Parijatet al.(2015) The 7 Quality Control (QC) tools are simple statistical tools used for problem solving. These tools were either developed in Japan, used widely in manufacturing & service sector to

effect continuous process of improvement .Ishikawa believed that95% of quality related problems in any organization can be solved with these basic tools.

In addition to that Benjamin (2017) Concluded that the Seven Quality Concepts (7QC) are a series of tools designed for the everyday person to be able to use. Each tool by itself provides valuable information, but together become an impenetrable wall of quality control to ensure success.

2.1.4.2Seven QC TOOLS DEFINITIONS:

According to R. Jagadeesh(2015)The Seven Quality Control Tools popularly called the 7 QC Tools، comprise graphical methods and help to transform the data into easily understandable diagrams or charts. This further helps to understand the situation or to analyze the problem easily and leads to developing solutions which aim towards quality improvement. Further, these Charts and diagrams help to highlight the important aspects of a problem clearly so that the concerned persons can focus attention on them and start developing the solution. These 7 QC tools can together enable a quality problem to be analyzed and solved and also help to prevent a problem from recurring so that the quality problem is once for all solved.

As stated athttps://asq.org/quality-resources/quality-glossary

Quality Tool: is an instrument or technique to support and improve the activities of quality management and improvement.

Seven Tools of Quality: Tools that help organizations understand their processes to improve them. The tools are the cause and effect diagram, check sheet, control chart, flowchart, histogram, Pareto chart and scatter diagram.

2.1.4.3 SEVEN QUALITYTOOLS ARE:

2.1.4.3.1 Check Sheet

(Behnam, 2017) Defined Check sheets as: Check sheets are simple forms with certain formats that can aid the user to record data in a firm systematically. Data are “collected and tabulated” on the check sheet to record the frequency

of specific events during a data collection period. They prepare a “consistent, effective, and economical approach” that can be applied in the auditing of quality assurance for reviewing and to follow the steps in a particular process. Also, they help the user to arrange the data for the utilization later (Montgomery, 2009; Omachonu and Ross, 2004). The main advantages of check sheets are to be very easily to apply and understand, and it can make a clear picture of the situation and condition of the organization. They are efficient and powerful tools to identify frequently problems, but they don't have effective ability to analyze the quality problem into the workplace.

Defect type	Frequency	Comment
Hanger damage	𝍸 //	
Leak	𝍸	
Water spot	//	
De-Shaped	/	
Excess Plastic	𝍸𝍸 ////	
Particle in solution	𝍸𝍸 /	
Melting Cap	////	
High/Low Volume	//	/ High / low
without rubber	/	
Ring cap	/	
Dirty cap	𝍸 ///	
Dirty body	//	
Other	///	/ flow line // gripper

Figure (2.3): Check sheet (Tally) for defective Item During production
source : researcher + word 2013

As stated in https://hernowo1.wordpress.com/seven-basic-tools-of-quality/the-check-sheet/The check sheet is a simple document that is used for collecting data in real-time and at the location where the data is generated. The document is typically a blank form that is designed for the quick, easy, and efficient recording of the desired information, which can be either quantitative or qualitative. When the information is quantitative, the check sheet is sometimes called a tally sheet.

The purpose of Check sheets, according to Pratiket al, is to allow the user to collect data from a process in an easy, systematic, and organized manner.

1. Defective Item Check Sheet:

This type of check sheet is used to identify what types of problems or defects are occurring in the process. Usually these check sheets will have a list of the defects or problems that may occur in the process. When each sample is taken, a mark is placed in the appropriate column whenever a defect or a problem has been identified. The type of data used in the defective item check sheets is countable data.

2. Defective Location Check Sheet:

This type of check sheets are used to identify the location of the defect on the product. They are used when the external appearance of the product is important. Usually this type of check sheet consists of a picture of the product On this picture, marks can be made to indicate were defects are occurring on the surface of the product.

3. Defective Cause Check Sheet:

This type of check sheet tries to identify causes of a problem of defect. More than one variable is monitored when collecting data for this type of check sheets. For example, we could be collecting data about the type of machine,

Operator, fate, and time on the same check sheet.

4. Checkup Confirmation Check Sheet:

This type of check sheet is used to ensure that proper procedure is being followed. These check sheets usually will have a list of tasks that need to be accomplished before the action can be taken. Examples of checkup confirmation

Check sheets are final inspection, machine maintenance.

Operation checks and service performance check sheets.

2.1.4.3.2 Ishikawa Diagram

Behnam(2017) also emphasized that Kaoru Ishikawa is considered by many researchers to be the founder and first promoter of the 'Fishbone' diagram (or Cause-and-Effect Diagram) for root cause analysis and the concept of Quality Control (QC) circles. Cause and effect diagram was developed by Dr. Kaoru Ishikawa in 1943. It has also other names that are Ishikawa diagram Herringbone diagram ,fishikawa and fishbone because the shape of the diagram looks like the skeleton of a fish to identify quality problems based on their degree of importance (Neyestani, 2017). The cause and effect diagram is a problem-solving tool that investigates and analyzes systematically all the potential or real causes that result in a single effect. On the other hand, it is an efficient tool that equips the organization's management to explore for the possible causes of a problem (Juran and Godfrey, 1998). This diagram can provide the problem-solving efforts by "gathering and organizing the possible causes, reaching a common understanding of the problem, exposing gaps in existing knowledge, ranking the most probable causes, and studying each cause" (Omachonu and Ross,2004). The generic categories of the cause and effect diagram are usually six elements (causes) such as environment, materials, machine, measurement man, and method, as indicated in Figure 4. Furthermore, "potential causes "can be indicated by arrows entering the main cause arrow (Neyestani, 2017).

According toR.Jagadeesh(2015)the Diagram Consists of Two Sides:

1. Cause side – factors that influence the related effect orcharacteristic, and
2. Effect side – represents a problem or an outcome in a given situation or a result.

The two sides are connected by a thick arrow called the trunk. The arrow head leads to the effect side while branches and sub-branches added to the trunk represent the causes responsible for that effect.The major branches added to the trunk represent the main categories of causes and the small and tiny branches represent the sub-category of causes. The branches can be expanded or new branches can be introduced depending on the number of causes.

As Stated on https://blog.minitab.com/blog/understanding-statistics/five-types-of-fishbone-diagramsFish bones help you brainstorm potential causes of a problem--and see relationships among potential causes.

Brainstorming frequently gets a bad rap. Some people have had bad experiences with brainstorming sessions that were too loose, and consequently didn't result in any useful information or ideas. But when it's done in a structured way it's a very useful tool, and can reveal potential causes that wouldn't be immediately obvious.

These diagrams give you a great way to brainstorm within a well-defined structure. You place a central problem, or effect, on the far right of the diagram, then branch "affinities" or types of causes from the spine of the central effect. The specific causes then branch from the affinities.

Paulsen points to the effectiveness of this tool for root cause analysis, or as a way to explore several potential causes of problems, focusing on one particular type of diagram.

2.1.4.3.2.1 Types of fishbone Diagram

There are five different types of fishbone Diagram, each suited to a different challenge or approach.

1. **Simple Fishbone**

   Its basic form, the cause-and-effect diagram has no predetermined affinities, or categories of causes, so you can determine affinities that may be unique to your organization. For example, a public relations firm may have affinities that wouldn't
   be found in a manufacturing operation, and vice versa.

2. **S Fishbone**

   This type of C&E diagram is commonly used in the service industry. It organizes information about potential causes into four common categories: Suppliers, Systems, Surroundings, and Skills.

3. **8P Fishbone**

   This type uses 8 categories: Procedures, Policies, Place, Product, People, Processes, Price, and Promotion. This variation is also commonly used in the service industry, but can certainly be applied in nearly any type of business.

4. **Man Machines Materials Fishbone**

   This variation, commonly used in manufacturing, allows you to organize potential causes of a problem into these categories: Man, Materials, Machine, Methods, Measurements, and Environment. In some cases, two additional categories are included: Management/Money and Maintenance.

5. **Design of Experiments Fishbone**

   A last type of Fishbone diagram allows structured brainstorming about potential factors for a response variable to help you design an experiment. You can use this diagram to organize information about

potential factors of response variables into Controllable, Uncontrollable, Held-Constant, and Block able Nuisance categories

This type of Fishbone that isn't pre-built in to Companion, but it’s incredibly easy to create a new tool template yourself.

2.1.4.3.2.2 fishbone diagram procedure

As stated on https://asq.org/quality-resources/fishbone

Fishbone Diagram is used when identifying possible causes for a problem and When a team’s thinking tends to fall into ruts.

Materials needed: marking pens and flipchart or whiteboard.

1. Agree on a problem statement (effect). Write it at the center right of the flipchart or whiteboard. Draw a box around it and draw a horizontal arrow running to it.
2. Brainstorm the major categories of causes of the problem. If this is difficult use generic headings: Methods,Machines (equipment),People (manpower),Materials

, Measurements and Environment.

3. Write the categories of causes as branches from the main arrow.
4. Brainstorm all the possible causes of the problem. Ask "Why does this happen?" As each idea is given, the facilitator writes it as a branch from the appropriate category. Causes can be written in several places if they relate to several categories.
5. Again ask "Why does this happen?" about each cause. Write sub-causes branching off the causes. Continue to ask "Why?" and generate deeper levels of causes. Layers of branches indicate causal relationships.

6. When the group runs out of ideas, focus attention to places on the chart where ideas are few.

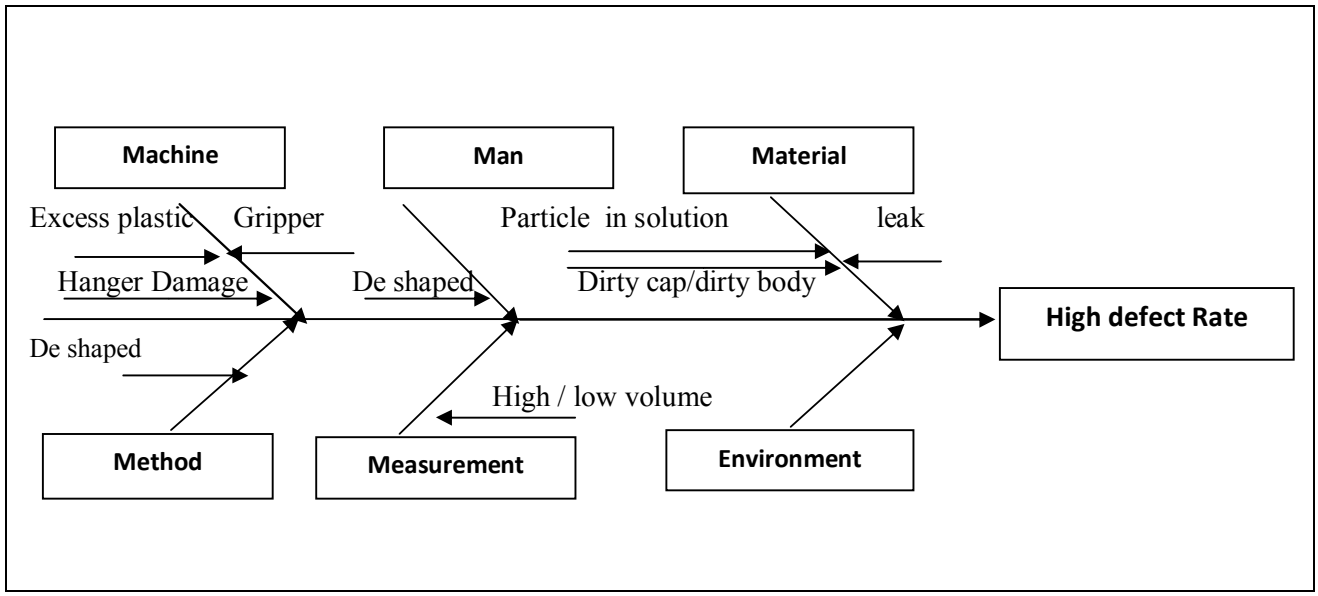


Figure (2.4):high defect rate causes at Ain Sudan production floor

Source: researcher+ word2013

2.1.4 .3.3Histogram

Behnam(2017) defined Histogram as is very useful tool to describe a sense of the frequency distribution of observed values of a variable, It is a type of bar chart that visualizes both attribute and variable data of a product or process, also assists users to show the distribution of data and the amount of variation within a process. It displays the different measures of central tendency (mean, mode, and average). It should be designed properly for those working into the operation process can easily utilize and understand them. Also, a histogram can be applied to investigate and identify the underlying distribution of the variable being explored (Omachonu and Ross, 2004؛ Forbes and Ahmed, 2011). Figure 5 illustrates a histogram of the frequency of defects in a manufacturing process.

Histograms provide a visual interpretation of numerical data by indicating the number of data points that lie within a range of values (Taylor, 2017) ،

.(Data collected is used to describe the tendency with which an issue occurs. In other

Words, the statistical likelihood something will occur. Unlike a control chart, time has no influence over statistical probability (PMI, 2013, p. 238).

The method of histogram creation stated onhttps://asq.org/quality-resources/histogram

And when to use it and histogram Analysis as below:

2.1.4 .3.3.1 When to Use a Histogram

Use a histogram when:

1. The data are numerical
2. You want to see the shape of the data's distribution, especially when determining whether the output of a process is distributed approximately normally
3. Analyzing whether a process can meet the customer's requirements
4. Analyzing what the output from a supplier's process looks like
5. Seeing whether a process change has occurred from one time period to another
6. Determining whether the outputs of two or more processes are different
7. You wish to communicate the distribution of data quickly and easily to others

2.1.4 .3.3.2 How to Create a Histogram

1. Collect at least 50 consecutive data points from a process.
2. Use the histogram worksheet to set up the histogram. It will help you determine the number of bars, the range of numbers that go into each bar, and the labels for the bar edges. After calculating W in Step 2 of the worksheet, use your judgment to adjust it to a convenient number. For example, you might decide to round 0.9 to an even 1.0. The value for W must not have more decimal places than the numbers you will be graphing.
3. Draw x- and y-axes on graph paper. Mark and label the y-axis for counting data values. Mark and label the x-axis with the L values from the

worksheet. The spaces between these numbers will be the bars of the histogram. Do not allow for spaces between bars.

4. For each data point, mark off one count above the appropriate bar with an X or by shading that portion of the bar.

2.1.4 .3.3.3 Histogram Analysis

1.Before drawing any conclusions from your histogram, be sure that the process was operating normally during the time period being studied. If any unusual events affected the process during the time period of the histogram, your analysis of the histogram shape likely cannot be generalized to all time periods.

2. Analyze the meaning of your histogram's shape.

2.1.4 .3.3.4 Typical Histogram Shapes and What They Mean

1. **Normal Distribution**

A common pattern is the bell-shaped curve known as the "normal distribution." In a normal or "typical" distribution, points are as likely to occur on one side of the average as on the other. Note that other distributions look similar to the normal distribution. Statistical calculations must be used to prove a normal distribution.

It's important to note that "normal" refers to the typical distribution for a particular process. For example, many processes have a natural limit on one side and will produce skewed distributions. This is normal—meaning typical—for those processes, even if the distribution isn’t considered "normal."

2. **Skewed Distribution**

The skewed distribution is asymmetrical because a natural limit prevents outcomes on one side. The distribution’s peak is off center toward the limit and a tail stretches away from it. For example, a distribution of analyses of a very pure product would be skewed, because the product cannot be more than 100 percent pure. Other examples of natural limits are holes that cannot be

smaller than the diameter of the drill bit or call-handling times that cannot be less than zero. These distributions are called right- or left-skewed according to the direction of the tail.

3. Double-Peaked or Bimodal

The bimodal distribution looks like the back of a two-humped camel. The outcomes of two processes with different distributions are combined in one set of data. For example, a distribution of production data from a two-shift operation might be bimodal, if each shift produces a different distribution of results. Stratification often reveals this problem.

4. Plateau or Multimodal Distribution

The plateau might be called a "multimodal distribution." Several processes with normal distributions are combined. Because there are many peaks close together, the top of the distribution resembles a plateau.

5. Edge Peak Distribution

The edge peak distribution looks like the normal distribution except that it has a large peak at one tail. Usually this is caused by faulty construction of the histogram, with data lumped together into a group labeled "greater than.

6. CombDistribution

In a comb distribution, the bars are alternately tall and short. This distribution often results from rounded-off data and/or an incorrectly constructed histogram. For example, temperature data rounded off to the nearest 0.2 degree would show a comb shape if the bar width for the histogram were 0.1 degree.

7. Truncated or Heart-Cut Distribution

The truncated distribution looks like a normal distribution with the tails cut off. The supplier might be producing a normal distribution of material and then relying on inspection to separate what is within specification limits from what is out of spec. The resulting shipments to the customer from inside the specifications are the heart cut.

8. Dog Food Distribution

The dog food distribution is missing something—results near the average. If a customer receives this kind of distribution, someone else is receiving a heart cut and the customer is left with the "dog food," the odds and ends left over after the master's meal. Even though what the customer receives is within specifications, the product falls into two clusters: one near the upper specification limit and one near the lower specification limit. This variation often causes problems in the customer's process.

