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Original article

Comparative *In vitro* Evaluation of Different Brands of 40 mg Furosemide Tablets

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Abstract

Concerns about medication failure and the high rates of morbidity and mortality linked to the distribution and use of fake, counterfeit, and inferior medications are major concerns for patients, healthcare providers, and drug regulatory agencies. To provide the intended therapeutic effect, a medication must include the appropriate quantity of the active pharmacological ingredient in addition to the necessary physical properties. One popular and effective diuretic medication that is mostly used to treat oedema and hypertension is furosemide. The market today offers a wide variety of furosemide formulations intended for oral consumption. The purpose of this study is to examine a number of Furosemide tablet brands sold in Al Bayda, Libya, to confirm that they comply with the regulatory requirements specified by the US Pharmacopoeia and the British Pharmacopoeia as well as label claims. Furosemide tablets of six different brands were chosen at random from several local pharmacies in Al Bayda, Libya. In addition to other significant evaluation criteria like weight variation, hardness, friability, disintegration time, dissolution test, and drug content assay, the samples' visual qualities were also analyzed. The findings verified that all brands were deemed to be of good quality and met the requirements of the official Pharmacopoeias. Additionally, they had dissolution profiles that were comparable to the innovator's, enabling their interchangeability.

Keywords: Furosemide Tablets, Quality Control, Dissolution Test, Similarity Factor.

Introduction

Diuretics are among the many drug classes that are necessary for the efficient treatment of hypertension [1]. Loop diuretics are crucial for treating congestion and fluid overload in heart failure patients [2]. One of the most commonly prescribed loop diuretics is furosemide (FURO), which was approved by the FDA in July 1982 [3]. FURO is primarily prescribed to treat oedema and hypertension. In addition, it is used to treat severe hypercalcemia when accompanied with appropriate rehydration, as well as hepatic cirrhosis, renal failure, nephrotic syndrome, and cerebral or pulmonary oedema [1]. In the renal tubules, FURO disrupts the reabsorption of water, salt, and chloride, which increases urine production. It accomplishes this by inhibiting NKCC2, a kidney-specific sodium-potassium-chloride cotransporter that is essential for the uptake and excretion of sodium, potassium, and chloride ions [3]. FURO is categorized as Class IV according to the Biopharmaceutics Classification System (BCS); it has low solubility and low permeability [4,5]. FURO is known to have a low oral bioavailability, which is mostly caused by its poor permeability and consistency [6]. It is effectively absorbed by the upper small intestinal and stomach epithelium [4,5], exhibiting a high protein binding rate of 91-99% and an oral bioavailability ranging from 37% to 51% [4,7].

Concerns about the quality of drugs are common, especially in developing countries. The use of inadequate and ineffective medications puts treatment at risk and may ultimately fail to achieve the intended health objectives. The pharmaceutical quality of vital drugs on the market must be continuously evaluated to ensure their quality. The significance of this factor is increased when it comes to treatments used for chronic illnesses, which necessitate regular daily care for a long time. Since FURO tablets are frequently prescribed as vital, life-saving medications for prolonged use, it is vital to conduct routine quality control assessments once they are introduced to the market [1]. This study aimed to examine the pharmaceutical quality of various generic brands of conventional FURO 40 mg tablets available in Libya. Every brand was assessed for compliance with the USP and British Pharmacopoeia (BP) standards as well as label claims.

Methods

Materials

The FURO reference standard was obtained from Sanofi-Aventis, Egypt. Freshly produced distilled water, potassium dihydrogen phosphate, sodium hydroxide pellets, and hydrochloric acid were the reagents utilised. Every reagent used was of analytical quality.

FURO 40 mg tablets of six different brands were obtained from local pharmacies in Al Bayda City, Libya. The six brands were randomly coded as shown in Table 1 from F1 to F6. F1 was identified as the reference. Every brand of FURO tablet was bought within its expiration date and in its original package.

