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A COMPARATIVE ANALYTICAL STUDY OF GENERIC AND BRANDED FRUSEMIDE TABLETS

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ABSTRACT: This research examines both generic and brand-name alternatives to frusemide pills. The most often utilized loop diuretic is frusemide. Assessing the quality of various sorts is essential for safeguarding individuals. Standardized physicochemical assessments were conducted on both proprietary and generic tablets to verify compliance with pharmaceutical standards. In addition to solubility, weight, hardness, friability, disintegration time, and the active pharmaceutical ingredient were all quantified and monitored. We analyzed the algorithms' results to determine if they functioned differently. Minimal differences existed between brand-name and generic frusemide tablets, with both complying with regulatory standards. Although more economical and safer, generic frusemide appears to be comparably effective as branded medications, based on the existing data. In the healthcare industry, the utilization of more potent drugs is anticipated.

Keywords: *Frusemide, Loop diuretic, Generic drugs, Branded tablets, Comparative evaluation, Pharmaceutical quality, Dissolution research, Cost-effectiveness*

1. INTRODUCTION

Numerous firms are currently developing a number of novel drugs to treat patients. They produce both generic and name-brand pharmaceuticals. Various pharmaceutical companies give the same active ingredient distinct names. All members of the pharmaceutical industry must abide by the pharmacopoeial regulations.Generic medications are brand-name medications without a patent. The pharmaceutical company's founder initially manufactured branded goods. The active ingredients, dose, quality, and efficacy of these drugs are all the same. Numerous businesses offer generic drugs at different rates and under a range of brand names. Price discounts are available.Physicians, pharmacists, and the general public still despise generic medications.Brand-name drugs are not only safer than generic ones, but they are also better, more effective, and less likely to cause side effects.

Companies in the pharmaceutical sector set quality requirements for both name-brand and generic drugs. Both drug-testing techniques are used. The comparison and evaluation of brand-name and generic frusemide tablets has shown that the idea that brand-name drugs are better is untrue.Because frusemide prevents salt and chloride from being reabsorbed in the proximal, distal, and thick ascending limbs of Henle, more urine is generated. "This diuretic effect happens because sodium-potassium-chloride co-transporters are blocked, which stops sodium ions from moving from the luminal side to the basolateral side for reabsorption." "This inhibition leads to enhanced excretion of water, sodium, chloride, magnesium, hydrogen, and potassium ions."

2. MATERIALS AND METHODS

Quality control for both name-brand and generic loop diuretic pills was investigated as part of this research. The powerful loop diuretic frusemide (40 mg) is used to treat edema of the kidney, liver, lungs, and heart. It has the ability to stabilize blood pressure. Lasix, Fru, Frusenac, Diaqua-2, and Lo-Aqua are a few drugs that include frusemide. A single pill of Frusemide was shown to be equally effective as the name-brand and generic versions.

Drug Profile: The loop diuretic 4-Chloro-2-[(furan-2-ylmethyl)amino]-5-sulfamoylbenzoic acid (C12H11ClN2O5S), with a molecular weight of 330.74 grams, exhibits an oral bioavailability of 43 to 69%. It can be administered into the dermis, musculature, veins, or oral cavity. A daily dosage of 40–120 mg is recommended. Adults ought to administer 20–80 mg daily to regulate edema.

Chemicals and Reagents: The medication frusemide was obtainable in both branded and generic variants from a respected pharmacy in Chidambaram, Cuddalore. Zentiva Private Limited and Unicure India Ltd. both manufactured generic pills. They conducted the research.S.D. Fine Chemicals, located in Mumbai, India, provides chemicals of analytical purity (AR grade). No Borosil Ltd. Class A glassware was utilized during the investigation.

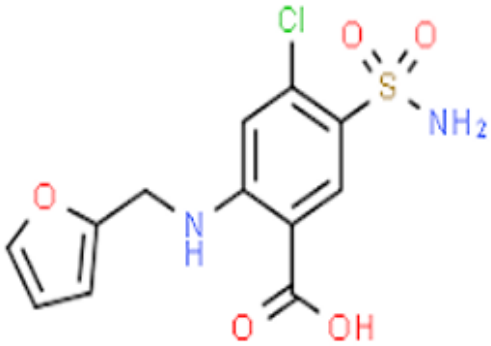

Fig. 1. Structure of frusemide

3. METHODOLOGY

An evaluation was conducted to ascertain the quality of both brand-name and generic frusemide 40 mg uncoated tablets in accordance with the Indian Pharmacopoeia 2018.

Evaluation Tests for Tablets

Tablets appearance

"Twenty tablets were chosen and analyzed for characteristics including color, shape, surface roughness, grooves, and additional surface imperfections."

Weight variation (%)

A Shimadzu automatic scale was used to weigh twenty generic and name-brand pills. They took a weight reading and noted it (X1). We calculated the average weight (XA) of each sample and the degree of variation among each tablet.

$$\% \text{ weight variation} = (X_1 - X_A) \times 100 / X_A$$

Thickness(mm)

Using digital vernier calipers (Labpro), we chose 10 tablets from the typical sample and compared them to ascertain each tablet's thickness. The average and standard deviation were computed to determine the thickness.

