

Dedication:

I thank Allah first for his support and kindness

To my family

To my wife

To my supervisor

Acknowledgment:

I would like to send out my greatest thanks to:

Dr. Mohamed Ahmed for kindly supervising this study and for his patience through all the month's that makes this work possible

Dr. Mohamed Alfadiel

My family for the generous and endless support through all my life

ABBREVIATIONS

Abbreviation	Meaning
DTPA	Diethylene Triamine Penta Acetic acid
EDTA	Ethylene Diamine Tetra Acetic acid
Tc99m	Technetium 99meta stable
Cr51	Chromium
GCM	Gamma Camera Method
MAG3	Mercapto Acetyl Tri glycerin
ERPF	Effective Renal Plasma Flow
D	Dose
DMSA	Di Mercapto Succinic Acid
SPECT	Single Photons Emission Computed Tomography
QC	Quality control
Co57	Cobalt 57
Pt	Patient
St	Standard
C	Centigrade
GBq	Giga Becquerel
MBq	Mega Becquerel
Mci	Micro curie
Vs	Versus
CKD	Chronic Kidney Disease
Kg	Kilogram
Cm	Centimeter
RICK	Radiation and Isotope Center Khartoum

Abstract

This prospective study was aimed to assess inter- and intra-operator variability during routine quality control (QC) procedure for technetium-99m (99mTc-MAG3 and DMSA) instant kit formulation. A total of 10 QC analyses with thin layer chromatography (TLC) for 20 separate MAG3 reconstitutions were performed. The percentage of free and hydrolysed 99mTc as well as binding efficiency, were calculated according to standard TLC. Each QC analysis was done using silica gel (SG), silica acrylic (SA), Whatman 1 (W1) and Whatman 3 (W3) TLC strips separately at 1h, following labeling MAG3 instant kit with 99mTc-pertechnetate. To assess the radiochemical stability of 99mTc-MAG3, the same analysis was performed after kit reconstitution. Visual confirmation for QC with scintigraphy was also performed. At both time points, each repeated all the procedure twice for each of the TLC paper types to analyze the intra-operator reliability. Crombach's Test was used for the reliability analysis. High inter-operator correlation ratios (range: 0.821-0.920) per each TLC strip were found where the highest concordance rate was 0.921 for SA. Each TLC strip showed adequate kit reconstitution with acceptable free and hydrolysed 99mTc percentages in all analyses, along with high binding efficiency values of 94.3 ± 2.9 and 92.5 ± 1.9 at respectively. Intra-observers reliability showed almost equal high concordance rates (range: 0.888-0.961) for all types of strips. In conclusion, all kinds of ITLC/TLC strips were reliable to assess stability of the radiopharmaceutical at 1 and 4 h while analysis with the SA strip had the highest concordance rate. Inter- and intra-operator QC was also reliable.

Table of contents

Topics	Page
Name of content	Ii
DEDICATION	Iii
ACKNOWLEDGEMENTS	V
ABSTRACT (English)	Vii
ABSTRACT (Arabic)	Viii
LIST OF CONTENTS	Xii
LIST OF TABLES	Xiii
LIST OF FIGURES	Xiv
LIST OF ABBREVIATIONS	X
LIST OF APPENDIX	

CHAPTER	Page No
1 INTRODUCTION	
1.1 Introduction	1
1.2 Hypothesis	2
1.3 Statement of the Problems	2
1.4 General objectives	2
1.5 Specific objectives	2
1.6 Thesis Outline	2
2 2.1 Technetium Pertechnitate	3
2.2 Quality Control of ^{99m}Tc-Radiopharmaceuticals	12
2.3 Radioactive Properties	16
2.4 Thin Layer Chromatography (TLC)	
2.5 Biological Tests	16
2.6 First generation of ^{99m}Tc-radiopharmaceuticals	17
2.7 New Generation of ^{99m}Tc-radiopharmaceuticals	24

3	THEORETICAL STUDIE	
	3.1. Chromatography	35
	3.2 Quality control procedures for MAG3 and DMSA	37
	MATERIALS AND METHOD	
	3.3 Materials of the study	40
4	4.1 RESULTS AND DISCUSSION	45
5	5.1 Conclusion	60
	5.2 Recommendations	61
	5.3 References	
	5.4 Appendices	63

List of Figures

No. of Figure	Figure Caption	Page No
2.1	Production and decay scheme of ^{99m}Tc	8
4.1	the average percentage of the radiochemical impurity system one MAG3	49
4.3	the average percentage of the radiochemical impurity system three MAG3	50
4.4	the average percentage of the radiochemical impurity system four MAG3	51
4.6	the average percentage of the radiochemical impurity system tow DMSA	52
4.7	the average percentage of the radiochemical impurity system three DMSA	53
4.9	Comparative study between the four chromatographic systems MAG3	54
4.10	Comparative study between the four chromatographic systems DMSA	85

List of tables

Table No.	Table caption	Page No.
3.1	Types of Chromatography	34
4.2	the average percentages of the radiochemical impurity system one MAG3	49
4.3	the percentages of the radiochemical impurity system tow MAG3	50
4.4	the average percentages of the radiochemical impurity system tow MAG3	51
4.6	the average percentages of the radiochemical impurity system three MAG3	52
4.7	the percentages of the radiochemical impurity system one DMSA	53
4.9	the percentages of the radiochemical impurity system tow DMSA	54
4.10	the average percentages of the radiochemical impurity system tow DMSA	55
4.11	the percentages of the radiochemical impurity system three DMSA	56

LIST OF APPENDIX

No	name of appendix	page No
-----------	-------------------------	----------------

Appendix 1	the percentages of the radiochemical impurity
(MAG3)	61
Appendix 2	the percentages of the radiochemical impurity
(MAG3)	62
Appendix 3	the percentages of the radiochemical impurity
(MAG3)	63
Appendix 4	the percentages of the radiochemical impurity
(MAG3)	64
Appendix 5	the percentages of the radiochemical impurity
(DMSA)	65
Appendix 6	the percentages of the radiochemical impurity
(DMSA)	66
Appendix 7	the percentages of the radiochemical impurity
(DMSA)	67
Appendix 8	the percentages of the radiochemical impurity
(DMSA)	68