Study of comparison of various quality control test for expired and non-expired medicine

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***Abstract*- Paracetamol is an antipyretic medicine that belongs to the non-steroidal anti-inflammatory drug class. There are some dosage forms on the market under different names that all have the general claim to be bioequivalent. The main purpose of this experiment is to determine the difference between expired and non-expired medicine. To our knowledge, very few of these studies have been conducted on expired drugs. In addition, most of these studies are related to the stable physical and chemical properties of expired drugs, and no studies have been conducted to confirm their efficacy. In this study, Paracetamol 650 mg standard tablets from different companies were selected. Compression parameters (such as weight change, brittleness, hardness, and dissolution profile) may be found in many ways. Evaluation of these limits is done before maturity, after maturity, and every six months for two years from the expiration date to form a basis. At the time of the research, the active ingredients of all drugs were guaranteed intellectual property, indicating that they retained their potency two years after expiration. Antibiotics, determined by the patterns of "radiant heat tail movement" and "acetic acid-induced writhing", were not significantly different in efficacy and per cent protection. This shows that the drug maintains its results. Small difference in time of explosion during expiration compared to the time difference.**

***Key words*: Paracetamol, friability test, weight variation test, hardness test, disintegration test, dissolution test.**

1. INTRODUCTION

The aim of this evaluation is to control the deficiency in tablet design, to learn the difference between continuous and non-continuous use, and to increase the quality of the drug [2]. Therapeutic outcome and bioavailability in the table depend on its absence (Kar A et al., 2015; DR Judge et al., 2014) [1]. The expiration date of the drug is the last day of the manufacturer's acceptance of its safety. The shelf life of drugs is between 12 and 60 months from the date of production [2]. The shelf life and expiration date of pharmaceutical products are estimated at various times through rapid tests that follow the product over time [3]. Values for estimating degradation type and degradation rate are standard and used as part of the lifecycle assessment process. The results are used to determine the shelf life of the product [11]. The expiration dates of unwanted medicinal products can be checked regularly, and changes can be clearly seen as the number of unhealthy products increases and the quality of additives increases [4]. Sometimes it is not easy to detect expired drugs because they are still being treated and their drugs have not changed [4]. The Shelf Life Extension Programme (SLEP) studies the long-term stability of drug stocks [10]. The plan can be used to record the process by recording changes in physicochemical properties in the stored drug, and studies are needed not only to examine the physical stability and potency of the drug but also to check the drug's efficacy and expiration date [11]. FDA regulations do not require the determination of how long a drug can be used after this period, allowing formulation to determine the expiration date without considering the long-term drug [10]. According to the analysis and safety analysis, it was observed that 88% of the products were delayed by at least 1 year from their original expiration date, with an average delay of 66 months, but the remaining stability period was different. Many medicines have an expiration date if they are properly stored. Due to batch variability, the stability and quality of a continuous pharmaceutical product can only be guaranteed by regular testing and analysis of each product. Many factors are used to determine shelf life. These requirements include the chemical stability of the active pharmaceutical ingredient dosage form, especially if the degradation products are related to patients. Also, anything that affects the bioavailability of the API will limit its shelf life [13]. The purpose of stability testing is to provide evidence of the quality of drugs or drug products that change over time under the conditions of various environmental factors such as temperature, humidity, and set and to reach the proper storage, retest, and shelf-life expectations [14] .The best evidence that drugs can last longer than their label comes from life programmes such as the Extension Program [15]. If a longer shelf life decreases drug waste, this measure could also decrease environmental issues [15]. Shelf life is measured by the expiration date, usually 1 to 5 years, and is usually adjusted for maintenance. Safety research for the pharmaceutical industry is resource-intensive and time-consuming [16]. Development and use of a simple, rapid, and cost-effective curve-based method for repeating the analysis of drug levels [17]. The region under the curve determines the region of maximum absorption for a drug [17]. Not enough Paracetamol had an effect on the corrosion process of steel solutions, based on chemical methods and electrochemical processes [18]. This article is based on the use of expired or unused drugs containing strong drugs that may cause health problems if patients do not take their medications. This approach of adding value to unused drugs can solve both the environmental and economic problems of contamination with active drugs and decrease the cost of disposing of expired drugs [20]. Medicines that have passed their expiration date decompose into the atmosphere. This article shows a new method for processing expired chemicals to analyse the practicalities of various nanomaterial combinations [21].

QUALITY CONTROL TESTS

1) Friability Test:

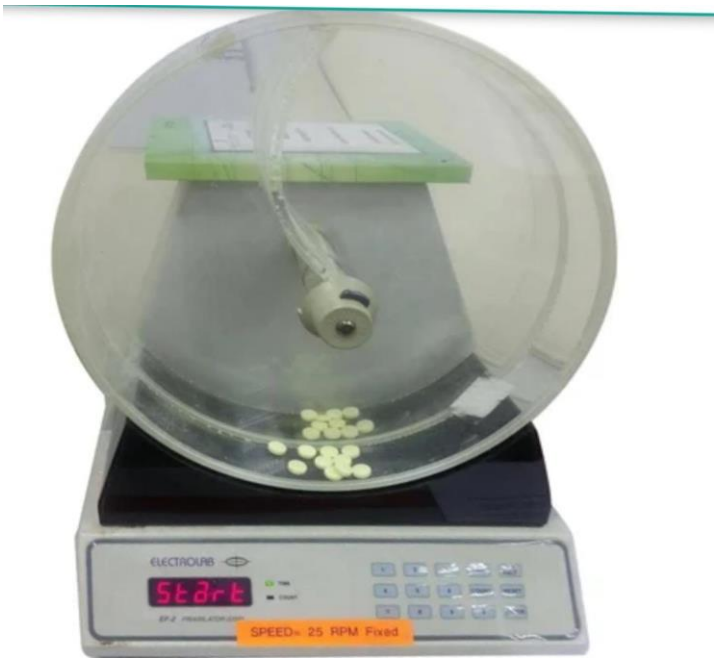

Fig.1.

Friability is the strength or toughness of compressed or uncoated tablets, which is determined using a Roche fragility tester or a Roche fragility tester. Tablet for average weight <650 mg and > 650 mg for this total 6 tablets taken. Tablets tested were weight dusted and placed in a drum crusher for rotation 100 times. Test-fail if the tablet is cracked or crumbed, losing more than 1% of the weight of the rolled tablet after 100 turns [3]. Brittleness is less than 0.8. This limitation is strictly adhered to when the tablet is attached to the layer [1].

2) Weight variation test:

For the weight variation test discussed here, it seems appropriate to measure batch quality by the percentage of defective tablets in the kit; this means tablets where the weight differences are more than 5% from the batch average [6]. It's important to note that defective tablets in a batch may not be considered "bad" in samples, as batches and intermediate samples often disagree [6]. For tablets weighing more than 80 mg, the difference is 10%; for tablets weighing 80 to 250 mg, the difference is 7.5%; and for tablets weighing more than 250 mg, the difference is 5%. The tolerance for Paracetamol is 5% [1].

Fig.2.

3) Hardness test:

At higher compression rates, the tablets exhibited a more elastic response than at lower rates. Compressing tablets at different depths in the mold does not affect the physical properties of the compressed tablets [7].

4) Disintegration test:

Disintegration is defined as the condition in which the tablet residue remaining in the final sieving device, except insoluble layer fragments, has soft material without a visibly hard, unsettled core [8]. The disintegration process involves breaking the tablet into smaller pieces. The faster the fragmentation, the faster the action. Fragmentation usually refers to the result of the separation of active substances. Thus, the experiments are similar to what the tablet would encounter in the gut in terms of temperature, pH, and

mechanic
[8].12 tablets were taken in the disintegration test at 37 ± 2°C containing simulated grape juice (0.1N HCl) using Electro Lab disi ntegration device. The time required for the tablet to break was recorded [8].

Fig.3.

5) Dissolution test:
Solubility testing is an important tool in indicating the efficacy of oral products [1]. The effect of this is that for the drug to be effective, it must first be liberated from the product and dissolved in the liquid in the stomach before being absorbed into the blood stream. In other words, the rate and extent of absorption of the drug depend on the dissolution of the drug from the dosage form [1].

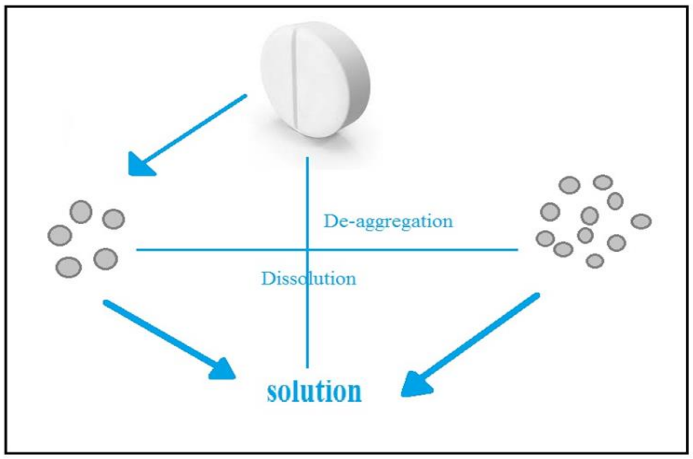

Fig.4.

Fig.5

Result:

The fact that the active ingredients of all drugs were properly intellectually guaranteed at the time of the research shows that they maintain their potential two-year post-expiry date [11]. While the breakup times of Paracetamol at expiry differed slightly over different times, the breakup time did not differ over the study period [11]. Expiring Paracetamol was tested by the Egyptian International Pharmaceutical Industry Corporation (EIPICO). We use expired drugs one month after the expiration date in order not to lose their effect. Prepare expired Paracetamol by dissolving the sample weight in distilled water. Each experiment was performed three times during the same period to ensure the accuracy of the results [19].

Conclusion: The NSAIDs in our study retain their strength, physical stability, and physical activity for up to one month after their expiration date. Current estimates of expiration dates for drugs do not accurately reflect the actual shelf life. Properly extending the shelf life of drugs can play a role in reducing drug shortages. In addition, extending the shelf life cannot reduce the cost of health care in the country [11]. Over the past few years, the FDA has introduced several life extension programs to delay replacement costs and prevent drug shortages from supply disruptions. The purpose of this review is to combine existing data on expired drugs with historical data [12].

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