Hardness (kg/cm^2)

For the purpose of determining the level of hardness of the pills, we utilized a Pfizer hardness tester. A total of ten tablets were evaluated for their level of hardness, and the standard deviation and mean of the results were recorded.

Friability(%)

In lieu of employing the drum, we inserted six tablets into the Roche friabilator (Erweka, Germany), with one tablet representing each of the generic and brand names. We washed the tablets quickly and reweighed them after the drum was spun 100 times at 25 rpm after they were removed. The friability was determined by examining the percentage of weight loss.

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

Where, W_1=Initial weight of tablets, W_2=Final weight of tablets.

Disintegration time(min)

"Disintegration time is considered a crucial factor in determining the ideal formulation." Disintegration utilizing a paddle-style USP type II dissolution apparatus with a water buffer (Erweka, Germany).The medium was maintained at 37 ± 0.5ºC and 28–32 rpm. The "disintegration time" of a tablet refers to the duration required for it to decompose.

In-vitro dissolution studies

The solvent used in this experiment was 900 milliliters of phosphate buffer with a pH of 5.8.

The phosphate buffer is prepared in the following manner: Option 1: In a 1000 mL vessel, combine 13.61 g of potassium dihydrogen phosphate with water.

The second solution necessitates 1000 milliliters of water and 35.81 grams of disodium hydrogen phosphate. Incorporate 3.6 ml of solution II into 96.4 ml of solution I before combining.

The USP dissolving apparatus was configured to operate at a rate of 50 rpm. The second section. Pills were present in each test vial. We collected samples at 15-minute intervals for a total of 45 minutes. The sample was precisely five milliliters in volume. To ensure that the dissolving media remained at a consistent volume, five milliliters of a fresh buffer solution were added to the beaker. The sample's absorbance at 271 nm was measured using a UV spectrophotometer after being diluted to 5 ml with a pH 5.8 phosphate buffer.

Assay of Frusemide Tablet

For ten minutes, 20 weighed and pulverized tablets and 0.1 g of powdered frusemide were mixed with 150 ml of 0.1 M sodium hydroxide (0.4 g in 100 ml of water). 250 ml of 0.1 M sodium hydroxide, filtered via paper. The UV absorbance measured 271 mm after diluting 5 ml with 200 ml of 0.1 M sodium hydroxide. To determine C12H11ClN2O5S, utilize the specific absorbance of 580 at 271 nm.

Calibration Curve

Scanning for λmax

In spectrum basic mode, we used the Spheronics-pc double beam spectrophotometer 2202 to scan solutions at 10 µg/ml in phosphate buffer pH 5.8 between 200 and 400 nm.

Preparation of calibration curve

To achieve a final concentration of 2-10 µg/ml, 100 µg/ml frusemide stock solution was added to 10 ml volumetric flasks with pH 5.8 phosphate buffer. At pH 5.8, phosphate buffer solutions had 271 nm absorption. Three days were spent developing calibration curve solutions.

4. RESULTS AND DISCUSSION

Result by Pictorial Representations of Evaluation Test for Tablets

Our investigation of brand-name and generic frusemide tablets, classified as loop diuretics, adhered to IP quality control standards. Convexity (brand-round, generic-round, and brand-flat with beveled edges), morphology, hue, and surface texture are present. There are no chips or fractures. The tablet weight variation complied with pharmacopoeial standards (brand -2.955%, generic -3.120%), hardness (brand -6.4 kg/cm², generic -6.2 kg/cm²), thickness (brand -0.406%, generic -1.014%), friability (brand -0.94%, generic -0.77%), dissolution (brand -98.3%, generic -96.7%), assay (brand -105.1%, generic -101.2%), and disintegration time (brand -1 minute 25 seconds, generic -1 minute 39 seconds). In 45 minutes, 96.7% of the medication was released by the generic pill, whereas 98.3% was released by the branded tablets. Consequently, each tablet adhered to pharmaceutical industry standards.Table 1. Label contents

Item	Cost of tablets - For 10 tablets Rs.	Batch No.	Manufacture Date	Expiry Date	Manufacturer
Generic	10	FST1012	11/2022	10/2024	Unicure India Ltd
Brand	5	3P1454A	04/2023	03/2026	Zentiva private Limited

Table 2. Results of appearance features of the different brands of frusemide 40 mg tablets

Parameter	Generic	Brand
Shape & Color	Round & white	Round & white
Surface texture &Convexity	Smooth & flat with beveled edges	Smooth & flat with beveled edges
Presence ofcracks & chips	None	None

