

Dedication

To

My parents,

Wife,

Brothers,

Sisters

And my children

.

Acknowledgment

First of all my sincere thanks to Allah Almighty for helping me to complete this work.

It is a pleasure to record my deep appreciation, and thanks to Prof. Ahmed Elsadig Mohammed Saeed for his wise guidance, which helped me to present this project in this shape.

Thanks to my family and colleagues for their continues support.

Abstract

In this thesis, the drug Glibenclamide, which is known by several commercial names, such as, Daonil, Euglucon, and Delmide, had been submitted to a stability study in terms of its stability as a raw material, by following stability study protocols, including heat factors, humidity, periods of storage, and transportation. The obtained results were compatible with specifications required by the British Pharmacopoeia.

A UV spectrophotometric method to determine the drug according to the accepted worldwide verification standard was developed and validated. The method has been characterized as simple way, rapid , low cost and accurate.

The method had been tested by analyzing the final product samples from different companies, by a number of analyst's chemists, using different UV spectrophotometers. The obtained results were satisfactory and consistent with the required pharmaceutical specifications, the relative standard deviation was less than 2%, which confirmed the accuracy of the performed method, and its suitability to conduct routine tests of pharmaceutical doses, and large quantities.

الملخص

في هذه الأطروحة أخضع عقار الجلينكلمايد (Glibenclamide) والذي يعرف بعدة أسماء تجارية منها الداونيل (Daonil) والايكلون (Euglucon) والدلمايد (Delmide) لدراسة ثباتية من ناحية ثبات العقار كمادة خام ، وذلك باتباع برتوكول دراسة الثباتية المعتمدة والتي اشتملت علي عوامل الحرارة، والرطوبة، وفترات التخزين، والنقل، وكانت النتائج المتحصل عليها تتوافق مع المواصفات المطلوبة حسب دستور الأدوية البريطاني .

تم في هذه الدراسة تعيين العقار باستخدام مضوائية طيفية الأشعة فوق البنفسجية وفقاً لخارطة التحقق المتعارف عليها عالمياً، وقد إتسمت الطريقة المقترحة بالبساطة، واليسر، والسرعة، وقلة التكاليف والمصادقية.

تم تطبيق طريقة التعيين علي عينات منتج نهائي مأخوذة من شركات مختلفة باشتراك عدد من المحللين الكيميائيين وإستخدام أجهزة تحليل كيميائي مختلفة، وكانت النتائج المتحصل عليها مرضية ومتوافقة مع المواصفات الصيدلانية المطلوبة فقيمة الإنحراف القياسي النسبي (RSD) كانت أقل من 2% الأمر الذي يؤكد دقة الطريقة المنفذه ، وصلاحيتها لإجراء التحاليل الروتينية للجرعات الصيدلانية والكميات الكبيرة.

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Abbreviation

Abbreviation	Definition
USAN	United States Adopted Names.
WHO	World Health Organization
INN	International Nonproprietary Names
NIH	National Institutes of Health
ATP	Adenosine triphosphate
pH	Potential OF Hydrogen
ICH	International Conference on Harmonization
RH	Relative humidity
AAPS	American Association of Pharmaceutical Scientists
BP	British Pharmacopoeia
SOPs	Standard operating procedure
AQC	Analytical quality control
LOD	Limit Of Detection
LOQ	Limit Of Quantitation
RSD	Relative standard deviation
RT	Room Temperature
SD	Standard deviation
USP	United States pharmacopeia
UV	Ultra violet
N.M.T	Not more than