DEDICATION

I dedicate this work to my parents

To my brothers

And to my lovely sister

Acknowledgement

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ABSTRACT

Oral suspensions of antibiotics are mainly available as dry powders for reconstitution. Many reconstituted antibiotic suspensions are kept refrigerated in order to get the optimal benefit from the drug. However, many patients do not keep to the specified storage conditions for different reasons like absence of a refrigerator and irregular power supply that may result in various degrees of degradation of the product. Scientists are therefore challenged on how to counsel patients when there is no refrigeration or erratic power supply for refrigeration. The aim of this study is to investigate the stability of reconstituted amoxicillin suspension in absence of refrigeration. Amoxicillin suspension samples obtained from Pharmaland Pharmaceutical were reconstituted and stored in three different storage conditions including different temperatures: 8 °C, 30°C and 40°C over a period of fourteen days. Samples from the suspension were assayed using a validated HPLC method. Percentage concentrations of amoxicillin were over 90% up to the seventh day, degradation was extensive by the 14^{th} day with amoxicillin concentration falling below 80% (67.4%, 72.4% at 40 °C). It is recommended that reconstituted suspension which is not properly refrigerated should be discarded after seven days.

مستخلص البحث

توجد المضادات الحيوية المعلقة التي تؤخذ بالفم على هيئة بودرة قبل تعليقها باضافة الماء، ومن أجل الحصول على الفائدة القصوى منها تحفظ هذه المضادات الحيوية في الثلاجات ، ومع ذلك العديد من المرضى لا يلتزمون بظروف التخزين المناسبة لجهلهم بها او لأسباب اخرى مختلفة منها عدم توفر الثلاجات وعدم انتظام إمدادات الطاقة التي قد تؤدي إلى درجات مختلفة من تدهور المستحضر وانخفاض تركيزه ، ولذلك كان من الضروري حماية المرضى عندما لا تكون ظروف التبريد متوفرة أو عند عدم انتظام إمدادات الطاقة.

الهدف من هذه الدراسة هوالتحقق من استقرارية الأموكسيسيلين ثلاثي الماء المعلق في محاكاة لظروف المنازل و ظروف عدم انتظام التيار الكهربائي وعدم توفر الثلاجات.أخذت العينات من مصنع فارمالاند للأدوية وتم تعليقها باضافة الماء ومن ثم تخزينها في ثلاثة ظروف تخزين مختلفة تشمل درجات حرارة مختلفة (8°C) (30°C) و(40°C) على مدى أربعة عشر يوما. تم تحليل العينات باستخدام جهاز كروماتوغراف السائل ذو الاداء العالي ، وكانت نسبة الأموكسيسيلين أكثر من 90% إلى اليوم السابع، ولكن حصل انخفاض واسع النطاق عند اليوم الرابع عشر في تركيز الأموكسيسيلين ثلاثي الماء لتنخفض دون 80% حيث كانت 67.4% و 72.6% عند درجة حرارة (40°C).

أخيرا اوصت هذه الدراسة بعدم استخدام الاموكسيسيلين المعلق غير المحفوظ بالثلاجة بعد اليوم السابع.

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ABBREVIATIONS

- BP British Pharmacopeia
- USP United State Pharmacopeia
- HPLC High Performance Liquid Chromatography
- RPLC Reverse Phase Liquid Chromatography
- GC Gas Chromatography
- PDA Photo Diode Array
- UV Ultra Violet
- FTIR Fourier Transformance Infera Red
- ODS Octa Decyl Silane
- TLC Thin layer Chromatography
- IEC Ion Exchange Chromatography
- BPC Base Peak Chromatogram
- GLC Gas Liquid Chromatography
- GSC Gas Solid Chromatography
- LLC Liquid Liquid Chromatography
- LSC Liquid Solid Chromatography
- DS Dry Suspension
- T.V Titer Volume