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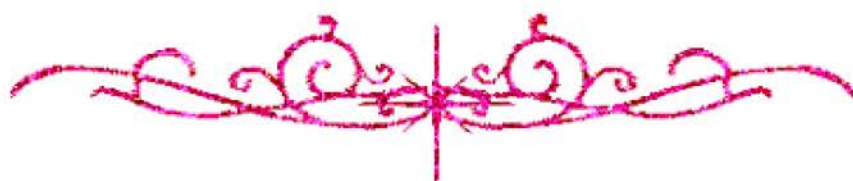
بسم الله الرحمن الرحيم



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شبكة المعلومات الجامعية التوثيق الالكتروني والميكروفيلم



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جامعة عين شمس

التوثيق الإلكتروني والميكروفيلم

قسم

نقسم بالله العظيم أن المادة التي تم توثيقها وتسجيلها
علي هذه الأقراص المدمجة قد أعدت دون أية تغيرات



يجب أن

تحفظ هذه الأقراص المدمجة بعيدا عن الغبار



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شبكة المعلومات الجامعية



بعض الوثائق الأصلية تالفة



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بالرسالة صفحات
لم ترد بالأصل



**“A Comparative Study On Safety And Efficacy Of
Different Types Of Insulin Available Commercially
In Egyptian Market ”**

B15272

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(Pharmaceutics)

Under the Supervision of

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بسم الله الرحمن الرحيم

(رب أوزعني أن أشكر نعمتك التي أنعمت علي و على والدي و أن أعمل
صالحا ترضاه و أدخلني برحمتك في عبادك الصالحين)

(النمل: ١٩)

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Abstract

Abstract

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, hearts, and blood vessels.¹ four types are recognized, but type 1 and type 2 represent (5%-10%) and (85%-90%) respectively. The third category, gestational diabetes, develops in 2% to 5% of all pregnancies but usually wanes when a pregnancy is over. Gestational diabetes first becomes apparent after 24 to 28 weeks of pregnancy. The primary concern for women who develop gestational diabetes is that approximately 40% will develop type 2 diabetes. The fourth category (about 1%-2% of all cases) includes all other factors that may include diabetes. Because of the breadth of this category, only the including factors are mentioned. These factors include malnutrition, surgery, drugs, infections, and other illnesses. Other factors include genetic defects, such as maturity-onset diabetes in youth. Type 1 to 3, which are classified as genetic defects of β -cell function. Leprechaunism, rabson-mendenhall syndrome, type A insulin resistance, and lipotrophic diabetes are classified as genetic defects of insulin action.

In all instances, self-care is integral to the effective management of this disease. Practitioners can assist patients with diabetes by cultivating a relationship that will allow the practitioner to assess the patient's capability for self-care, identify gaps in the patient's knowledge of diabetes care, teach them proper self-care strategies, and monitor self-care measures. The practitioner should be a part of the network of health care providers engaged in coordinating the patients' health care and should be their resource of information on drugs, devices, and monitoring system used in treatment.

All insulin used in Egypt are imported from outside, some companies import the crystals of insulins and complete the preparation in the production department.

Insulin are distributed by many distributing companies, most of these companies do not follow good storage practice and most of them transport insulin to rural areas in unqualified trucks.

Distances may be more than 500 kilometer and in summer temperature may reach up to 45°C or more which may affect the insulin stability, therefore the aim of this thesis is to know how long insulin will be stable at high temperature compared to refrigerator and room temperature.

Thus the work in this thesis is divided into two chapters :-

Chapter I:-The Physical and the Chemical Stability of Some Selected Insulin Suspensions

Chapter II:-Comparison Between Safety and Efficacy of Human Insulin Produced Locally 30/70 (100u/MI) and Human Multinational Insulin 30/70 (100U/MI).

Chapter I

**The Physical and the Chemical Stability of Some Selected
Insulin Suspensions**

The work in this chapter includes determination of the physical and the chemical stability of human insulin suspensions 30/70 of two brands one of them produced locally but the other imported from America (Multinational).

Samples were stored at 3 different temperatures namely 4°C in refrigerator, 25°C at controlled room temperature and 45°C in incubator for one Year.

Source of crystals of locally produced insulin was Poland

Two types of locally produced insulin were used (40iu/ml) and (100iu/ml) but American insulin has only one type of units (100iu/ml).

The study of physical characters of insulin suspensions include visual examination of appearance at the above three temperatures for one year, determination of PH, and inspection of crystal shape and size using light microscope. On the other hand the study of the chemical stability includes the determination of total potency of two brands of human insulin suspensions (30/70) at three different temperatures namely 4°C, 25°C, 45°C. by using a validated method of high performance liquid chromatographic assay (HPLC).

At specified time intervals samples were withdrawn weekly during the first three months then monthly during the second three months, and at the end of first year. for assay by using HPLC method.

At the end of one year, the insulin suspensions were tested for impurities by size-exclusion chromatography.

The same batch was used during the study.

The results indicate that

Physical Stability:-

A- Appearance:-

The samples were tested visually for the appearance, discoloration, caking and resuspendability. These suspensions were stored at temperatures of 4°C, 25°C and 45°C for one year. Samples examined at frequent intervals.

At 4°C:- It was apparent that there was no change in appearance for suspensions stored at 4°C for the two brands of insulin and the sediment is easily redispersed.

At 25°C:- No discoloration was observed for two brands. When suspensions stand for a time, sedimentation occur but the suspension retain their consistency after slight shaking specially for American crystals.