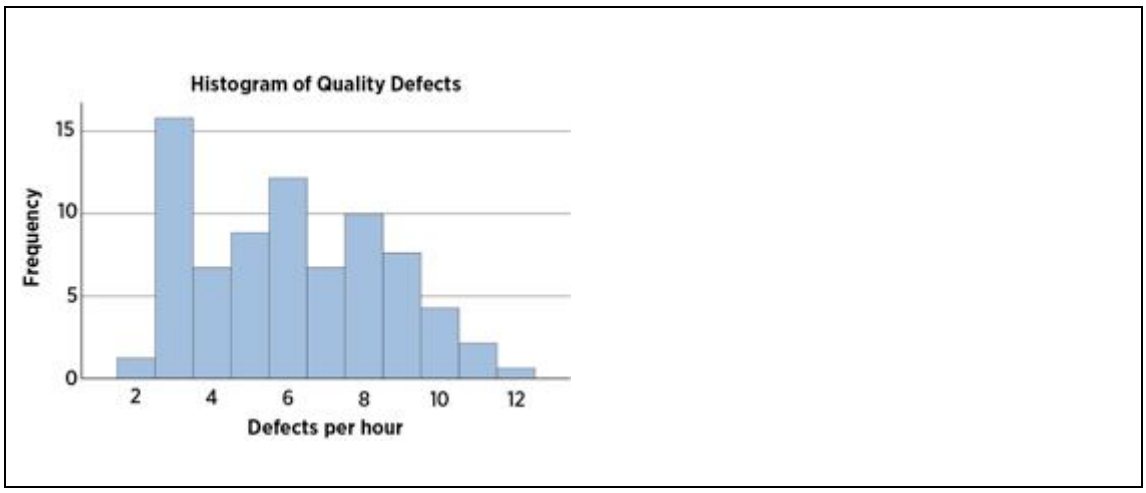


Figure (2.5): histogram of quality defects

Source: https://asq.org/quality-resources/histogram

2.1.4 .3.4Pareto Analysis

According toFaisal et al. (2010)Pareto analysis is a statistical technique in decision-making that is used for the selection of a limited number of tasks that produce significant overall effect. It is one of the most commonly used, and easy to implement method. Pareto analysis is a relatively simple methodology that is used when trying to determine which tasks or factors in an organization will have the most impact (Cervone, 2009). It ranks the data/factors in the descending order from the highest frequency of occurrences to the lowest frequency of occurrences. The total frequency is summed to 100 percent. The "vital few" items occupy a substantial amount (80 percent) of cumulative percentage of occurrences and the "useful many" occupy only the remaining

20 percent of occurrences, which is also known as the 80-20 rule developed by the Italian Economist Vilfredo Pareto(Karuppusami and Gandhinathan, 2006).The results of a Pareto analysis are typically represented through a Pareto cart. The chart represents the various factors under consideration in ranked order.

The presentation of this chart is in the form of a paragraph in descending order and helps to predict easily which factors are vital few by providing a clear indicator through superimposing a line graph that cutsan 80 percent cumulative percentage and also helps in determining those factors which have least amount of benefits and vice-versa. Joseph Juran extended this concept and found it to be applicable in a broad array of aspects in everyday life (Cervone, 2009).

Behnam (2017) case also involved Pareto Analysis which It introduced by an Italian economist, named Vilfredo Pareto, who worked with income and other unequal distributions in 19th century, he noticed that 80% of the wealth was owned by only 20% of the population. Later, Pareto principle was developed by Juran in 1950. A Pareto chart is special types of histogram that can easily be apply to find and prioritize quality problems, conditions, or their causes of in the organization (Juran and Godfrey, 1998). On the other hand, it is a type of bar chart that shows the relative importance of variables, prioritized in descending order from left to right side of the chart. The aim of Pareto chart is to figure out the different kind of "nonconformity" from data figures, maintenance data, repair data; parts scrap rates, or other sources. Also, Pareto chart can generate a mean for investigating concerning quality improvement, and improving efficiency ,"material waste, energy conservation, safety issues, cost reductions", etc., as Figure7 demonstrated concerning Pareto chart, it can able to improve the production before and after changes(Montgomery, 2009; Kerzner, 2009;Omachonu and Ross, 2004).

https://asq.org/quality-resources/pareto stated that A Pareto chart is a bar graph. The lengths of the bars represent frequency or cost (time or money), and are arranged with longest bars on the left and the shortest to the right. In this way the chart visually depicts which situations are more significant; also it stated when to Use a Pareto Chart, the Procedure to create it and some Examples of Pareto Chart.

2.1.4 .3.4.1When to Use a Pareto Chart

1. When analyzing data about the frequency of problems or causes in a process.
2. When there are many problems or causes and you want to focus on the most significant.
3. When analyzing broad causes by looking at their specific components when communicating with others about your data.

2.1.4 .3.4.2 Pareto Chart Procedure

1. Decide what categories you will use to group items.
2. Decide what measurement is appropriate. Common measurements are frequency, quantity, cost and time.
3. Decide what period of time the Pareto chart will cover: One work cycle? One full day? A week ؟
4. Collect the data, recording the category each time, or assemble data that already exist.
5. Subtotal the measurements for each category.
6. Determine the appropriate scale for the measurements you have collected. The maximum value will be the largest subtotal from step 5. (If you will do optional steps 8 and 9 below, the maximum value will be the sum of all subtotals from step 5.) Mark the scale on the left side of the chart.
7. Construct and label bars for each category. Place the tallest at the far left, then the next tallest to its right, and so on. If there are many categories with small measurements, they can be grouped as “other“.

8. Calculate the percentage for each category: the subtotal for that category divided by the total for all categories. Draw a right vertical axis and label it with percentages. Be sure the two scales match. For example, the left measurement that corresponds to one-half should be exactly opposite 50% on the right scale.
9. Calculate and draw cumulative sums: add the subtotals for the first and second categories, and place a dot above the second bar indicating that sum. To that sum add the subtotal for the third category, and place a dot above the third bar for that new sum. Continue the process for all the bars. Connect the dots, starting at the top of the first bar. The last dot should reach 100% on the right scale.
10. Steps 8 and 9 are optional but are useful for analysis and communication.

2.1.4 .3.4.3 Pareto Chart Examples

Figure(2.6) shows how many customer complaints were received in each of five categories.

Figure(2.7) takes the largest category, "documents," from Figure 8, breaks it down into six categories of document-related complaints, and shows cumulative values.

If all complaints cause equal distress to the customer, working on eliminating document-related complaints would have the most impact, and of those, working on quality certificates should be most fruitful.

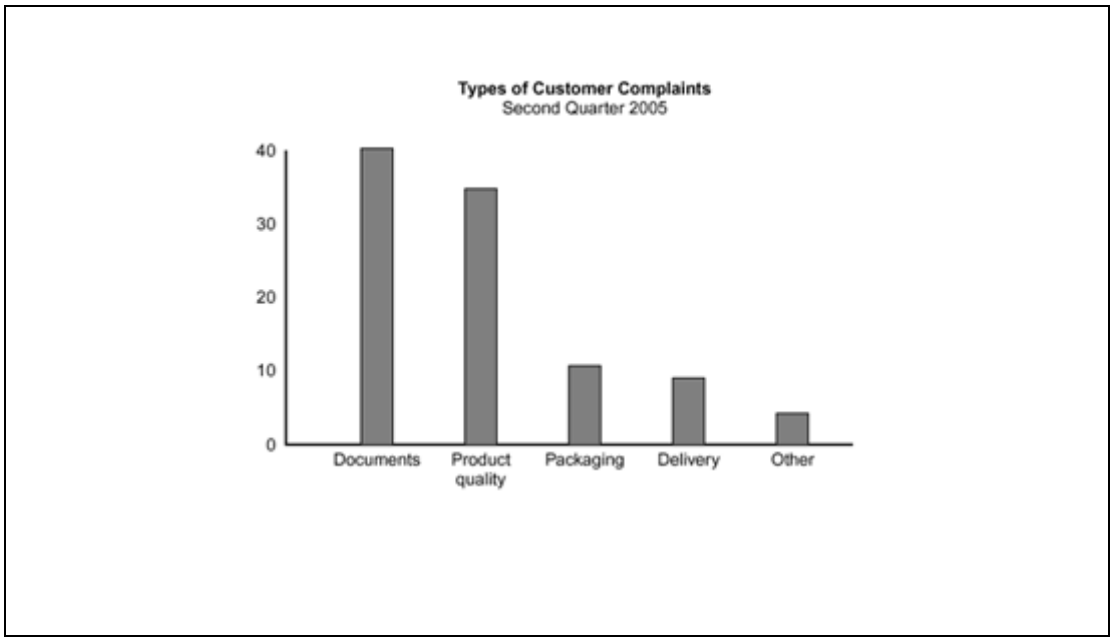


Figure (2.6): types of customer complaint

Source:https://asq.org/quality-resources/pareto

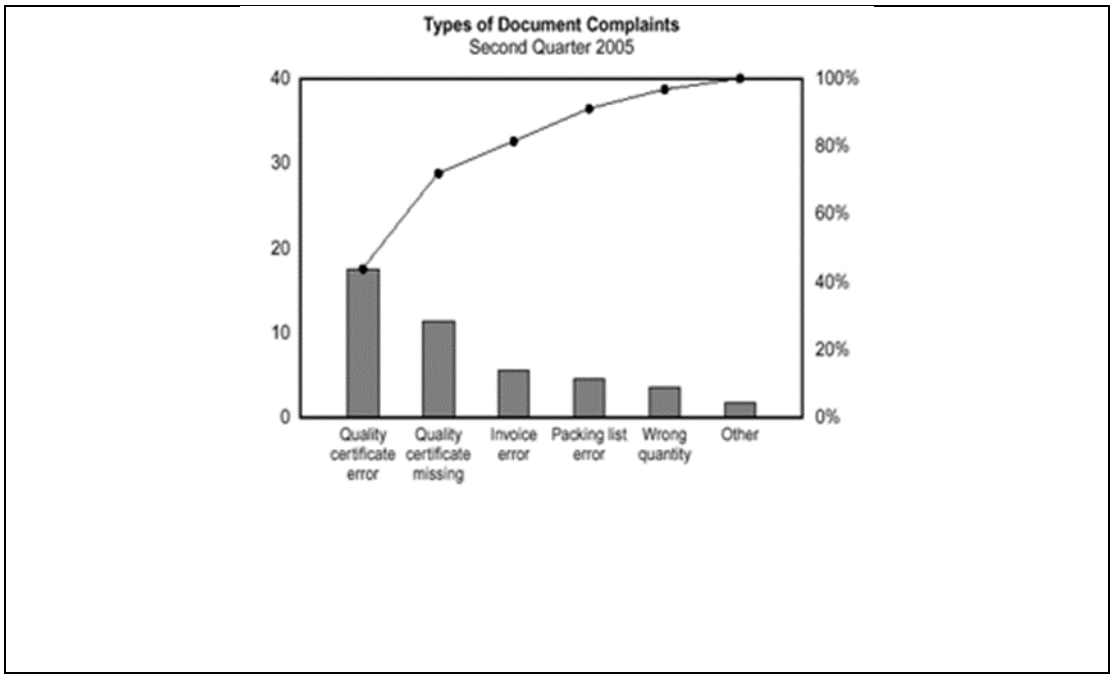


Figure (2.7): types of document complaint

Source:https://asq.org/quality-resources/pareto

2.1.4.3.5 Scatter Diagram

Behnam(2017) also Emphasized that Scatter diagram is a powerful tool to draw the distribution of information in two dimensions, which helps to detect and analyze a pattern relationships between two quality and compliance variables (as an independent variable and a dependent variable), and understanding if there is a relationship between them, so what kind of the relationship is (Weak or strong and positive or negative). The shape of the scatter diagram often shows the degree and direction of relationship between two variables, and the correlation may reveal the causes of a problem. Scatter diagrams are very useful in regression modeling (Montgomery, 2009; Oakland, 2003). The scatter diagram can indicate that there is which one of these following correlation between two variables: a) strong Positive correlation; b) strong Negative correlation, c) No correlation (random pattern) , d) moderate Positive correlation , e) weak Positive correlation , f) moderate Negative correlation ,g) Weak Negative correlation.

As stated at https://asq.org/quality-resources/scatter-diagramScatter diagram also called: X-Y graph, the scatter diagram graphs pairs of numerical data, with one variable on each axis, to look for a relationship between them. If the variables are correlated, the points will fall along a line or curve. The better the correlation, the tighter the points will hug the line, it also Stated when to use a Scatter Diagram, it Procedure, some Examples and Considerations for a Scatter Diagram as below:

2.1.4.3.5.1 When to Use a Scatter Diagram

1. When you have paired numerical data
2. When your dependent variable may have multiple values for each value of your independent variable
3. When trying to determine whether the two variables are related, such as:
    1. When trying to identify potential root causes of problems.

2. After brainstorming causes and effects using a fishbone diagram to determine objectively whether a particular cause and effect are related.
3. When determining whether two effects appear to be related both occur with the same cause.
4. When testing for autocorrelation before constructing a control chart.

2.1.4.3.5.2Scatter Diagram Procedure

1. Collect pairs of data where a relationship is suspected.
2. Draw a graph with the independent variable on the horizontal axis and the dependent variable on the vertical axis. For each pair of data, put a dot or a symbol where the x-axis value intersects the y-axis value. (If two dots fall together, put them side by side, touching, so that you can see both.)
3. Look at the pattern of points to see if a relationship is obvious. If the data clearly form a line or a curve, you may stop because variables are correlated. You may wish to use regression or correlation analysis now. Otherwise, complete steps 4 through 7.
4. Divide points on the graph into four quadrants. If there are X points on the graph:
5. Count X/2 points from top to bottom and draw a horizontal line.
6. Count X/2 points from left to right and draw a vertical line.
7. If number of points is odd, draw the line through the middle point.
8. Count the points in each quadrant. Do not count points on a line.
9. Add the diagonally opposite quadrants. Find the smaller sum and the total of points in all quadrants.

   A = points in upper left + points in lower right

   B = points in upper right + points in lower left

Q =the smaller of A and B

N = A + B

10. Look up the limit for N on the trend test table.
11. If Q is less than the limit, the two variables are related.
12. If Q is greater than or equal to the limit, the pattern could have occurred from random chance.

2.1.4.3.5.3 Scatter Diagram Examples

1. Variable A is the temperature of a reaction after 15 minutes. Variable B measures the color of the product. You suspect higher temperature makes the product darker. Plot temperature and color on a scatter diagram.
2. Variable A is the number of employees trained on new software, and variable B is the numbers of calls to the computer help line. You suspect that more training reduces the number of calls. Plot number of people trained versus number of calls.
3. To test for autocorrelation of a measurement being monitored on a control chart, plot this pair of variables: Variable A is the measurement at a given time. Variable B is the same measurement, but at the previous time. If the scatter diagram shows correlation, do another diagram where variable B is the measurement two times previously. Keep increasing the separation between the two times until the scatter diagram shows no correlation.

2.1.4.3.5.4 Scatter Diagram Considerations

1. Even if the scatter diagram shows a relationship, do not assume that one variable caused the other. Both may be influenced by a third variable.
2. When the data are plotted, the more the diagram resembles a straight line, the stronger the relationship.

3. If a line is not clear, statistics (N and Q) determine whether there is reasonable certainty that a relationship exists. If the statistics say that no relationship exists, the pattern could have occurred by random chance.
4. If the scatter diagram shows no relationship between the variables, consider whether the data might be stratified.
5. If the diagram shows no relationship, consider whether the independent (x-axis) variable has been varied widely. Sometimes a relationship is not apparent because the data do not cover a wide enough range.

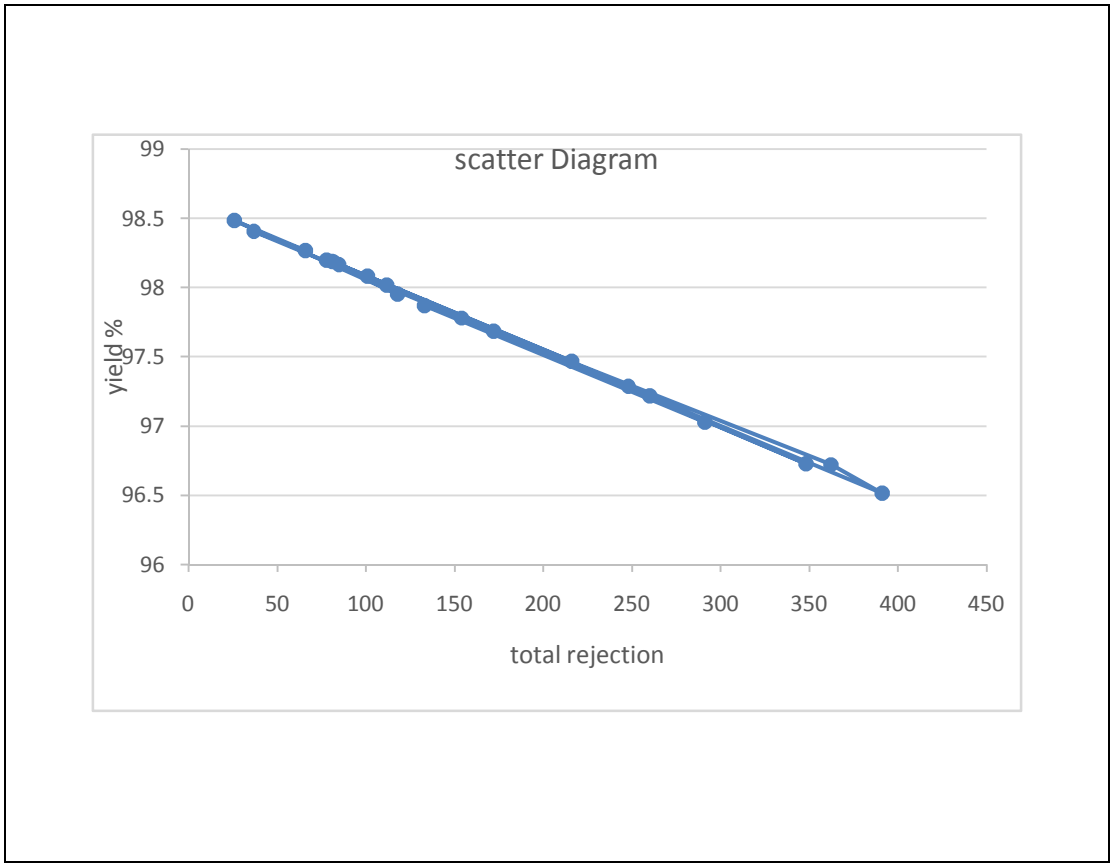


Figure (2.8): Scatter Diagram for total yield and total rejection (Strong Negative correlation)

Source: researcher + excel 2013

2.1.4 .3.6FLOWCHART

Behnam(2017) conclude that Flowchart presents a diagrammatic picture that indicates a series of symbols to describe the sequence of steps exist in an operation or process. On the other hand, a flowchart visualize a picture including the inputs, activities, decision points, and outputs for using and understanding easily concerning the overall objective through process. This chart as a problem solving tool can apply methodically to detect and analyze the areas or points of process may have had potential problems by "documenting" and explaining an operation, so it is very useful to find and improve quality into process (Forbes and Ahmed, 2011).