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Methods

Visual examination

Ten tablets were chosen at random from each batch, and their external features, such as color, shape, surface texture, the existence of grooves, and any surface imperfections, were examined visually [8].

Thickness and diameter

A random selection of ten tablets from each brand was made to have their diameter and thickness measured. These dimensions must be kept within ±5% of the established standard value [8,9].

Weight Uniformity Test

A ME235S, Sensitive electronic balance (SARTORIUS AG, Germany) was used to weigh twenty tablets of each brand separately. The percentage difference from the mean value and the average weights for each brand was estimated. Each tablet's weight deviation as a percentage of the average weight was calculated. If the weights of no more than two tablets differ from the average weight by more than the permitted percentage (±7.5%) and no tablet deviates by more than double that percentage (±15%), the batch is considered to meet USP criteria [1], [3], [8–13].

Hardness test

Tablet hardness was measured for each brand using the TBH 220 D hardness tester (Erweka® GmbH, Germany). From each brand, ten tablets were chosen at random, and every tablet was compressed. The tablet's breaking force was measured in newtons [1], [3], [8]–[11].

Friability test

The investigation involved weighing twenty tablets of each brand and putting them in a Friability tester (TAR 220; Erweka® GmbH, Germany) that ran for four minutes at 25 rpm. The tablets were subsequently dusted and reweighed. The following formula was used to determine the percentage of friability:

$\%\ \text{Friability} = (W_1 - W_2) \times 100/W_1$

Where W_1 = The tablet's initial weight. W_2 = The tablet's final weight following testing [1], [3], [8]–[11].

Disintegration test

A DTG 3000 Disintegration tester (COPLEY SCIENTIFIC, UK) was used to test six tablets of each brand at 37 ± 0.5°C in phosphate buffer pH 6.6. The disintegration time was calculated when there were no more particles in the tester's basket [14].

Preparation of a stock solution of Furosemide

A 100 mg of FURO that had been carefully weighed was added to a 100 ml volumetric flask. A total of fifty milliliters of phosphate buffer (pH 6.6) was used to dissolve the medicine, and the volume was adjusted to 100ml. The final solution was referred to as "stock" since it contained a concentration of 1 mg/ml.

Standard Calibration Curve Preparation

To create FURO solutions with different concentrations (40–100 µg/ml), the stock solution was diluted as necessary. The absorbances of the solutions were measured at λmax=273 nm using the GENESYS 10S UV-Vis Spectrophotometer (Thermo Fisher Scientific, USA). The regression equation was derived using a plot of absorbance against FURO concentration [9].

Assay of drug content

After 20 tablets of each brand were finely ground, a precisely weighed quantity of powder equal to 40 mg FURO was transferred to a 100 ml volumetric flask. Consequently, seventy milliliters of phosphate buffer (pH 6.6) were added and shaken for fifteen minutes. The volume was adjusted to 100ml and filtered. A 100 ml of phosphate buffer (pH 6.6) was used to further dilute 10 ml of the filtrate. Subsequently, 5 ml was put into a 25 ml volumetric flask, and the remaining volume was filled with PB pH 6.6.

The absorbance of the assay preparation was measured at λmax=273 nm using a GENESYS 10S UV-Vis Spectrophotometer (Thermo Fisher Scientific, USA) with phosphate buffer pH 6.6 used as a blank. The experiment was conducted in triplicate [3,9].

Dissolution test

The USP-II paddle, a DT600 HH dissolution apparatus (Erweka® GmbH, Germany), was used to test the dissolution of each formulation, and 900 millilitres of phosphate buffer pH 6.6 was utilized as the dissolution medium. The medium was allowed to reach an equilibrium temperature of 37 ± 0.5°C. After inserting the tablet and covering the vessel, the apparatus was operated at 50 rpm. Five milliliters of the dissolving sample were removed at predetermined intervals and replaced with an equivalent volume of the fresh dissolution medium to maintain sink conditions. The samples were filtered, and a GENESYS 10S UV-Vis

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Spectrophotometer (Thermo Fisher Scientific, USA) was used to spectrophotometrically analyze the samples at 273 nm.
A calibration curve derived from standard propranolol samples was used to calculate each sample's concentration. The percentage of dissolutions was calculated [15].