As stated on http://profsite.um.ac.ir/~ahad/QualityTools.pdfA flow chart shows the steps in a process i.e., actions which transform an input to an output for the next step. This is a significant help in analyzing a process but it must reflect the actual process used rather than what the process owner thinks it is or wants it to be. The differences between the actual and the intended process are often surprising and provide many ideas for improvements, In making a flow chart, the process owner often finds the actual process to be quite different than it was thought to be. Often, non-value-added steps become obvious and eliminating these provides an easy way to improve the process. When the process flow is satisfactory, each step becomes a potential target for improvement. A danger in flow charting is the use of assumed or desired steps rather than actual process steps in making the chart. The utility of the chart will correlate directly to its accuracy. Another danger is that the steps plotted may not be under the control of the user. If the analyst does not "own the process" the chart may not be too helpful. It may, however, be quite useful to a process improvement team including all the functions involved.

As it was stated in https://asq.org/quality-resources/flowchartFlowchartalso called: process flowchart, process flow diagram, A flowchart is a picture of the separate steps of a process in sequential order. It is a generic tool that can

be adapted for a wide variety of purposes, and can be used to describe various processes, such as a manufacturing process, an administrative or service process, or a project plan.

Elements that may be included in a flowchart are a sequence of actions, materials or services entering or leaving the process (inputs and outputs), decisions that must be made, people who become involved, time involved at each step, and/or process measurements, this website also provide a detailed explanation of when to use a Flowchart, procedure to illustrate a flow chart, Flowchart Considerations and the common Symbols which are used in Flowcharts as shown below:

2.1.4 .3.6.1 When to Use a Flowchart

1. To develop understanding of how a process is done.
2. To study a process for improvement.
3. To communicate to others how a process is done.
4. When better communication is needed between people involved with the same process.
5. To document a process.
6. When planning a project.

2.1.4 .3.6.2 Flowchart Basic Procedure

2.1.4.3.6.2.1 Materials needed: Sticky notes or cards, a large piece of flipchart paper or newsprint, and marking pens.

1. Define the process to be diagrammed. Write its title at the top of the work surface.
2. Discuss and decide on the boundaries of your process: Where or when does the process start? Where or when does it end? Discuss and decide on the level of detail to be included in the diagram.
3. Brainstorm the activities that take place. Write each on a card or sticky note.
4. Arrange the activities in proper sequence.

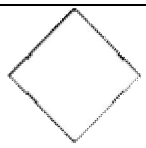
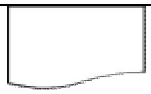
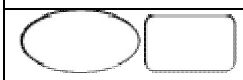
5. When all activities are included and everyone agrees that the sequence is correct, draw arrows to show the flow of the process.
6. Review the flowchart with others involved in the process (workers, supervisors, Suppliers, customers) to see if they agree that the process is drawn accurately.

2.1.4.3.6.3 Flowchart Considerations

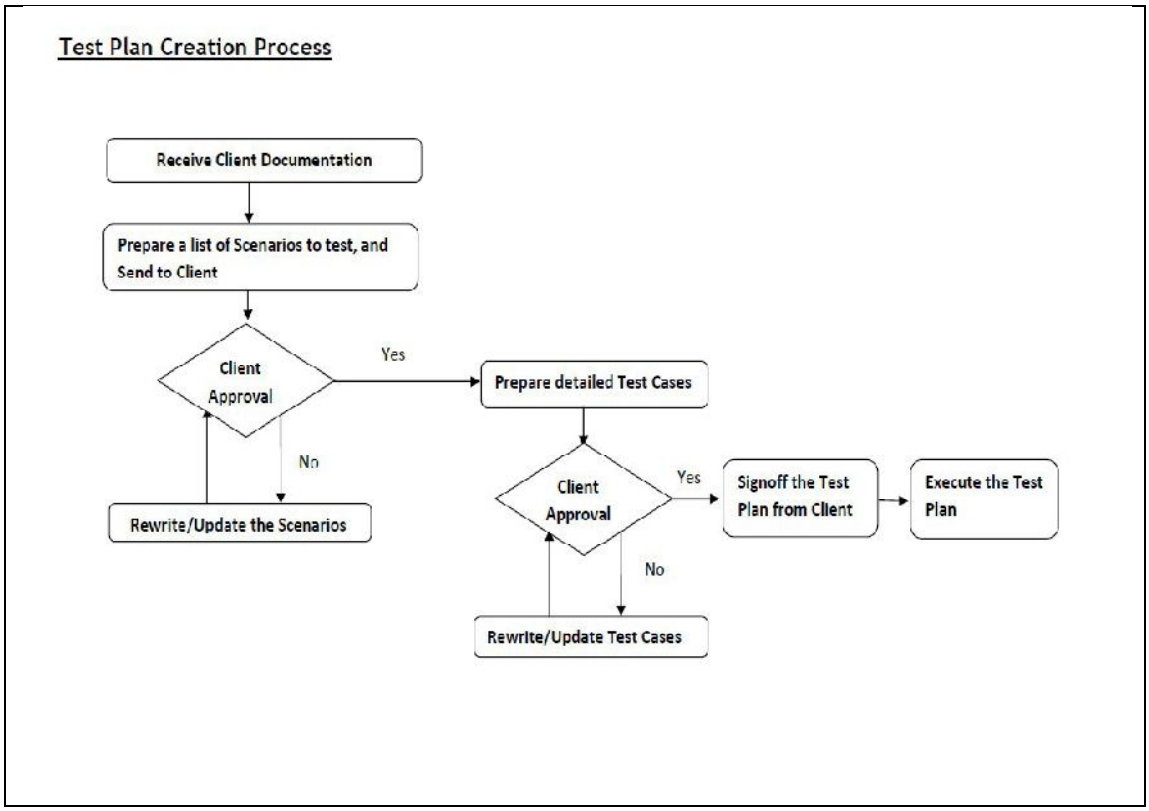
1. Don’t worry about drawing the flowchart the "right way." Ultimately, the right way is the way that helps those involved understands the process.
2. Identify and involve in the flowcharting process all key people involved with the process. This includes suppliers, customers, and supervisors. Involve them in the actual flowcharting sessions by interviewing them before the sessions and/or by showing them
3. The developing flowchart between work sessions and obtaining their feedback.
4. Do not assign a "technical expert" to draw the flowchart. People who actually perform the process should do it.

2.1.4.3.6.4 Commonly Used Symbols in Flowcharts

Table (2-1): Flowchart Symbols

Symbol	Using
	One step in the process. The step is written inside the box. Usually, only one arrow goes out of the box.
	Direction of flow from one step or decision to another.
	Decision based on a question. The question is written in the diamond. More than one arrow goes out of the diamond, each one showing the direction the process takes for a given answer to the question. (Often the answers are "yes" and "no.")
	Delay or wait
	Link to another page or another flowchart. The same symbol on the other page indicates that the flow continues there.
	Input or output
	Document
	Alternate symbols for start and end points

Source: https://asq.org/quality-resources/flowchart



Figure(2.9): Flow chart of review process

Source: Behnam 2017

Also we find that the levels and types of flow chart are demonstrated in https://www. edrawsoft.com/flowchart-tutorial.html as below:

2.1.4.3.6.5 Levels of Flowchart Detail

When you develop a flowchart, consider how it will be used and the amount and kind of information needed by the people who will use it. This will help you determine the level of detail to include.

1. Macro Level. The top leadership may not need the amount of detail required by the workers in a process. A big picture or macro-level view of the process may be enough for their purposes. Generally, a macro-level flowchart has fewer than six steps. Think of it as a view of the ground from an airplane flying 30,000 feet above sea level.
2. Mini Level. The term (mini or midi) is used for a flowchart that falls between the big picture of the macro level and the fine detail of the micro

level. Typically, it focuses on only one part of the macro-level flowchart. Using the airplane analogy, you see the level of detail as if looking at the ground from 10,000 feet above sea level.

3. Micro level. People trying to improve the way a job is done need a detailed depiction of process steps. The micro-level or ground level view provides a very detailed picture of a specific portion of the process by documenting every action and decision. It is extensively used to chart how a particular task is performed.

2.1.4.3.6.6 Types of Flowcharts

Besides the three levels of detail used to categorize flowcharts, there are three main types of flowcharts: linear, deployment, and opportunity. The level of detail can be depicted as macro, mini, or micro for each of these types.

The viewgraphs that accompany the explanation below will show how one process produce the Plan of the Day (POD), which might be depicted using one of the following three flowchart types:

1. **Linear flowchart** a linear flowchart is a diagram that displays the sequence of work steps that make up a process. This tool can help to identify rework and redundant or unnecessary steps within a process.
2. **Deployment flowchart** a deployment flowchart shows the actual process flow and identifies the people or groups involved in each step. Horizontal lines define customer-supplier relationships. This type of chart shows where the people or groups fit into the process sequence, and how they relate to one another throughout the process.
3. **Opportunity flowchart** an opportunity flowchart, a variation of the basic linear type, differentiates process activities that add value from those that increase cost only.
4. **Value-added steps** (VA) are essential for producing the required product or service. In other words, the output cannot be produced without them.

5. **Cost-added** only steps are not essential for producing the required product or service. They may be added to a process in anticipation of something that might go wrong, or because of something that has gone wrong. For example, end-of-process inspection might be instituted because of defects, errors, or omissions that occurred in the past. Other CAO steps may depend on actions in supplier processes, for instance, waiting for approvals or the availability of equipment.

2.1.4.3.7 Control Chart

Behnam(2017) mentioned in his case that Control chart or Shewhart control chart was introduced and developed by Walter A. Shewhart in the 1920s at the Bell Telephone Laboratories, and is likely the most "technically sophisticated" for quality management(Montgomery, 2009). Control charts are a special form of "run chart that illustrates the amount and nature of variation in the process over time". Also, it can draw and describe what has been happening in the process. Therefore, it is very important to apply control chart, because it can observe and monitor process to study process that is in "statistical control" (No problem with quality) accordant to the samplings or samplings are between UCL and LCL (upper control limit (UCL) and the lower control limit (LCL)). "Statistical control" is not between UCL and LCL, so it means the process is out of control, then control can be applied to find causes of quality problem, as shown in the Figure below that a point is in control and B point is out of control. In addition, this chart can be utilized for estimating "the parameters" and "reducing the variability" in a process (Omachonu and Ross, 2004). The main aim of control chart is to prevent the defects in process. It is very essential for different businesses and industries, the reason is that UN satisfactoriness products or services are more costly than spending expenses of prevention by some tools like control charts (Juran and Godfrey, 1998).A Control Chart is presented in the following Figure.

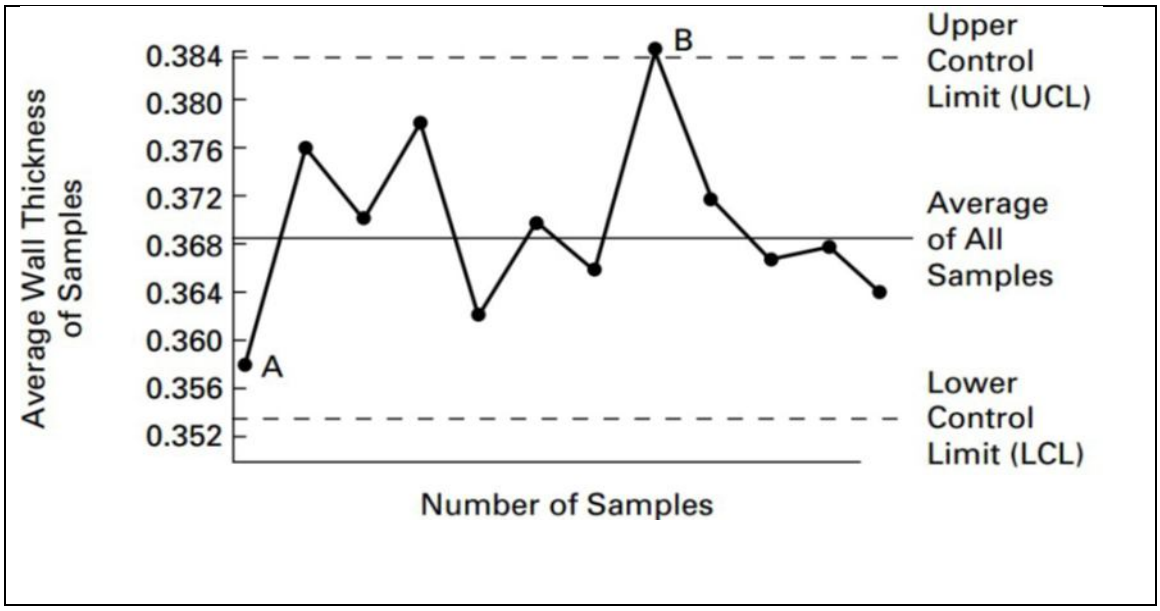


Figure (2.10): The Shewhart control chart

Source: Behnam(2017)

R. Jagadeesh(2015) stated that A control chart is a line graph used to assess and validate the stability of a process, The graph consists of a horizontal center line and twoparallel lines called upper control limit and lower control drawn on either side of the center line. Data pertaining to quality characteristics collected over a period of time and the values are plotted as points on the graph in the chronological order. The points are connected by straight lines. The spread and position of the points on the graph relative to the center line and the control limits indicate the state of control of the process. They also help in distinguishing the random causes from the assignable causes which need to be investigated further. When all the points are within the control limits, and these points do not exhibit any abnormal pattern, then the underlying process is said to be under statistical control. In such cases no action may be necessary and the process is allowed to continue. If the points fall outside the control limits or display any abnormal pattern, then the process is deemed to be out of control and under the influence of special causes. In such cases the process would be stopped and investigated for causes. Then the required corrective action is taken and the process is

continued .The control charts used in industries are divided into two groups namely Control charts for variables, and Control charts for attributes.

As it mentioned in https://asq.org/quality-resources/control%20chart control chart Also called: She chart, statistical process control chart, the control chart is a graph used to study how a process changes over time.

Data are plotted in time order. A control chart always has a central line for the average, an upper line for the upper control limit, and a lower line for the lower control limit. These lines are determined from historical data. By comparing current data to these lines, you can draw conclusions about whether the process variation is consistent (in control) or is unpredictable (out of control, affected by special causes of variation). This versatile data collection and analysis tool can be used by a variety of industries and is considered one of the seven basic quality tools.

Control charts for variable data are used in pairs. The top chart monitors the average, or the centering of the distribution of data from the process. The bottom chart monitors the range, or the width of the distribution. If your data were shots in target practice, the average is where the shots are clustering, and the range is how tightly they are clustered. Control charts for attribute data are used singly.

2.1.4.3.7.1When to Use a Control Chart

1. When controlling ongoing processes by finding and correcting problems as they occur
2. When predicting the expected range of outcomes from a process
3. When determining whether a process is stable (in statistical control)
4. When analyzing patterns of process variation from special causes (non-routine events) or common causes (built into the process)
5. When determining whether your quality improvement project should aim to prevent specific problems or to make fundamental changes to the process.

2.1.4.3.7.2 Control Chart Basic Procedure

1. Choose the appropriate control chart for your data.
2. Determine the appropriate time period for collecting and plotting data.
3. Collect data, construct your chart and analyze the data.
4. Look for "out-of-control signals" on the control chart. When one is identified, mark it on the chart and investigate the cause. Document how you investigated, what you learned, the cause and how it was corrected.

2.1.4.3.7.2.1 Out-of-control signals

1. A single point outside the control limits. In Figure 1, point sixteen is above the UCL (upper control limit).
2. Two out of three successive points are on the same side of the centerline and farther than 2 σ from it. In Figure 1, point 4 sends that signal.
3. Four out of five successive points are on the same side of the centerline and farther than 1 σ from it. In below Figure, point 11 sends that signal.
4. A run of eight in a row are on the same side of the centerline. Or 10 out of 11, 12 out of 14, or 16 out of 20. In Figure 1, point 21 is eighth in a row above the centerline.
5. Obvious consistent or persistent patterns that suggest something unusual about your data and your process.
6. Continue to plot data as they are generated. As each new data point is plotted, check for new out-of-control signals.
7. When you start a new control chart, the process may be out of control. If so, the control limits calculated from the first 20 points are conditional limits. When you have at least 20 sequential points from a period when the process is operating in control, recalculate control limits.

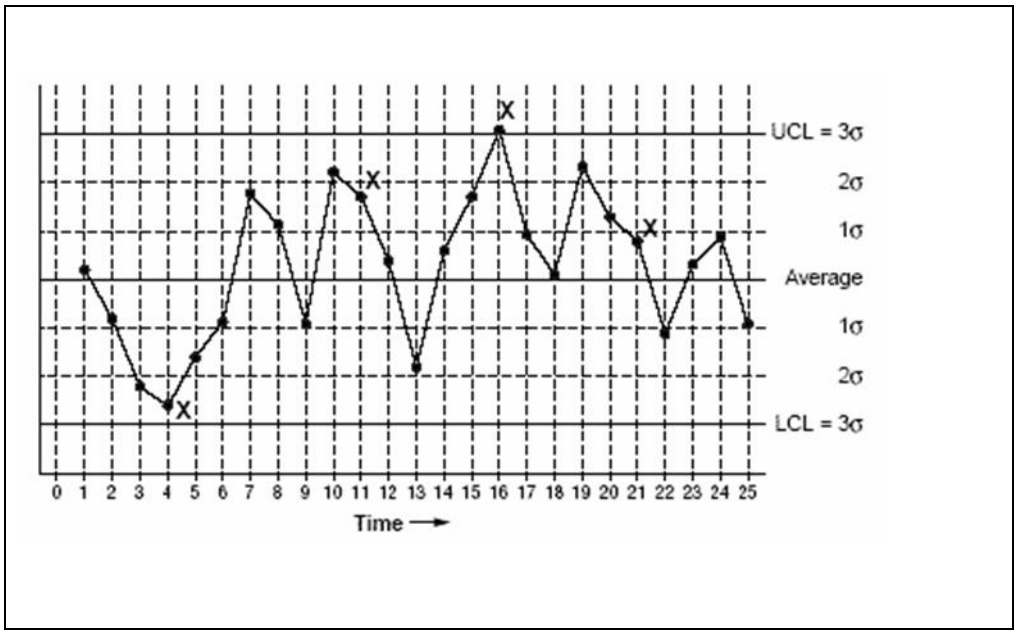


Figure (2.11): Control Chart: Out-of-Control Signals

Source :https://asq.org/quality-resources/control%20chart

2.1.4 .4 Application of 7 QC Tools in Industries

, according to R. Jagadeesh (2015),7QC tools have been used across many types of industries, particularly when the companies embark on a journey of total quality management or continuous improvement. The first step inthe quality improvement drive usually starts from using the 7 QC tools، because these tools provide for data collection, analysis and improvement.In a textile mill while implementing the ISO 9000 standards, the company used these basic quality tools to effectively improve the quality, (Sarkar, 1998).A manufacturing industry used these quality control tools to minimize the variation and to reduce the number of defects, (Escalante, 1999). The use of these tools in a plastics manufacturing company in Portugal (Dias &Saraiva, 2004) reaffirms the use in diverse industries. How these tools are helpful in a process industry can be understood by referring to a case study of a chemical industry, (Paliska, Pavletiæ, &Sokoviæ, 2008).

It should be noted that the basic QC tools can be used from the beginning of the product development process to the last phase of production and delivery

besides the continuous improvement process, (Sokoviæ‹Jovanoviæ, Krivokapiæ, &Vujoviæ, 2009). A cable manufacturing company in Sweden used these tools to increase the electrical resistance in cables thereby saving the copper as the raw material‹Sabet Azad &Mokhlesi, 2009). The application of 7 QC tools in a milk producing cooperative enabled the organization in building a culture of continuous improvement, (Trehan&Kapoor, 2011). How these quality tools are used to study the production processes, find the root cause of the problems and to improve quality in a tire retreading industry indicates the application of these tools in lesser known industries, (Behnam&Alvelos, 2011). In the construction industry‹ for example, the basic quality tools have been used to improve the quality of the processes, save materials, and money, (Aichouni, 2012).

It may be noted that, as a byproduct of the application of these quality tools, the thinking process of the people involved also improves and better analysis is possible, (Magar&Shinde, 2014.(Both Amit and Murugan were surprised to see the diverse application of the basic QC tools and got a clear picture of what needs to be done and how the improvement journey should proceed toward the desired results.

2.1.5 PRODUCT DEFECT RATE

2.1.5.1 Product Definition:

According to S.C. Sharma (2008) a product is the output of any process. This may be (a) goods (b) software (c) service.

2.1.5.2 Defect:

As stated onhttps://asq.org/quality-resources/quality-glossary

Defect A product's or service's non fulfillment of an intended requirement or reasonable expectation for use, including safety considerations, in the same site it mentioned that

A defective unit; a unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.

According to Charles s.(1996) Defectis: The non-fulfillment of intended usage requirements .

S.C.Sharma(2008) emphasized that defect it is non fulfillment of specified requirements, and cover the departure or absence of one or more quality characteristics from intended used requirement.

2.1.5.3 Defect Rate:

The definition of defect rate as was stated at https://www. Collinsdictionary.Com/ dictionary/english/assay

the percentage of output that fails to meet a quality target ,defect rate can be used to Evaluate and control programs ,projects .services and processes.

Calculation:

A defect rate is calculated by the following formula:

Defect rate =(defects/out but tested)× 100

2.1.6 COMPANY BACKGROUND

2.1.6.1BREIF INFORMTION OF THE MANUFACTURER:

Ain Sudan Pvt. Ltd. Co. is one of Sudanese companies which produced pharmaceutics alproducts specifically intravenous infusion ,located at East Giad Industrial City, it has large production line, warehouses and three laboratories for chemical and microbiological tests and instrument calibration.

ACTIVITIES AT SITE

1. Manufacturing Pharmaceutical products.
2. Storing starting material and finished products.
3. Testing raw material and finished products.

TYPE OF PRODUCTS MANUFACTURED

1. Liquid Dosage Forms

1.1 Large Volume Parenteral (LVP) terminally sterilized.

1.2 Non-Sterile Products Hemodialysis Solution.

2.1.6.2 Large Volume Parenteral (LVP)

Parenteral preparations are sterile preparations intended for administration by injection, infusion or implantation into the human or animal body.

Parenteral preparations may require the use of excipients, for example to make the preparation isotonic with respect to blood, to adjust the pH, to increase solubility, to prevent deterioration of the active substances or to provide adequate antimicrobial properties, but not to adversely affect the intended medicinal action of the preparation or, at the concentrations used, to cause toxicity or undue local irritation.

Containers for parenteral preparations are made as far as possible from materials that are sufficiently transparent to permit the visual inspection of the contents, except for implants and in other justified and authorized cases.

Intravenous fluids are medications usually in volumes greater than 100 ml and are called large volume parenterals. The fluids which are administered through the veins must be sterile, particle and pyrogen-free, as well as must carry labels containing the constituents for normal fluid as per the label claims (British Pharmacopoeia،2002).

The fluids which are administered through the veins must be sterile, particle and pyrogen-free, as well as must carry labels containing the constituents for normal fluid as per the label claims (British Pharmacopoeia, 2010).

In order to achieve sterile solution the intravenous solutions subjected to terminal sterilization process by autoclaving; this is done at 107˚C for 45 minutes, delaying inside autoclave or increasing the temperature result in increased the decomposition of dextrose in case dextrose 5%, dextrose 10% and mixture of sodium chloride and dextrose (NSD5) The kinetics of

the decomposition of dextrose have been investigated over a temperature range of 106°C to 127°C.

2.1.6.3 Methods of preparation of sterile products:

As it mentioned in British pharmacopeia (2010) Sterility is the absence of viable micro-organisms. The sterility of a product cannot be guaranteed by testing; it has to be assured by the application of a suitably validated production process. It is essential that the effect of the chosen sterilization procedure on the product (including its final container or package) is investigated to ensure effectiveness and the integrity of the product and that the procedure is validated before being applied in practice. It is recommended that the choice of the container is such as to allow the optimum sterilization to be applied. Failure to follow meticulously a validated process involves the risk of a non-sterile product or of a deteriorated product. Revalidation is carried out whenever major changes in the sterilization procedure, including changes in the load, take place. It is expected that the principles of good manufacturing practice (as described in, for example, the European Community Guide to GMP) will have been observed in the design of the process including, in particular, the use of:

— qualified personnel with appropriate training,

— Adequate premises,

— Suitable production equipment, designed for easy cleaning and sterilization,

— Adequate precautions to minimize the bio burden prior to sterilization,

— validated procedures for all critical production steps,

— Environmental monitoring and in-process testing procedures.

The methods described here apply mainly to the inactivation or removal of bacteria, yeasts and molds. For biological products of animal or human origin or in cases where such material has been used in the production process, it is necessary during validation to demonstrate that the process is capable of the removal or inactivation of relevant viral contamination.

Wherever possible, a process in which the product is sterilized in its final container (terminal sterilization) is chosen. When a fully validated terminal sterilization method by steam, dry heat or ionizing radiation is used, parametric release, that is the release of a batch of sterilized items based on process data rather than on the basis of submitting a sample of the items to sterility testing, may be carried out, subject to the approval of the competent authority.

2.1.6.4 Process of production of intravenous fluids:

Making IV and other sterile solutions is complex and time-intensive, requiring the highest standards in quality and safety.

From the start of the process, the order and receipt of raw material supplies to the delivery of finished product to healthcare providers or patients. To start the process, raw materials that make up IV and other sterile solutions are ordered, processed and inspected. This includes water purified in a multiple step process and many different raw materials. The flexible plastic containers themselves are manufactured as part of the process. Raw materials and water for injection are weighed and mixed to create the solutions. They are sampled and tested then injected into the machine which it called BFS machine (blowing, filling, and sealing) as one step process. The solution is filtered firstly through pre-filter 0.45 micron then followed by 0.22 micron bacteriological free final filter

before filling nozzles. The filtered solution finally filled in a low density polyethylene (LDPE) bottle which is performed in an automatic bottle pack machine that blow, fill and seal the bottle of LDPE in a single continuous operation in area with high cleanliness condition (class A). Then the final products are placed within trolleys and terminally sterilized in counter pressure water cascade autoclave at 107˚C for holding time of 45 minutes (British pharmacopoeia, 2010).

2.1.6.4.1 Blow/fill/seal technology (BFS):

Archana Zala(2015) mentioned that Aseptic blow-fill-seal (BFS) technology is the process by plastic granules are comes under applicable heat which provides different size and shape, at a time products filled with fillers, sterile filtered product are seals in sequence of operations within the controlled sterile environment of a single instrument of production. The blow-fill-seal process is aseptic processing technology, which is accepted by worldwide in the allowed for the industrial engineering aseptic production. Blow-fill-seal systems are providing too much flexibility for packaging and different - different design of product, low economical cost and a high sterility assurance. Due to instruments, minimum number of operating personnel and small space can produce the large number of the production. A variety of polymers may be used in the process, low and high-density polyethylene and polypropylene being the most popular. Low and high density polymer are use in difference types of packaging. The inner sides of packages (which interact with product) are made up of low density polymer and outer side is made up of high density polymers.

2.1.6.4.2Production by BFS Technology

The same author summarized the Production by BFS Technology as below detailed steps.

1. Extruding

The plastic parison, extruded from polymer, is accepted by the opened blow mold and cut below the die of the parison head. Plastic polymer is convert liquid phase to solid phase, which is suitable for input polymer in blow mold and stop the flow of polymer.

2. Molding

The main mold closes and simultaneously seals the bottom. The special mandrel unit settles onto the neck area and forms the parison into a container, using compressed air. Small containers are formed by vacuum.

3. Filling

By way of the special mandrel unit, the product precisely measured by the dosing unit, is filled into the container.

4.Sealing

After the special mandrel unit retracts, the head mold closes and forms the required seal by vacuum.

5.Mold opening

With the opening of the blow mold, the container exits from the machine and the cycle repeats itself Transfer for further processing is achieved by means of conveying. The cycle is then repeated to produce another filled container. The filled containers are tested and checked to ensure that they meet the very strict specifications laid down for such products. The duration of the complete cycle is between 10-18seconds, depending on the container design and the amount of liquid to be filled.

2.1.6.5 PRODUCT QUALITY DIMENSIONS:-

2.1.6.5.1 Normal Saline (NS 0.9% W/V) Product

1.definition of NS product:

Sodium Chloride Intravenous Infusion is a sterile solution of Sodium Chloride 9gin 1 Liter of Water for Injections.

The intravenous infusion complies with the requirements stated under Parenteral Preparations and with the following requirements.

2.Content of sodium chloride, NaCl

95.0 to 105.0% of the stated amount.

3.labeling

The strength is stated as the percentage w/v of Sodium Chloride. The label states that solutions containing visible solid particles must not be used.

When the preparation is intended for intravenous infusion, the label states the approximate concentrations, in mille moles per liter, of the sodium ions and the chloride ions. For a preparation containing 0.9% w/v of Sodium Chloride the concentration of each ion is stated as 150 mille moles per liter.

For concentrated solutions supplied for the preparation of Sodium Chloride Intravenous Infusion by dilution, the label states 'Sterile Sodium Chloride Concentrate' as the title of the preparation.

When Sodium Chloride Intravenous Infusion or Sodium Chloride Injection is prescribed or demanded and no strength is stated, Sodium Chloride Intravenous Infusion (0.9% w/v) shall be dispensed or supplied.

2.1.6.5.2 NS PRODUCT DIMENSIONS:

2.1.6.5.2.1Conformance

As stated on https://en.wikipedia.org/wiki/Eight_dimensions_of_quality

All products and services involve specifications of some sort. When products are developed, these specifications are set and a target is set, for instance the materials used or the dimension of the product. Not only the

target but also the tolerance (the range of permitted deviation from the target) is defined. One problem with this approach is that there is little interest in whether the specifications have been met exactly as long as the tolerance limits are met. On the one hand, this can lead to the so-called "tolerance stack-up". When two or more parts are to be fit together, the size of their tolerances often determine how well they will match. Should one part fall at a lower limit of its specification and a matching part at its upper limit, a tight fit is unlikely. The link is likely to wear more quickly than one made from parts whose dimensions have been centered more exactly. This problem can be addressed by taking a different approach to measuring quality. Instead of measuring a simple conformance to specifications, the degree to which parts or products diverge from the ideal target is measured. Using this approach is better even though some items fall beyond specification limits. The traditional approach would have favored because it produces more items within the specification limit. It was demonstrated that the problem of "tolerance stack-up" is worse when the dimensions of parts are more distant from the target than when they cluster around it, even if some parts fall outside the tolerance. This approach requires a fresh look at the common process quality factor of 'defect rate', to take into account the fact that two parts may each pass the 'tolerance test' separately but be unusable when the attempt is made to join them together.

2.1.6.5.2.1.1NS product Specification:

As stated at https://asq.org/quality-resources/quality-glossary

Specification is Document that states the requirements to which a given product or service must conform. Also, documents that provide requirements, specifications, guidelines or characteristics that can be used to ensure that materials, products, processes and services are fit for their

purpose. Also S.C.Sharma (2008) Defined Specification as it is Document that prescribes the requirements with which the product or service had to conform.

No.	Test		Specification limits
1	Appearance		A colorless Solution
2	Assay		95.0% -105.0 % , 0.855 -0.945 w/v
3	PH		4.5-7.0
4	Particul ate	10 µm	Not more than 25 Particle/ml
		25µm	Not more than 3 Particle/ml
5	Bacterial Endotoxin		Not more than 0.25 IU/ml
6	Sterility		Must Comply

Table (2-2) NS .0.9% w/v Specification

(Source: researcher + British pharmacopoeia, 2010).

In this Study I will focus on pH and assay for normal saline to both in process and finish product samples.

1.pH

The pH is a number which represents conventionally the hydrogen ion concentration of an aqueous solution. For practical purposes, its definition is an experimental one. The pH of a solution to be examined is related to that of a reference solution (pHs) by the following equation:

$PH=pH_s–(E-E_s)/K$

in which E is the potential, expressed in volts, of the cell containing the solution to be examined and Es is the potential, expressed in volts, of the cell containing the solution of known pH (pHs), k is the change in

potential per unit change in pH expressed in volts, and calculated from the Nernst equation.

The potential metric determination of pH is made by measuring the potential difference between 2 appropriate electrodes immersed in the solution to be examined: 1 of these electrodes is sensitive to hydrogen ions (usually a glass electrode) and the other is the reference electrode (for example, a saturated calomel electrode).(British pharmacopoeia, 2010).

2.Assay

An assay is a test of a substance to find out what chemicals it contains. It is usually carried out to find out how purea substance is. This definition was stated in https://www.collinsdictionary.com/dictionary/english/assay

2.1.6.5.2.2 Reliability:

As stated on https://en.wikipedia.org/wiki/Eight_dimensions_of_quality Reliability is the likelihood that a product will not fail within a specific time period. This is a key element for users who need the product to work without fail. This dimension reflects the probability of a product malfunctioning or failing within a specified time period. Among the most common measures of reliability are the mean time to first failure, the mean time between failures, and the failure rate per unit time. Because these measures require a product to be in use for a specified period, they are more relevant to durable goods than to products and services that are consumed instantly. This time was determined by stability study which proves that NS product can be stable for 5 years. (Researcher)

2.1.6.5.2.3Durability:

As stated on https://en.wikipedia.org/wiki/Eight_dimensions_of_quality

Durability measures the length of a product's life. When the product can be repaired, estimating durability is more complicated. The item will be used until it is no longer economical to operate it. Technically, durability can be defined as the amount of use one gets from a product before it deteriorates. Also the durability can be determined by stability study which proves that NS product can be stable for 5 years that mean the shelf life for NS is 5 years so after this period of time the consumer should not use the product. (Researcher).