Analysis of the similarity factor

The dissolution profiles were estimated by plotting the percentage of drug released against time. The model-independent similarity factor f2, which is provided by the US FDA, was compared and is shown in the following equation:

$f2=50 \log\{[1+1/n\sum^{n=1}(R_t-T_t)^2]^{-0.5} x\ 100\}$

Where n is the number of time points, Rt and Tt are the dissolution values at each time point for reference and test products, respectively, at a time.
The two dissolution profiles are the same or equivalent when the f2 value is 50 or above. A dissolving profile that differs from the innovator product and is therefore not interchangeable is indicated by an f2 value less than 50 [13].

Results and Discussion

Visual examination

According to the current study, every brand that was examined was scored and showed a uniform white look, round shape, flat surfaces, undamaged appearance, and no odour. No indications of spurious, wrongly labeled, falsified, or counterfeit items as defined by the WHO were found during the visual evaluation of physical attributes, packaging, and labeling. There were no obvious defects in the tablets, and none of the FURO tablet brands were incorrectly, insufficiently, or completely labeled, which would have led to concerns that the product was a fake.

Table 1. Description of the studied brands of FURO tablets

Brand code	Country of origin	Shape & Color	Surface texture & Convexity	Scoring	Coating
F1	France	Round & white	Smooth & flat with beveled edges	Scored	Uncoated
F2	Greece	Round & white	Smooth & flat with beveled edges	Scored	Uncoated
F3	United Kingdom	Round & white	Smooth & flat with beveled edges	Scored	Uncoated
F4	Morocco	Round & white	Smooth & flat with beveled edges	Scored	Uncoated
F5	Egypt	Round & white	Smooth & flat with beveled edges	Scored	Uncoated
F6	Turkey	Round & white	Smooth & flat with beveled edges	Scored	Uncoated

Table 2. Quality control test results of the studied brands of FURO tablets

Brand code	Mean Weight (mg)	%Deviation from Mean Weight	Hardness ± SD (N)	Friability (%)	Disintegration time ± SD (min)	Assay ± SD (%)	Similarity factor (f2)
F1	162.62	±2.87	73.75±20	0.22	2.31 ± 0.02	105 ± 0.01	62.8
F2	163.47	±3.14	71.25±23	0.14	5.28 ± 0.04	96 ± 0.003	62.8
F3	165.13	±2.54	82.8±7	0.36	5.19 ± 0.3	110 ± 0.01	53.6
F4	160.18	±1.88	107.5±13	0.34	2.19 ± 0.2	106 ± 0.07	58.5
F5	161.57	±2.64	83.8±1.6	0.62	1.7 ± 0.1	110 ± 0.05	59.8
F6	161.85	±2.38	78.33±9	0.48	1.15 ± 0.2	99 ± 0.02	64.9

Thickness and diameter

All of the brands under investigation had thickness and diameter values that were clearly inside the allowed range.

Weight Uniformity

(Table 2) shows that all six FURO products passed the weight uniformity test and met the USP requirements for weight uniformity, with none of the brands deviating by more than ±5% from the mean value. Each tablet brand had a weight that ranged from 160.18±1.88 mg to 165.13±2.54 mg.