2.1.6.5.2.4 Ethics

As stated on https://en.wikipedia.org/wiki/Eight_dimensions_of_quality

The aesthetic properties of a product contribute to the identity of a company or a brand. Faults or defects in a product that diminish its aesthetic properties, even those that do not reduce or alter other dimensions of quality, are often causes for rejection. Aesthetics refers to how the product looks feels, sounds, tastes, or smells. It is clearly a matter of personal judgment and a reflection of individual preference. Nevertheless, there appear to be some patterns in consumers' rankings of products on the basis of taste. Ain Sudan products has color full labels, and design team select this color carefully to be appropriate to the segment which use it, for example they select the purple for QSD5 which is given to Children in order to make them more comfortable, also if the label has blue color that means the product contains sodium chloride 9% and the brown color for products which contain dextrose. (Researcher).

2.1.6.6 DEFECTIVE PRODUCTS AT PRODUCTION FLOOR

At Ain Sudan QMS every physical defect during production or transfer from store is segregated or isolated. Rejected components or semi-finished product are clearly identified and the quantity rejected is recorded.(AIN SUDAN SMF)

2.1.6.6.1PRODUCT DEFECTS TYPES

1. Hanger damage
2. Leak
3. Water spot
4. De-Shaped
5. Excess Plastic
6. Particle in solution
7. Melting Cap
8. Dirty cap
9. High/Low Volume
10. without rubber
11. Ring cap
12. gripper

(AIN SUDAN SMF)

2.1.6.7 COMPANY QUALITY CONTROL SYSTEM

2.1.6.7.1 DESCRIPTION OF QUALITY CONTROL SYSTEM

Quality Control System is developed and designed to ensure that products contain the correct materials of specified quality and quantity and are manufactured under specific conditions and follow standard procedures, whereby they consistently meet the established specifications for identify, strength, purity, quality and safety.(AIN SUDAN SMF)

2.1.6.7.2ACTIVITIES OF QUALITY CONTROL DEPARTMENT

1. Quality Control consists of chemical and microbiological laboratory. Quality Control involves all analytical functions conducted in the laboratory, including sampling, inspection and testing of starting materials, in-process and bulk product, finished product and stability testing. It also includes environmental monitoring program, validation test, review of batch documentation, sample retention program and established and maintaining current specifications of material of products and their test method.
2. Tests that are carried out include chemical, microbiological and physical test which ever applicable to the requirement of each item.
3. Ensuring that the quality of products and materials has been satisfactorily judged according to Quality Specifications before products and materials are distributed to customer and released for use.

2.2 PREVIOUS STUDIES

2.2.1PREVIOUS STUDIES USED 7QC TOOLS:

Attention to the issue of quality has increased in recent decades due to its role in the survival of Organizations in the competition race and in the markets. Several researches have touched on the issue of quality and the use of the seven basic quality control tools in diagnosing, analyzing and correcting deviations, if any, in Organizations whether providing services or producing products, especially the Pareto diagram and the cause and effect diagram. Among these researches“ Quality Tools – Systematic Use In Process Industry" which was written by G. PALISKA, D. PAVLETIC, M. SOKOVIC in 2007 aimed to show on practical examples that there is real possibility of application of 7QC tools. They found that how simple

graphical visualization can clearly present data and support decision making process, Analyzing the number of damaged cement bags during transport in the last three business years, it can be concluded that number of damaged bags is in increase-the past and current corrective activates taken within company wasn't successful in solving problem. Furthermore, the research shows to what extent are selected tools in usage and what reasons of avoiding their broader application are. In this research each of 7QC tools had been tested and its applicability in The frame of selected business had been shown, Systematic approach is explained on the example of selected company in process industry which is ISO 9000:2000 certified, Another study on practical application of quality tools by Dr. Duško Pavletić, Dr. mirko soković, M.SC. Glorija Paliska (2008). It investigated possibilities of successful application of 7QC tools in several companies in power generating and process industry as well as government, tourism and health services. It is shown that 7QC tools can be used in all process phases, from the beginning of a product development up to management of a process, on day to day basis, in systematic manner. It also shows, in modern production processes, it is necessary to implement integrated quality management system that involves quality management, responsible environmental performance and safe working environment. Javed Iqbal, Nasir Minhas (2010) explained Usage of SBQTs and their influence on the performance of software development organizations at their study of usage and impact of seven basic quality tools on the organizational performance of software firms. The result of this study was the Analysis of collected data which indicated that most of the software development companies use the Ishikawa's Seven Basic Quality Tools and a deep study of the Indicators of the Organizational Performance proves the fact that usage of these tools has significantly contributed towards the development of the software which are in time, within budget, conforming to the quality standards and congregate

the customer expectations . In addition, Implementation of 7 QC tools by using kaizen approach for SME manufacturing industry is another study of the topic of 7 QC tools. This study was carried out by Lau Ee Shuang in 2012. It aimed to use appropriate 7 quality control (7 QC) tools to analysis data and to improve product quality and performance of production using kaizen approach by reducing or elimination of scrap. Another study which titled The use of traditional management tools in approach of the food waste problems in food industry by Dragan S. Janjušić, Dragan Đ. Psodorov and Snježana M. Gagić in 2012 which was conducted to present a simple solution, based on combination of traditional management tools, for better analysis of causes of return goods (from the market) due to quality in consistent or other similar problems connected with manufacturer. They concluded that the manager could use basic quality management knowledge to overcome some expensive implementation systems, especially in medium or small enterprises. The benefits of that should be less defect products, efficacy production, satisfied customers, money savings and finally less food throwing. Specifically, the implementation of three QC7 techniques: check sheets, histogram and cause and effect chart, will not solve the food waste problems of the food industry in general and create foolproof technological process, but it will certainly provide better focus on problems and sometimes final solutions can be achieved. We find that ChiragkumarS. Chauhan,Sanjay C. Shah Shrikant P. Bhatagalikar also carried out study on using 7QC tools in 2013 titled Quality improvement by applying seven quality control (7 qc) tool in process industry to investigate possibilities of successful application of 7QC tools in several companies in power generating and process industry as well as government, tourism and health services. They concluded that Quality tools has important place in data collecting, analyzing, visualizing and making sound base for data founded decision making. The paper stresses on the use of the seven

basic quality tools to improve processes and to solve problems, also there is other On Study titled the Use of Quality Tools: a case study which was carried by Fábio A. Fernandes, Sérgio D. Sousa in 2013 aimed to use quality tools to improve the level of quality management in an industry in the installation phase. First a diagnostic of quality management functions is made to identify priority areas for quality improvement, later quality tools are used to carry out effective actions to improve quality. This study showed practically why and how quality tools are used framed on the PDCA cycle as an effective support for continuous improvement. Agdeep Singh and Prem Singh (2014) were able to use of SPC tools in the problem analysis in their study Assessment of procurement-demand of milk plant using quality control tools: a case study which was demonstrated figure shows the comparison of three vital causes, which were old plant and machinery, improper production planning and handling losses due to which the loss of milk occurred before and after implementation of the tools. After taking modified action against three vital causes in Procurement – Demand mismatch percentage losses reduced by 42%, 48% and 41% for old plant and machinery, improper production planning and handling losses respectively. Another study of Application of 7 quality control (7 QC) tools for continuous improvement of manufacturing processes was carried by Varsha M. Magar and Dr. Vilas B. Shinde (2014) to provide an easy introduction of 7 QC tools and to improve the quality level of manufacturing processes by applying it. The study showed that Statistical QC is chiefly concerned in making sure that several procedures and working arrangements are in place to provide for effective and efficient statistical processes , to minimize the risk of errors or weaknesses in procedures or systems or in source material , Seven QC tools are most helpful in troubleshooting issues related to quality, All processes are affected by multiple factors and therefore statistical QC tools can be applied to any

process and The continuous use of these tools upgrades the personnel characteristics of the people involved. It enhances their ability to think generate ideas, solve problem and do proper planning. Furthermore Pratik K. Gadre, Devendra P Jadhav, Shivraj GGaikwad and Anirudh V Jadhav(2015)presented a study on use Of Seven Quality tools aimed to Improve quality and productivity In Industry to provide the use of 7-Quality Tools (QC) to improve the quality of products in any industry they conclude that Seven QC tools are most helpful in troubleshooting issues Related to quality. It has been observed that by application of seven Quality tools performance of company has improved drastically by 95%,Selection of Quality control technique has influenced three factors: ease of use of technique, ability to measure product specification fulfillment, ability to improve critical quality and productivity problems, Quality tools has important place in data collecting, analyzing, visualizing and making sound base for data founded decision making, The development of quality tools has been successful in providing customers with more consistent and quality products and In short, 7 Quality Tools have proofed to be useful in enhancing the development of industry. There is also another study about Reduction in Defects of Car Body Panel using 7QC Tools Approach by Parijat Bhangale, Prof. Rajesh Dhake and Prof. Gajanan Gambhire(2015) which aimed to resolve the paint defect on car body panel and to reduce rework and body panel rejection the result after implementing the corrective action plan the count of defective car bodies is reduced from 58 in 1st month to 2 in 4thmonth . The cost incurred in poor quality which is Rs. 245,622 is saved per month, All worker got training on sanding process and methods to ensure that the no defect will pass ahead to next station of shop. The communication channel is established to control the defects and Recalibration of defect severity is done with workers of paint shop, body shop & assembly shop so that no defect will flow ahead

in channel. Further more, implementation of seven tools of Quality in educational arena: a case Study by V.Jayakumar, F.MohammedAjmalsheriff, A.Muniappan ,G.Bharathiraja and G. Ragul I(2017) to highlight the general principles of TQM involved and to point out how this approach has been and can be used to improve the quality of an academic institution. This study concluded that the academic excellence tools carried out in our work can be effectively implemented in the higher educational institutions to enhance the quality of education and thereof students' satisfaction. Another study on Implementation of quality control tools and techniques in manufacturing industry for process improvement was carried out by Heena Sharma and Dr. N.M Suri In(2017) to identify the defect of the company and create a better solution to improve the production line performance on implementation of Quality control tools in manufacturing process in order to eliminate production waste and minimize rejection and rework, improving production performance and to enhance customer satisfactions it deduce that Quality tools i.e. Pareto chart and Cause and effect diagram are used to identify and evaluate different defects and causes for these defects responsible for Rejection/rework of materials at different stages (In process, Final Stage). In the Quality management system Quality tools can be much wider applied with certain success. Quality tools are not so wider spread as expected although they are quite simple for application an easy for interpretations. Quality Control Tools could improve process performance by reducing product variability and improves production efficiency by decreasing scrap and rework, other study on Application of quality tools in manufacturing industries in simple ways: a case study by Avinaw Pratik and Priyanka Kumari in 2017 was conducted to identify the defect and provide solution to improve the quality by using quality tools in this study. Why analysis and Cause and effect diagram are used to identify and evaluate different defects and causes for these defects responsible for

rejection/rework of materials at different stages (In process, Final Stage) using these two techniques to identify the root cause after action taken.The result was found satisfactory.

2.2.2 distinguishes between the current study and previous studies

In order to define what distinguishes this study from previous studies, some comparisons were made, which were presented as follow:

2.2.2.1 In terms of study area:

Previous studies were conducted outside Sudan, whether in Arab, American, Asian or European companies, while the current study was conducted at AIN SUDAN Company in Sudan.

2.2.2.2 In terms of scope:

This study was created at a pharmaceutical company which produces sterile products and its main focus is on NS product. It depends mainly on representative data for product yield and defect rate which were recorded at production section as well as the result of pH and assay from chemical lab.

2.2.2.3 In terms of the objective of the study:

This study differs from previous studies in that it aimed to investigate the role of using 7QC tools in Quality and Defect Rate. It aimed to achieving the following specific objectives: to identify the 7QC Tools, To demonstrate how to use an appropriate 7 quality control (7 QC) tools in problems solving, To prove that 7QC tools have positive Impact on product quality and defect rate, To improve quality of product and decrease defective Items of the production line therefore defect rate reduction at production line in Ain Sudan through using 7QCtools and To Propose Approach or model to help the organizations to use this tools To improve quality of product and decrease defect Rate

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2.2.2.4 In terms of the methodology:

The current study can be considered as an exploratory study based on real data, which was collected from the relevant departments, and then was analyzed based on a set of statistical methods and tools to reach conclusions that serve the objectives of the study.

CHAPTER THREE

METHODOLOGY OF THE RESEARCH

METHODOLOGY OF THE RESEARCH

3.0 INTRODUCTION:

According to Faisal et al. (2013) Research methodology is very important as it can guide researchers on what steps needs to be taken in order to accomplish the objectives of the research (Tsang and Antony,2001; Antony et al., 2002).

In order to accomplish the objective of this research study, an empirical Study was adopted, a historical Data was collected and Recorded then analyzed. Methodology was adopted and was carried out in the selected Departments of AIN SUDAN.

The researcher identified the main statistical source of his field study terms as necessary information and data and his qualification to using an experience in his field of this group consist of tables of product yield , defective items ,pH and assay which has the ability to check and monitor the quality of IV Products in AIN SUDAN company.

In the light of this approach, some types of Seven QC tools will be used.

This section discusses contain study design, study area, population, ethical consideration and methodology which contain Problem Identification, data collection procedures and data analysis used in the study.

3.1 STUDY DESIGN

The study is designed to achieve the objective set by the researcher. The present research uses An Empirical cross-sectional study design. In this study, the method which was adopted to collect data is return to recorded historical data which is commonly used in similar kind of research.

3.2 STUDY AREA

This study was conducted in AIN SUDAN production area and laboratories

Company area: Giad City

Industry: pharmaceutical

Main Products: Intravenous Infusion

3.3 STUDY POPULATION

In this study data was collected directly from two departments QC and QA as follow:

3.3.1 From QA department:

-Represented data for 20 Batch from two consecutive years (2017 and 2018) which include types of defects and their quantity in addition to product yield.

- produced quantities/Bottles for 4 consecutive years (2014, 2015, 2016, 2017)and for the 4 quarters for each year.

3.3.2 From QC department:

- Data for one year 2017 which include pH and assay for produced batches in that year (38 batches).

3.4 ETHICAL CONSIDERATION

1. I got approved from AIN SUDAN General Manager to carry out the study by necessary data and Information needed from QC and QA departments.
2. Information which provided by AIN SUDAN from quality assurance department and laboratories is kept confidential and used only for this study.
3. I deal with the provided data honestly, fairly, respectfully and carefully.

3.5METHODOLOGY

3.5.1 Problem Identification

In AINSUDAN production line (BFS) it was observed that there was large number of rejected products which lead to the decrease the total Yield and the quality of product has been studied depending on the conformity result from quality control department.

3.5.2 Data Collection

3.5.2.1 Data collection Tools

Recorded historical data as well as access to books, Journals, websites and previous studies that benefit the research.

3.5.2.2 Data collection procedure

The data was collected during the period from 05.12.2019 to 08.12.2019 from quality control and quality assurance departments (Historical data) after AIN SUDAN general Manager approved , it collected from annual product review which contain in details batch number ,Manufacturing date ,produced quantities ,yield ,defect types if any and their quantities.

3.6 Data Analysis

By using SPSS program and Excel 2016.

CHAPTER 4

IMPLEMENTATION OF SEVEN QUALITY TOOLS

DATA ANLYSIS AND RESULTS

IMPLEMENTATION OF SEVEN QUALITY TOOLS

DATA ANLYSIS AND RESULTS

4.0 INTRODUCTIN

In this section data are tabulated for different batches from the Concerned Department of AIN SUDAN Company – these data are displayed together with the SPSS analysis and evaluation.

4.1 Results and discussions

Quantity/Bottle

Table (4-1): produced quantities/Bottles for 4consecutive years (2014, 2015, 2016 and 2017)to the 4 quarters for each year

Years	Q1	Q2	Q3	Q4	Total
2014	0	57526	269364	467811	794701
2015	418811	386904	404103	674036	1883854
2016	369683	338144	408150	1428316	2544293
2017	456827	1689497	2019292	2024549	6190165

Source: data collection

Descriptive

Table (4-2): descriptive analysis for produced quantities/Bottles for 4 consecutive years (2014, 2015, 2016 and 2017)

	N	Mean	Std. Deviation	Std. Error	Minimum	Maximum
2014	4	198675.25	213561.792	106780.896	0.00	467811.0
2015	4	464213.50	122577.16	61288.58275	386904.0	647036
2016	4	636073.25	528937.04	264468.5214	338144.0	1428316

2017	4	1547541.2	743840.075	371920.0377	456827.0	2024549
Total	16	711625.81	673116.855	168279.2139	0.00	2024549

Source: IBM SPSS 25

ANOVA

Table (4-3):Anova for produced quantities/Bottles for 4 consecutive years (2014, 2015, 2016and2017)

	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	4101952183812.188	3	1367317394604.063	6.096	0.009
Within Groups	2691537926471.250	12	224294827205.938		
Total	6793490110283.430	15			

Source: IBM SPSS 25

The value of (F) test calculated to signify the differences between the means of the study for the hypothesis was (6.096) with signify value (0.009) which is less than the level of significant value (0.05) These refer to the existence of differences statistically differences between the means.

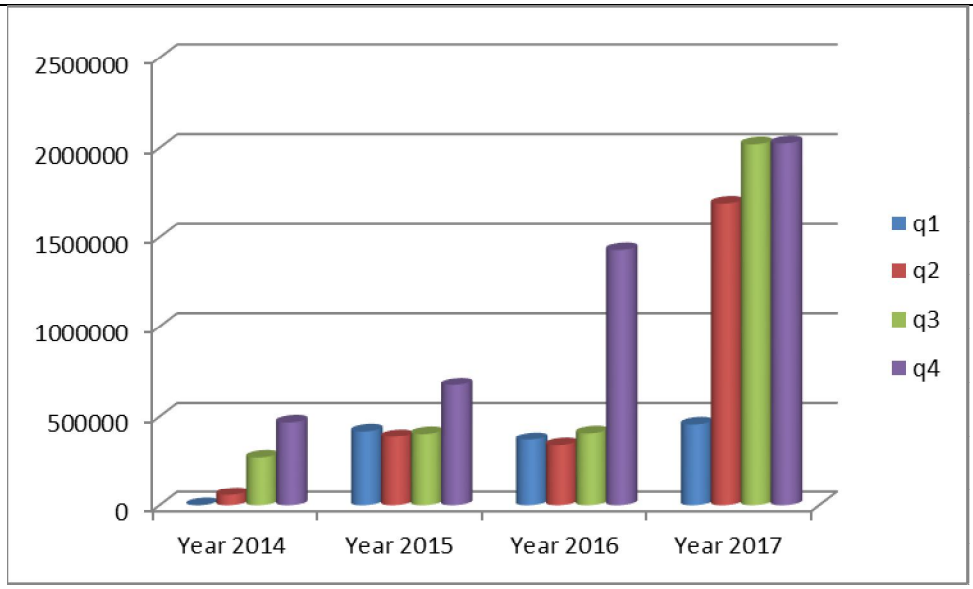


Figure (4-1):Histogram for produced quantity for the 4years(2014, 2015, 2016and 2017) and the 4 quarters for each year

Source: excel 2016

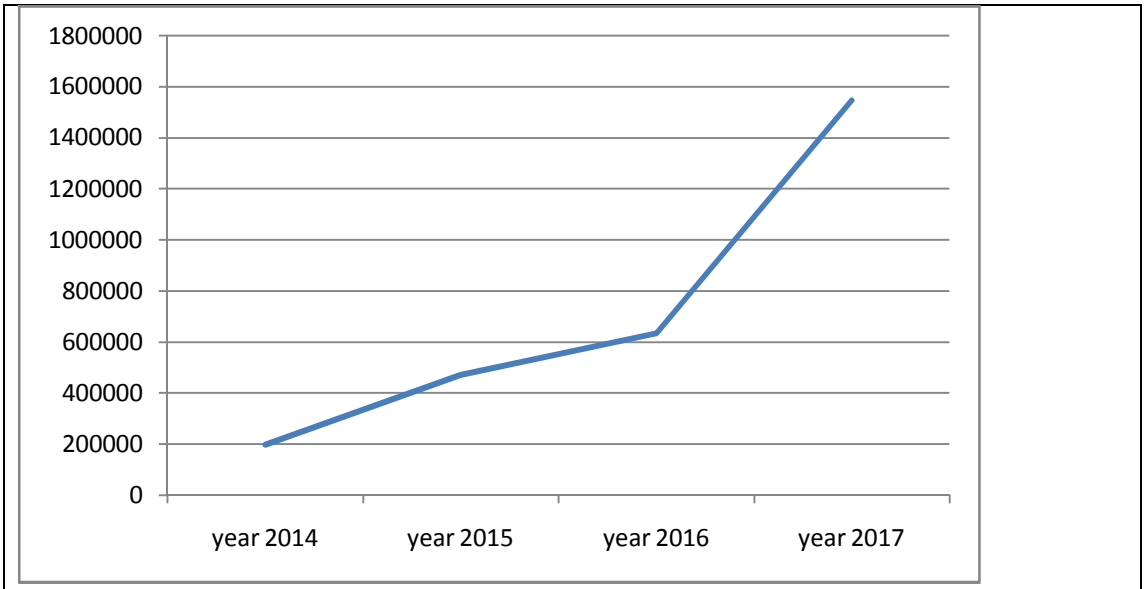


Figure (4-2):Comparison between produced quantity for the 4years (2014, 2015, 2016and 2017) and the 4 quarters for each year

Source: excel 2016

Table (4-4): t-test result showing group means of the PH for In Process and finished product at 2017

Valid	Mean	Std. Deviation	t	Df	Sig. (2-tailed)	Scale
In process	5.5939	0.36563	-1.580	136	0.11	Insignificant
Finished Product	5.6600	0.30015				

Source: IBM SPSS 25

The value of (T) test calculated to signify the differences between the numbers of individuals of the study for the hypothesis was (-1.580) with signify value (0.11) which is great than the level of significant value (0.05) refer that there are no statistically significant differences between pH for the in process and the Finished product.

The below Figure illustrates the control chart to pH (in process)

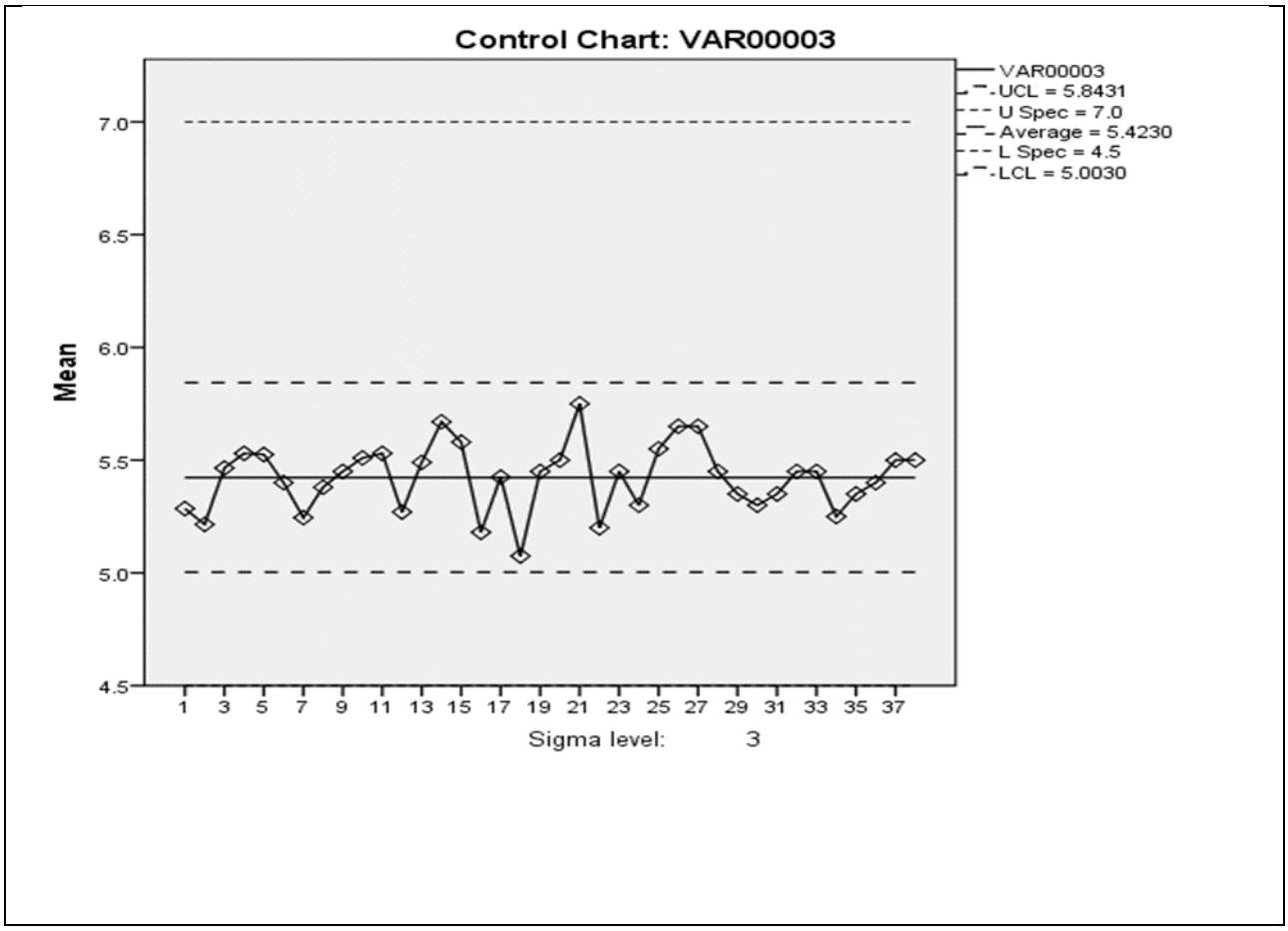


Figure (4-3): control chart for PH (in process)

Source: IBM SPSS 25

UCL = (7.0) LCL = (5.5) and average = (5.42), the chart above represent process and as long as the all the points are within the limits and there are no patterns, only common causes of variation are present. The process is said to be "in control"

Also Figure No (4.4) illustrates the control chart for PH (finished product) as follow:

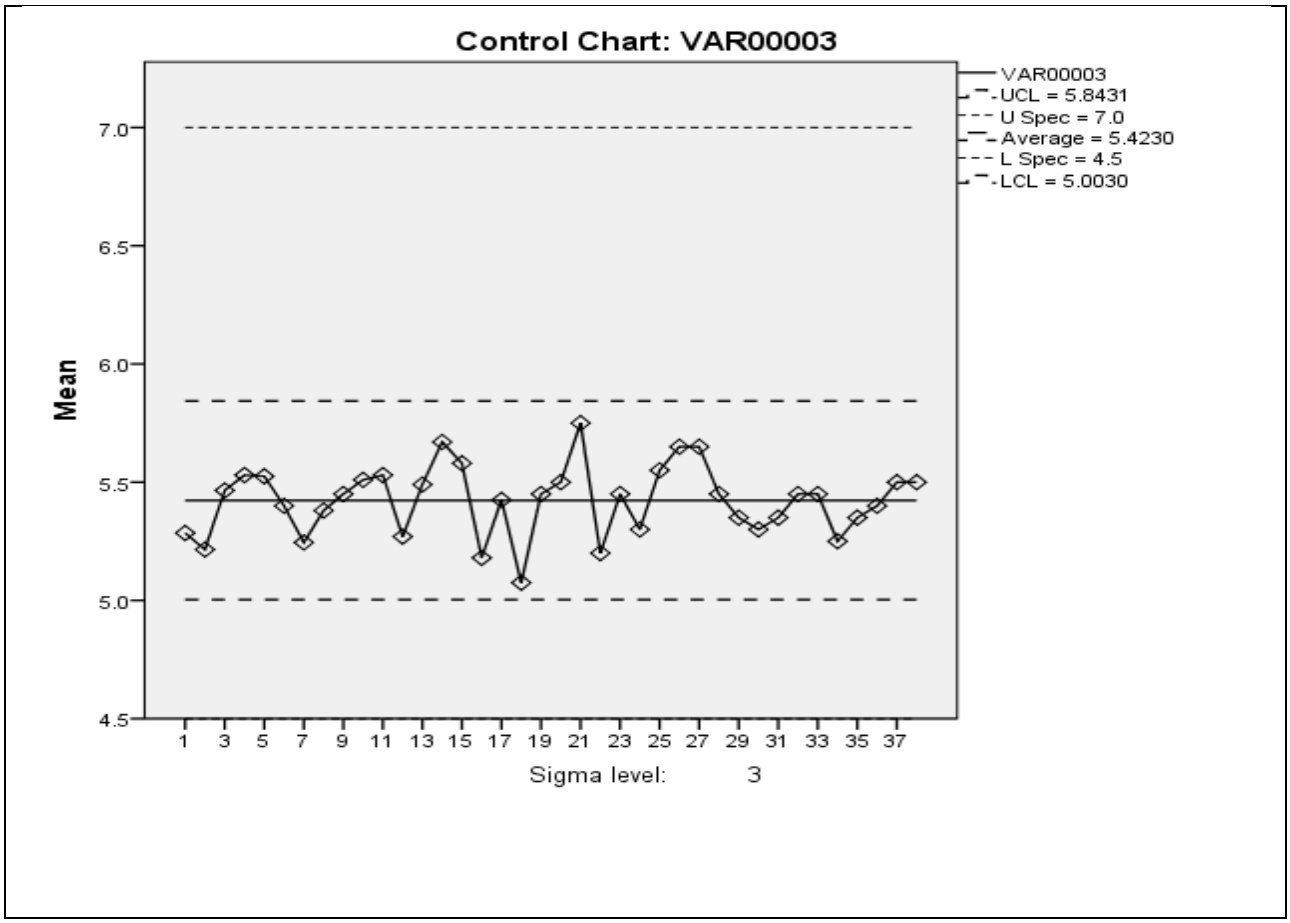


Figure (4-4): control chart for PH (finished product)

Source: IBM SPSS 25

UCL = (7.0) LCL = (5.5) and average = (5.42), the chart above represent process and as long as the all the points are within the limits and there are no patterns, only common causes of variation are present. The process is said to be "in control"

Table (4-5): t-test result showing group means of the Assay %W/V

Valid	Mean	Std. Deviation	t	Df	Sig. (2-tailed)	Scale
in process	0.8995	0.00647	2.131	136	0.03	Significant
Finished	0.8986	0.00574				

Source: IBM SPSS 25

The value of (T) test calculated to signify the differences between the numbers of individuals of the study for the hypothesis was (2.131) with signify value (0.03) which is less than the level of significant value (0.05) These refer to the existence of differences statistically for the Assay between in process and finished product.

The Figure bellow illustrates the control chart to assay W/V% (in process)

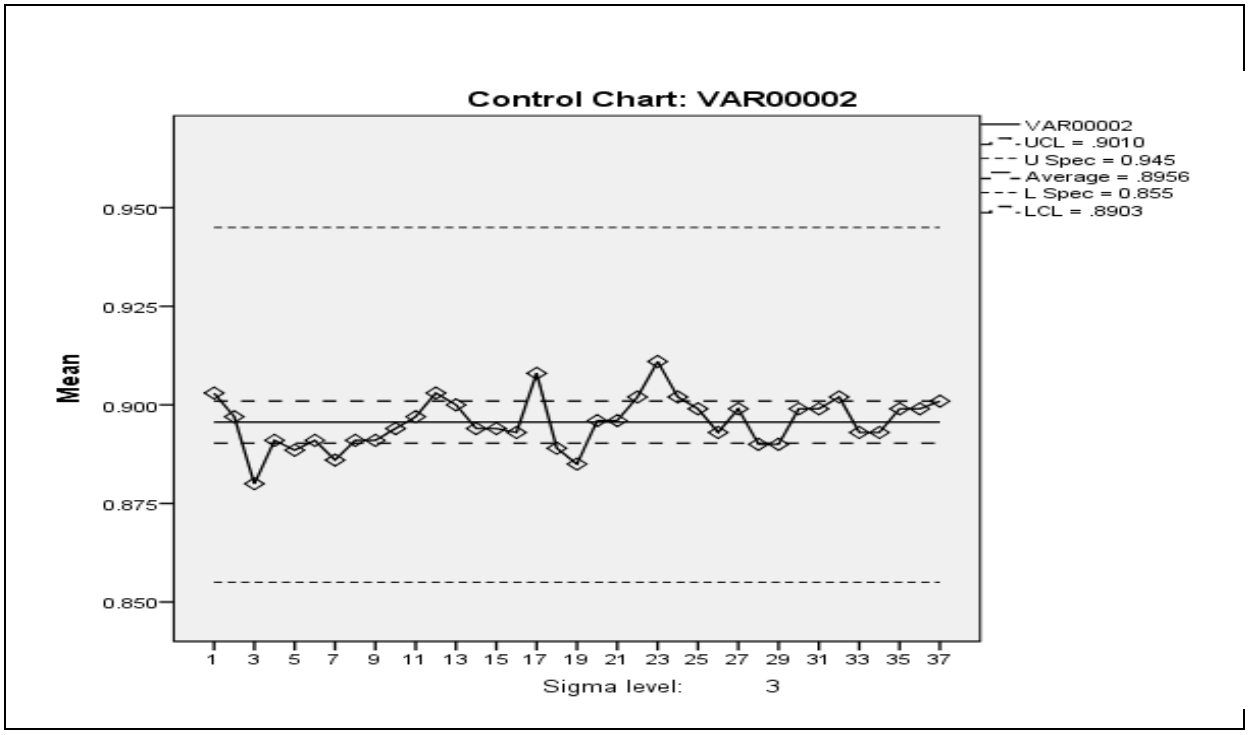


Figure (4-5): control chart to assay W/V% (in process)

Source: IBM SPSS 25

UCL = (0.945) LCL = (0.855) and average = (0.8956), the chart above represent process and as long as the all the points are within the limits and there are no patterns, only common causes of variation are present. The process is said to be "in control"

The Figure below illustrates the control chart to assay W/V% (finished product)