Hardness

According to (Table 2), the hardness results of FURO tablets fell between 71.25 ±23−107.5±13 N. F4 needed the most pressure to fracture, whereas F2 needed the least. For tablets to be sufficiently hard, a force of roughly 40 N is necessary [1]. According to the observed data, the hardness of each of the chosen FURO brands is satisfactory.
Hardness is a crucial factor since tablets must be strong enough to withstand handling forces during packaging, breakage during storage, and transportation. The longer breakdown period of very hard tablets eventually results in a decrease in bioavailability [1]. Additionally, the hardness of tablets is significantly

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influenced by granulation properties. Formulation design, manufacturing procedures, and parameter configurations must all be carefully optimised in order to produce tablets with the necessary properties and mechanical strength [8]**.** Controlling the tablet's hardness is crucial for medications that may have bioavailability issues or that are susceptible to variations in dissolution release patterns.

Friability

The results presented in (Table 2) demonstrate that the brands under investigation have a percentage of friability that meets the USP criterion that the tablets not lose more than 1% of their initial weight, demonstrating strong mechanical resistance. Pharmaceutical formulations with high degrees of friability are more prone to mechanical degradation, which could lead to the loss of the active component and a reduction in the compound's therapeutic efficacy. This can have a substantial impact on the formulation's cosmetic appearance, consumer acceptance, and difficulty with weight variation or content uniformity [1], [3].

Disintegration Time

According to official pharmacopoeias, tablets that are film-coated and uncoated should dissolve in 30 minutes. The observed disintegration times for every FURO brand under investigation were less than 15 minutes, demonstrating that every brand met the official pharmacopoeias' quality control standards. As a result, the active pharmaceutical ingredient would dissolve after 15 minutes of consumption [3]. The results of Table 2 indicate that the average disintegration time of FURO tablets ranged from 1.15 to 5.28 minutes. Orally ingested tablets must disintegrate in order for the medication to dissolve in gastrointestinal fluids at the site of absorption before it is completely absorbed [8]. The process of disintegration is crucial because better absorption leads to increased bioavailability, which in turn produces more successful therapeutic effects. The mechanism, disintegrant concentration, and incorporation technique are some of the other aspects that affect tablet disintegration. Furthermore, the degree of compression force used in tablet manufacturing and the properties of the binder system have a significant influence [8]. Excessive compression may be the cause of an extremely long tablet disintegration time. Furthermore, irregular disintegration suggests batch irregularities and a lack of homogeneity [1].

FURO calibration curve

The λmax was found to be at 273 nm. The regression equation of the standard calibration curve developed for the determination of FURO concentration with a concentration range of 40–100µg/ml was y = 0.0017x + 0.0531 with a determination coefficient of R^2= 0.9952.

Assay of drug content

In accordance with USP 32 (2009), the data displayed in Table 2 indicates that every brand of FURO tablets was within the designated limits and satisfied the assay requirements, which are set between 90% and 110% [3].

The assay test's objective is to verify that the tablet's active ingredient content corresponds to the amount specified on the label. The concentration of a product's active ingredient affects both its overall quality and therapeutic properties. The effectiveness of treatment may be adversely affected by underdosing due to insufficient levels of the active pharmaceutical ingredient (API). On the other hand, high API levels may result in overdosing, which raises the possibility of adverse drug reactions in addition to having a negative impact on treatment outcomes [1].

Dissolution Test

According to official pharmacopoeia requirements, at least 80% of the drug's labelled dose must be delivered in less than 30 minutes. Figure 1 shows that the dissolution rate profiles essentially overlap and that every brand passed the dissolution test during the evaluation period. More than 80% of the medication was released from the FURO tablets in the first ten minutes, demonstrating an immediate release profile. This was followed by a sustained release phase. The results of this investigation show that the dissolution profiles of the different FURO products under investigation are comparable.

Analysis of the similarity factor

To confirm the similarities in dissolving profiles, all generated profiles were compared to the innovator's profile (F1) using the similarity factor (f2) as a measure. Table 2 displays the (f2) values for the brands under investigation in comparison to brand F1. All of the brands under investigation had (f2) values higher than 50, according to the similarity factor calculations, suggesting that the profiles of the five marketed brands, F2, F3, F4, F5, and F6, are comparable to those of the innovative brand F1. The dissolution profiles of every brand that was examined were found to be interchangeable with the innovator brand F1.