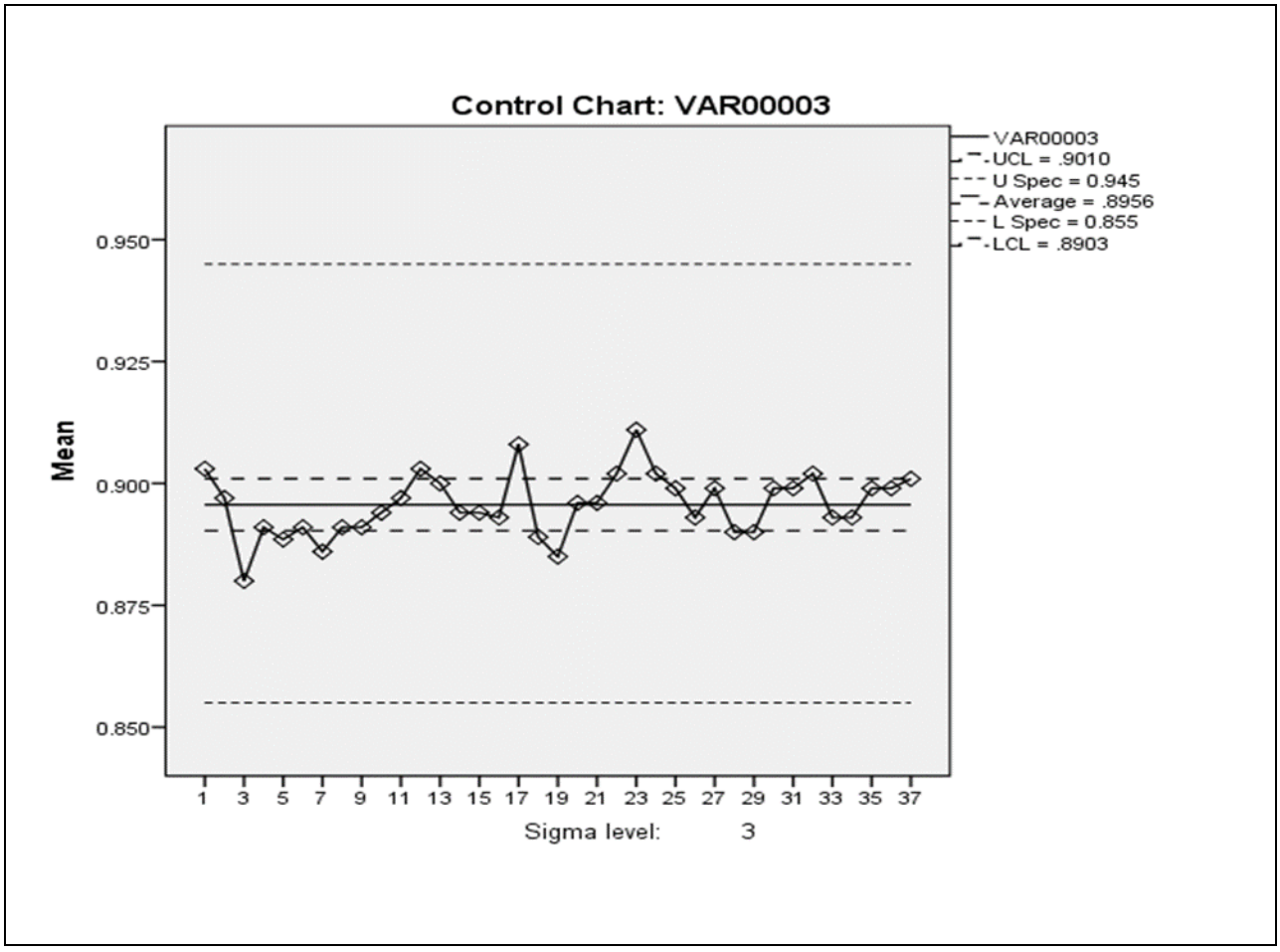


Figure (4-6): control chart to assay W/V% (finished product)

Source: IBM SPSS 25

UCL = (0.945) LCL = (0.855) and average = (0.8956), the chart above represent process and as long as the all the points are within the limits and there are no patterns, only common causes of variation are present. The process is said to be "in control"

Table (4-6):- yield and defect rate to 24 batches for year2017

YIELD%	Defect rate %
95.71697	2.996516
98.05005	0.649984
98.03354	0.680491
97.82082	0.887813
97.51051	1.19625
98.1256	0.592759
97.54125	1.164672
98.05153	0.670784
98.2139	0.506505
97.41407	1.300996
98.26148	0.446741
97.14962	1.559643
96.94346	1.774073
97.63897	1.081917
98.22971	0.482807
97.2276	1.482914
85.29286	13.42221
96.3427	2.372155
97.99564	0.728375
97.93573	0.787402
97.90263	0.803364
97.96987	0.734302
98.34245	0.382511
97.50026	1.228683

Source: data collection

Table (4-7): Correlations between yield and defect rate for year 2017

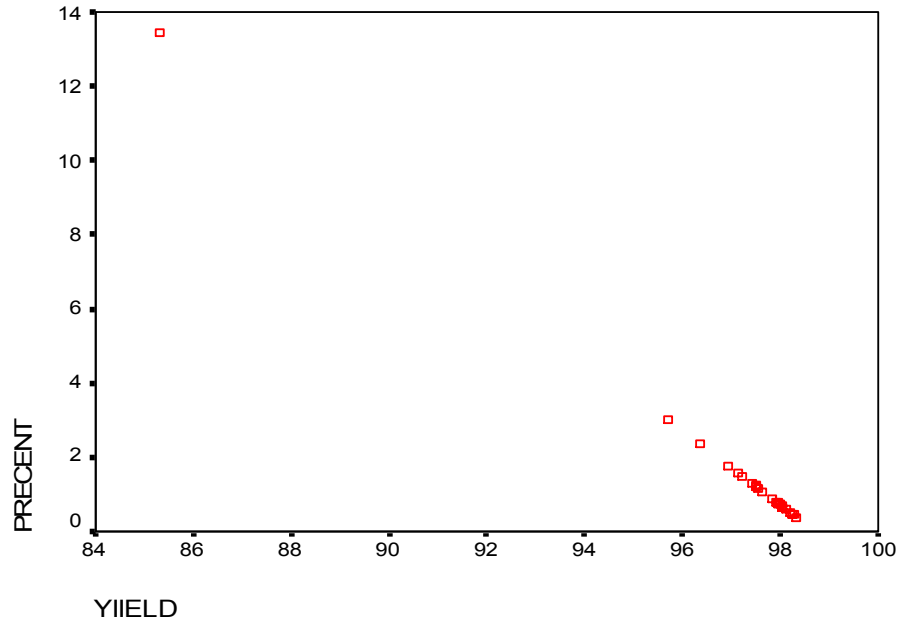
		Yield	**defect rate**
Yield	Pearson Correlation	1	-1.000(**)
	Sig. (2-tailed)	.	0.000
	N	24	24
defect rate	Pearson Correlation	-1.000(**)	1
	Sig. (2-tailed)	0.000	.
	N	24	24

Source: IBM SPSS 25

** Correlation is significant at the 0.01 level (2-tailed).

The value of (R) test calculated to signify the relationship between the yield and defect rate of the study for the hypothesis was (-1.0) with signify value (0.000) which is less than the level of significant value (0.05) These refer to the existence of Complete Inverse relationship between the yield and defect rate.

The following Figure illustrates the Scatter between Yield and defect rate for year 2017.



Note: percent ≡ defect rate percentage

Figure (4-7): the Scatter between Yield and defect rate for year 2017

Source: IBM SPSS 25

Table(4-8): yield and defect rate to 20batchesfor year 2018

yield	defect rate
97.68566	1.025613
96.72296	2.010554
96.51717	2.19686
98.40835	0.301124
98.26694	0.453261
98.48638	0.238993
97.95565	0.746349
98.1994	0.518273
96.7297	1.977264
98.0849	0.638366
98.02112	0.698741

98.1666	0.554282
98.19033	0.532255
97.47098	1.251198
98.18819	0.536635
97.2908	1.426739
97.7816	0.929258
97.87153	0.825324
97.02992	1.674047
97.2191	1.494937

Source: Data Collection

Table (4-9): Correlations between yield and defect rate for year 2018

		Yield	**defect rate**
Yield	Pearson Correlation	1	-1.000(**)
	Sig. (2-tailed)	.	0.000
	N	20	20
defect rate	Pearson Correlation	-1.000(**)	1
	Sig. (2-tailed)	0.000	.
	N	20	20

Source: IBM SPSS 25

** Correlation is significant at the 0.01 level (2-tailed).

The value of (R) test calculated to signify the relationship between the yield and defect rate of the study for the hypothesis was (-1.0) with signify value (0.000) which is less than the level of significant value (0.05) These refer to the existence of Complete Inverse relationship between the yield and defect rate.

The below Figure illustrates the Scatter between yield and defect rate foryear2018

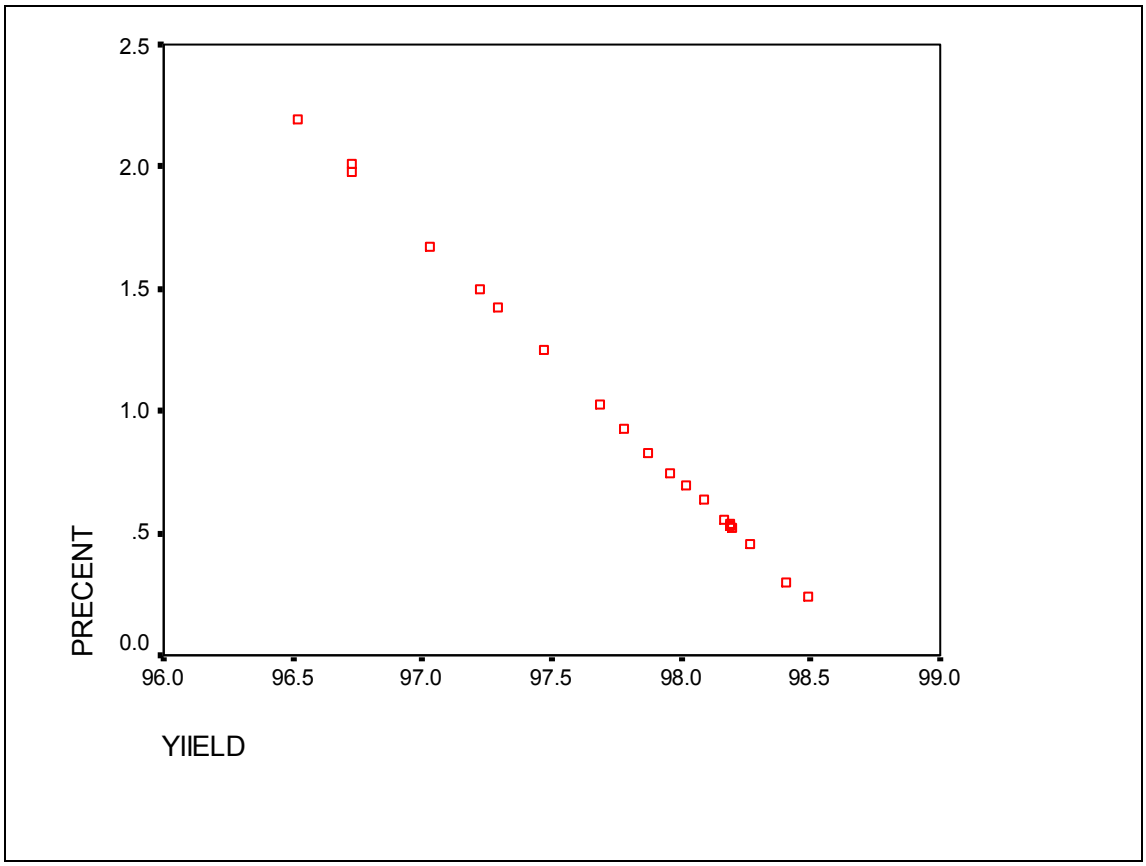


Figure (4-8): Scatter between yield and defect rate for year 2018

Source: IBM SPSS 25

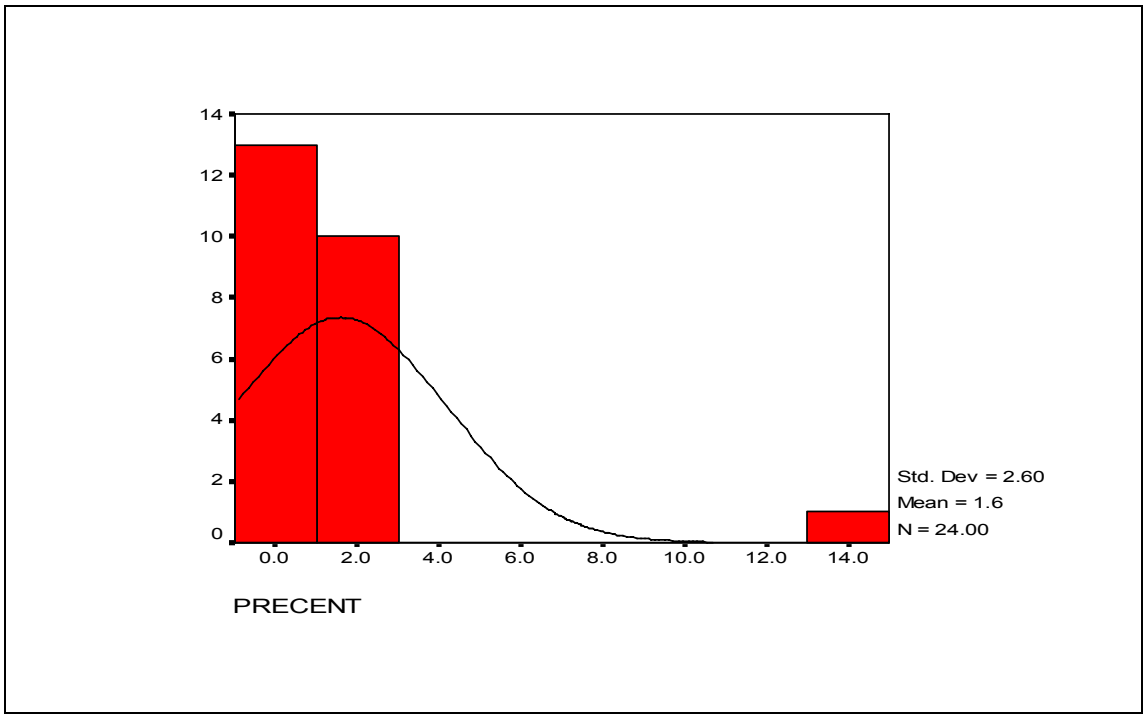


Figure (4-9): Histogram to the percentage(Defect Rate) for year 2017

Source: IBM SPSS 25

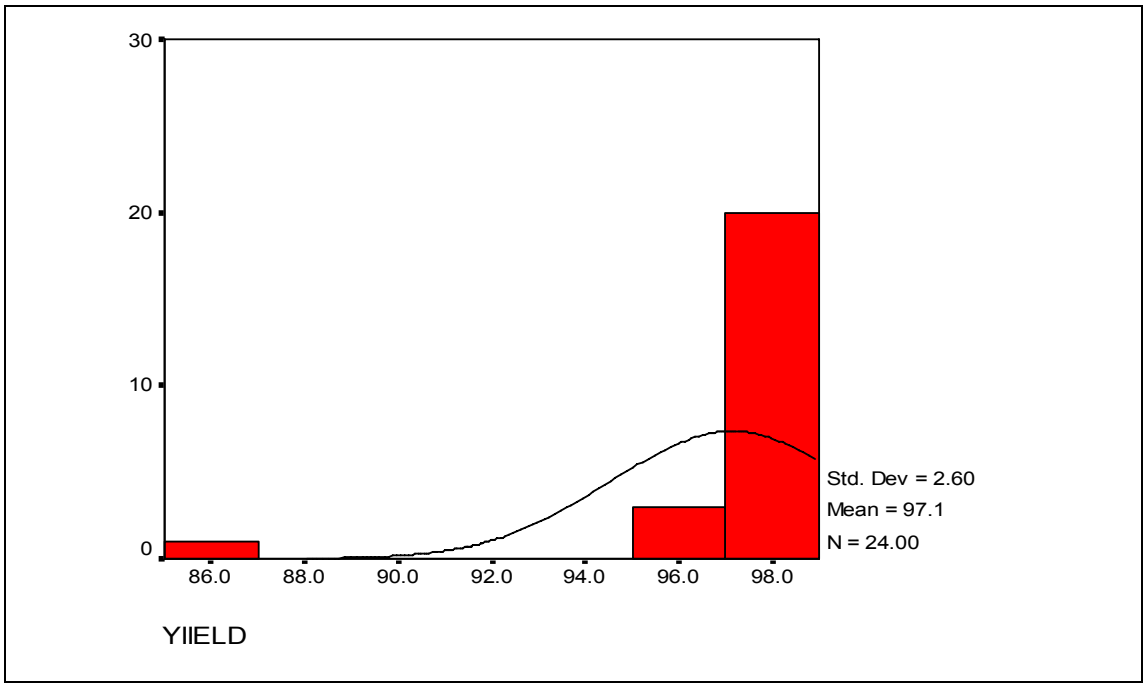


Figure (4-10):the Histogram to the yield for year 2017

Source: IBM SPSS 25

Table (4-10): illustrates the frequency and percentage of differentdefecttypes for 20 batch in2017:

Defect type	**Frequenters**	**Percentage**
Leak	2290	34.6%
Hanger damage	103	1.6%
Gripper	0	0.0%
De-shaped	32	0.5%
Particles	46	0.7%
Excess Plastic	655	9.9%
Scratch	0	0.0%
Dirty Cap	202	3.1%
Dirty body	2555	38.7%
Waterspots	652	9.9%
without rubber	55	0.8%
L.H.volume	1	0.01%
cap seal	19	0.3%
Total	6610	100.0%