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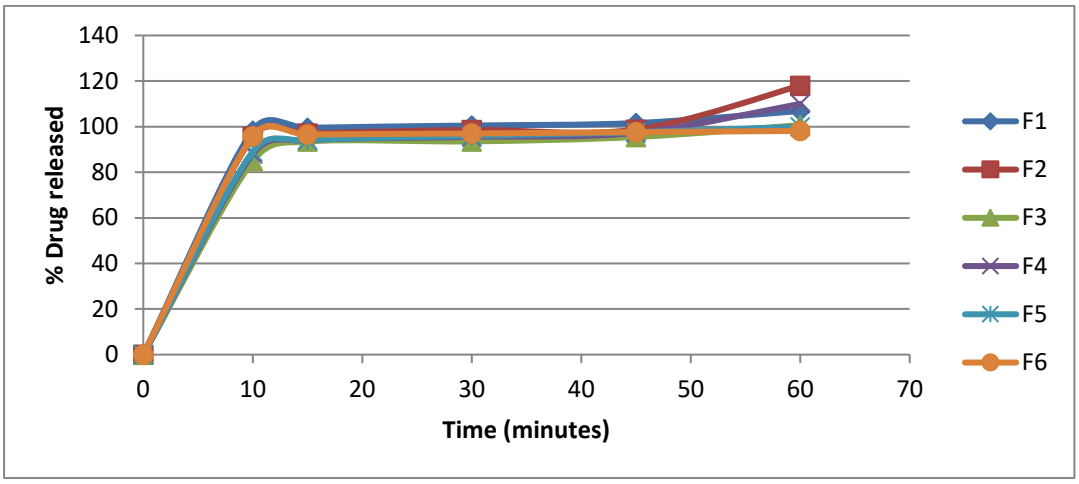

Fig. 1. Dissolution profiles of FURO tablet brands under investigation

Conclusion

The objective of this study was to assess the quality and physicochemical equivalency of six different FURO brands that are presently available on the market. The study found that all brands were made up of round, disc-shaped tablets with white, slightly beveled edges. Each of the various FURO tablet brands had the same weight and geometric measurements. All of the tablets' weights revealed deviations from the mean that were within acceptable bounds; none of them deviated more than ±7.5% from the mean. Average weights for each brand were similar. The tablet must have sufficient mechanical strength to withstand breaks and withstand erosion, and chipping during all post-manufacturing handling procedures.

Through handling, packaging, and transportation, each brand demonstrated the ability to withstand pressure, with measurements ranging from 71.25 to 107.5N. The friability and tablet cohesiveness of every brand under investigation were satisfactory, staying below 1% w/w. The right dosage of medication must be delivered by tablets in order to minimize toxicity and guarantee successful therapeutic results. In terms of active component content, the evaluation's findings fell within the acceptable range of 90–11%. Tablet disintegration is necessary for both their dissolution and the drug's efficient absorption. Every brand met the disintegration time requirements. Within 15 minutes, the tablets had broken down and been reduced to their original granules and particles.

According to the dissolution profile, every brand under study released over 80% of its active pharmaceutical ingredient in less than 30 minutes, meeting the USP and BP specified limits. As a result, it can be concluded that all FURO tablet brands are of high quality, have dissolving profiles that are comparable to the innovator's, and may be used interchangeably.

The findings verified that every brand that was chosen exhibited acceptable quality and complied with the necessary official requirements. This guarantees that these brands can be used safely and successfully even though they are produced by different pharmaceutical companies, proving that they are not fake, counterfeit, or substandard but rather suitable for consumption. Any of the other three brands can be used as a substitute without any restrictions in the event that one of the selected brands is unavailable.

Conflict of interest. Nil

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