Source: IBM SPSS 25

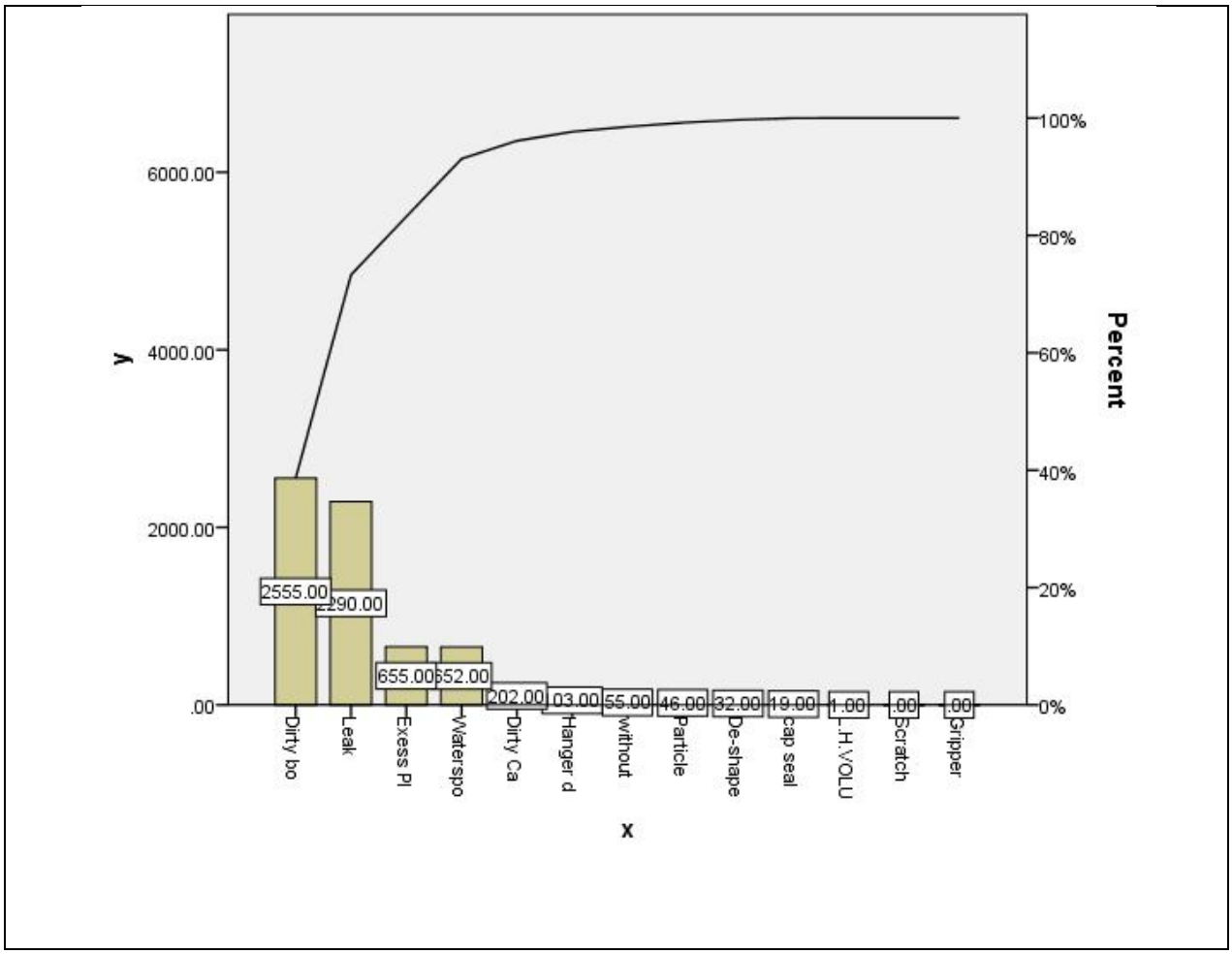


Figure (4-11): illustrates the Pareto chart for the defect types to 20 batch in 2017

Source: IBM SPSS 25

The Cumulative percentage corresponds to the sum of all percentages previous to and including Defects. In this case, this would be the sum of the defects, dirty body and leak and Excess Plastic defects (38.7% & 34.6% & 9.9%). The last cumulative percentage will always be (100%).

Through the Pareto analyses, the Company should be able to know the direction of future process improvement. As long as some measures are taken to improvement actions, the defect rate can be reduced by less than quart.

Table (4-11): illustrates the frequency and percentage of different defect types for 20 batch in 2018:

Defect	**Frequenters**	**Percentage**
Leak	2034	60.5%
Hanger damage	67	1.9%
Gripper	0	0.0%
De-shaped	37	1.1%
Particles	3	0.1%
Excess Plastic	424	12.6%
Scratch	131	3.9%
Dirty Cap	126	3.7%
Dirty body	381	11.3%
Waterspots	84	2.5%
without rubber	0	0.0%
L.H.Volume	72	2.1%
cap seal	2	0.1%
ring cap	0	0.0%
Total	3361	100

Source: IBM SPSS 25

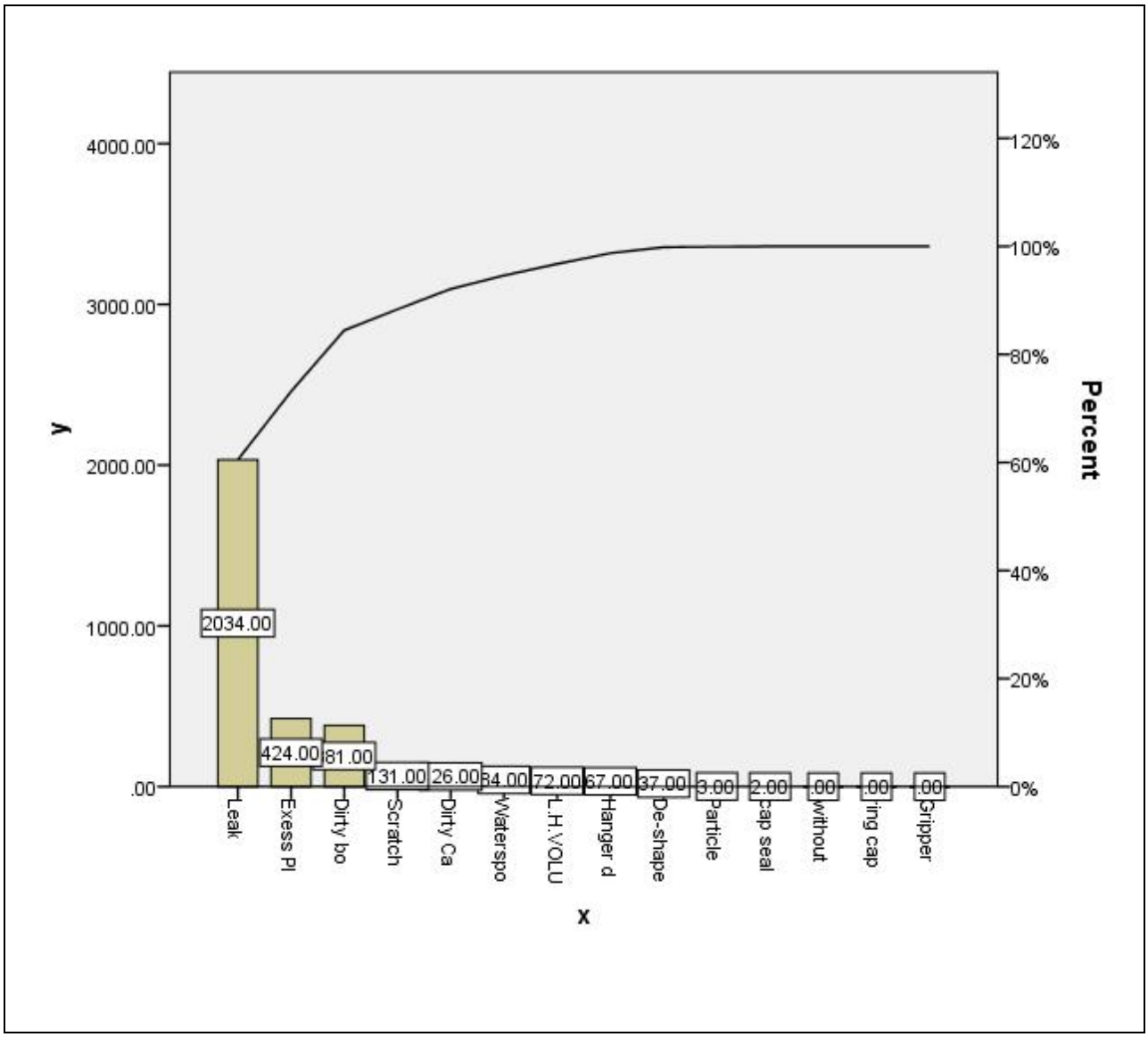


Figure (4-12): illustrates the Pareto chart for the defect types to 20 batch in 2018

Source: IBM SPSS 25

The Cumulative percentage corresponds to the sum of all percentages previous to and including Defects. In this case, this would be the sum of the defects, Leak and Excess Plastic and Dirty body defects (60.5% & 12.6% &11.3%). The last cumulative percentage will always be (100%).

Through the Pareto analyses, the Company should be able to know the direction of future process improvement. As long as some measures are taken to improvement actions, the defect rate can be reduced by less than quart.

a. Statistical methods

The methods which were used in the study are:

- Frequencies
- Percentage
- Mean
- Significant value
- Anova
- Correlation
- Pareto chart
- Scatter diagram
- Control chart
- Scatter diagram

CHAPTER FIVE

DISCUSSION, CONCLOSION ‹RECOMMENDATION

AND SUGGESTIONS

DISCUSSION, CONCLOSION ،RECOMMENDATION AND SUGGESTIONS

5.0 INTRODUCTION

In the previous chapter, the Data from QA and QC were presented, analyzed and results are illustrated using SPSS, in this chapter we will discuss the results , draw conclusion for this study which was conducted at AIN SUDAN and address the recommendations and limitations of the study finally make suggestions for further studies .

5.1DISCUSSION

The study tackled the discussion and interpretation of the findings of the research through the information which are resulted from literature review and previous studies and from the analysis of the Collected data, in addition to the results of the statistical analysis of the testing of the hypothesis. In the light of the problem and the objectives of the research and the investigation of the previous studies the researcher may formulate the research hypotheses as follows.

5.1.1Research hypothesis testing

The main hypothesis of the study is:

H1: Using the 7 QC tools has positive Impact on quality and Defect Rate.

H2: There is a direct relationship between defect rate and product Yield.

H3: There is significant relationship between using 7 QC tools and the continuous improvement in the organization.

H1: Using the 7 QC tools has positive Impact on quality and Defect Rate.

To test the validity of this hypothesis the statistical technique was used to prove the following sub hypotheses:

H1a: Using the 7 QC tools has positive Impact on quality.

H1b: Using the 7 QC tools has positive Impact on Defective Items Quantity.

This will demonstrate that there are not significant variation in the pH between in process and finish product test results and also there are not significant variation in the Assay between in process and finish product test results.

To test the validity of this sub hypothesis the study used SPSS program as demonstrated in chapter 4 above.

Figures (4-3,4-4,4-5 and 4-7) which used control chart as tool to control product quality level showed that the quality of NS Product is always under control for both in process and finish product test result .

Also table 6 showed that the value of (T) test calculated to signify the differences between the numbers of individuals of the study for the hypothesis was (-1.580) with signify value (0.11) which is greater than the level of significant value (0.05) refer that there are no statistically significant differences between pH for the in process and Finished product.

In addition, table 7 showed that the value of (T) test calculated to signify the differences between the numbers of individuals of the study for the hypothesis was (2.131) with signify value (0.03) which is less than the level of significant value (0.05) This suggests that there are statistically differences for the Assay between in process and finished product.

Also when we Compare table (4-10) and (4-11) and compare figure (4-11) and (4-12) we find that the total quantity of defective items decreased from6610 in 2017 to 3361 in 2018 and each separated type of defects decreased too.

Accordingly, we conclude that:

- using one of seven QC- control chart- has positive impact on quality because it can give an overview for the quality level through determination of LCL,CL and UCL that enables Companies to control their processes.

-The degree of quality does not Change for in process and finished product samples in case of pH but there are differences in the Assay between in process and finished product which may have occurred due to laboratory errors, different analysts, sterilization or sampling the in process sample from points with high concentration. These differences need to investigation, although it is not significant as it still under control within specifications limit.

-using check list and pareto chart for defective items quantity help the company to focus on three types of defect which are leak, excess plastic and dirty body in addition to the other types. The company was able to solve these problems through fishbone analysis and brainstorming to know the root causes of high defect rate and has succeeded in reducing the quantity by approximately 50% in 2018.

H2: There is direct relationship between defect rate and product Yield

In order to test the validity of this hypothesis data collected for 2 consecutive years (2017,2018) as in table (4-6) , (4-8) and with reference to table (4-7), (4-9) and according to figure (4-7) and (4-8) we find that:

- for 2017 The value of (R) test calculated to refer to the relationship between the yield and defect rate of the study for the hypothesis was (-1.0) with signify value (0.000) which is less than the level of significant value (0.05) These refer to a Complete Inverse relationship between the yield and defect rate .

- for 2018 The value of (R) test calculated to signify the relationship between the yield and defect rate of the study for the hypothesis was (-1.0) with signify value (0.000) which is less than the level of significant value (0.05)

These refer to a Complete Inverse relationship between the yield and defect rate .

So we can conclude that there is Complete Inverse relationship between defect rate and product Yield, this relationship is very clear in figures (4-7) and (4-8) .

H3: There is significant relationship between using 7 QC tools and continuous improvement in the organization.

For testing the validity of this hypothesis, see table (4-2) and (4-3)

We find that descriptive analysis for produced quantities/Bottles for 4consecutive years (2014, 2015, 2016 and2017).The value of (F) test calculated to signify the differences between the means of the study for the hypothesis was (6.096) with signify value (0.009) which is less than the level of significant value (0.05) This suggests that there are statistically differences between the means.

And with reference to figure (4-2) and (4-3) which clearly illustrate that there is incremental increasing in the quantity of produced items from year to year, and Figure (4-2) also showed that quantity of produced items has increased incrementally from quarter 1 till quarter 4 for each year.

5.2 MAIN RESULTS

5.2.1 The degree of quality does not Change for in process and finished product samples in case of pH but there are differences in the Assay between in process and finished product.

5.2.2 Using check list and pareto chart for defective items quantity help the company to focus on three types of defect which are leak, excess plastic and dirty body.

5.2.3 There is Complete Inverse relationship between defect rate and product Yield.

5.2.4 There is incremental increasing in the quantity of produced items from year to year, and from quarter 1 till quarter 4 that mean there is continues improvement on the organization.

5.3 CONCLUSIONS

5.3.1 This study explained the definitions of 7 QC tools and how to use various QC tools and how to use some of them in problem solving and their applications. It was concluded that these tools are used to recognize, analyze the problem, control the product standards and assist an organization for problem solving and process improvements.

5.3.2 The study concluded that we can use flow chart to detect and analyze the area or points of process that may have potential problems by documenting and explaining an operation, use control chart to find causes of quality problems, check sheet for data collection and it supports in identifying frequently problems. Histogram assists users to show the distribution of data and the amount of variation within a process, use scatter diagram to detect and analyze the relationship ,fishbone to analyze quality problems (root cause analysis) and finally pareto chart which is used to find and prioritize quality problems.

5.3.3 This study concluded that using one of the seven QC tools- control chart- has positive impact on quality because it can give an overview for the quality level through determination of LCL,CL and UCL that enables Companies to control their processes according to product specifications.

5.3.4 The study proved that statistically there are no statistically significant differences between pH for the in process and Finished product.

5.3.5 Also the study concluded statistically that there are statistically significant differences between assay for the in process and Finished product.

5.3.6 The study also proved that statistically through using check sheet and pareto chart the defective items quantity decreased by approx. 50% in 2018 compared to 2017, this shows the impact of 7QC tools implementation.

5.3.7 The study also concluded that using check list and pareto chart for defective items quantity help the company to focus on three types of defect which are leak, excess plastic and dirty body.

5.3.8 The study proved that statistically by using scatter diagram there is Complete Inverse relationship between defect rate and product Yield.

5.3.9 The study also concluded that there is incremental increasing in the quantity of produced items from year to year as an impact of 7QC tools implementation , ,also produced items has increased incrementally from quarter 1 till quarter 4 for each year .

5.3.10 This study practically shows how quality tools are used at AIN SUDAN to enhance continuous improvement and it proves that' statistically through using some of important seven QC tools which are check list, histogram, pareto chart and scatter Diagram.

5.4 RECOMMENDATIONS

5.4.1 The commitment by employees of the company to quality and using seven quality tools by all AIN SUDAN staff not only QA and QC staff and to be adopted by all organizations in Sudan.

5.4.2 It is necessary to work in a systemic way according to documented and planned program that includes 7QC tools implementation.

5.4.3 I strongly recommend to focus on decrease high defect rate at production line to increase product yield, specially this type of defect (leak ,excess plastic and dirty body) and to use cause and effect analysis to identify the root causes of these three main problems at Ain Sudan production line and suggest an action plan to avoid it .

5.4.4 It necessary to reduce or eliminate the defects in every department not only production lineat Ain Sudan plant, to achieve the required specification of customers in the final product, to decrease cost of poor quality, to save rework cost and to achieve more profits.

5.4.5 Also I recommend that all AinSudan departments should use defect analysis feedback to improve Quality and productivity.

5.5Limitation of the study

5.5.1 Shortage of sources and books references.

5.5.2 Difficulty in obtaining Historical data related to the company.

5.5.3 The differences between the produced batches quantity from year to year led to difficulty in collecting data.

5.5.4 The differences between the produced batches size also led to difficulty in data collection and the quantity of representative batches.

5.6Suggestions for further researches

The following studies are suggested:

5.6.1 Defect Reduction by using 7QC tools in AIN SUDAN Production line.

5.6.2 Using cause and effect Diagram to determine causes of variation in the Assay between in process and finish product test results.

5.6.3 Study on the impact of new seven tools on quality and defect rate.

5.6.4 Doing a comparative study on using another tool otherthan7 QC tools as continuous improvement tool.

5.6.5 Doing a comparative study on the using7QC tools in similar pharmaceutical organization at regional or international level.

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