Table 3. Results of evaluation test for tablets

Evaluation Test for Tablets								
Drug	Average weight (mg)	% weight variation	Hardness test	Thickness test	Friability	disintegration test	Dissolution rate	Assay
	Standard as per IP	<7.5%	3-10 kg/cm²	± 5 %	<1%	30mins	Not less than 70%	90-110%
Generic	131.7	3.120	6.2	1.014	0.94	1 min39sec	96.7	101.2
Brand	165.3	2.955	6.4	0.406	0.77	1 min25sec	98.3	105.1

Table 4. Result of calibration curves data of frusemide using pH 5.8 phosphate buffer

S.no	Concentration (µg /ml)	Absorbance
1	2	0.107
2	4	0.226
3	6	0.343
4	8	0.436
5	10	0.578

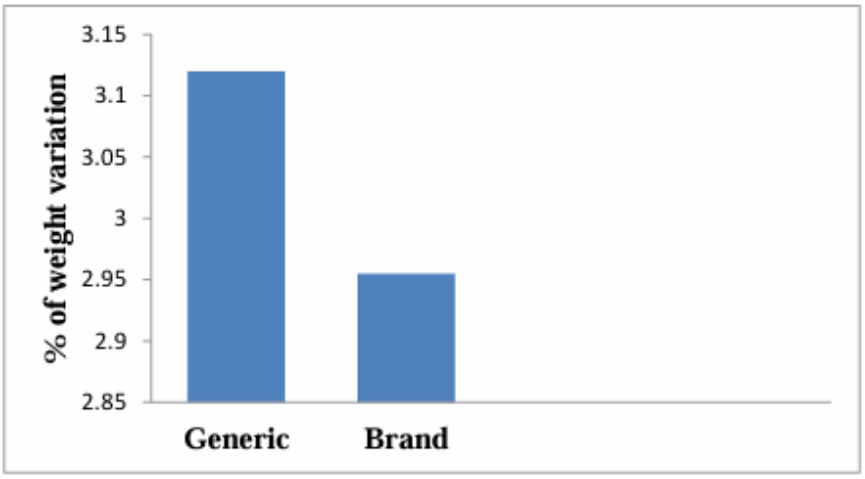

Fig. 2. % of weight variation of frusemide tablets

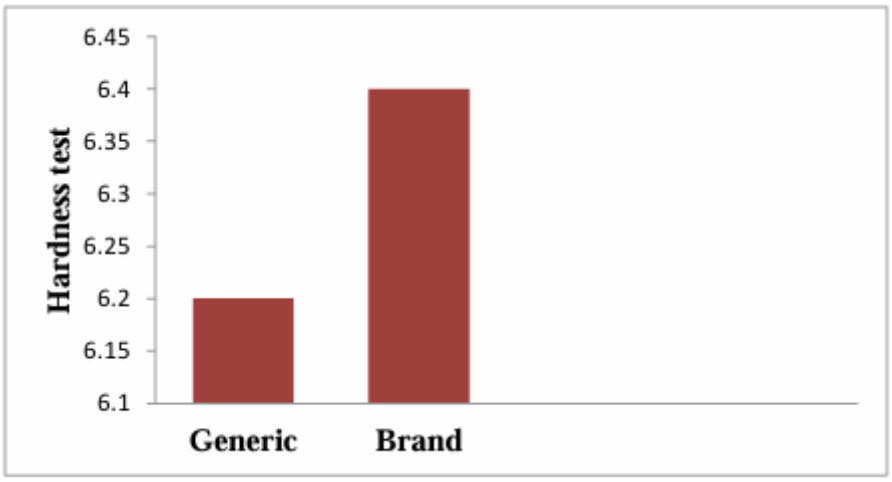

Fig. 3. Hardness of frusemide tablets

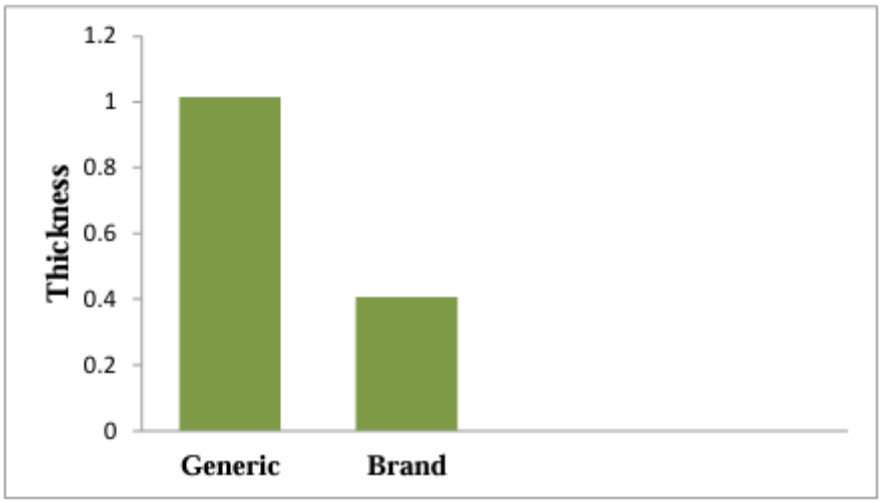

Fig. 4. Thickness of frusemide tablets

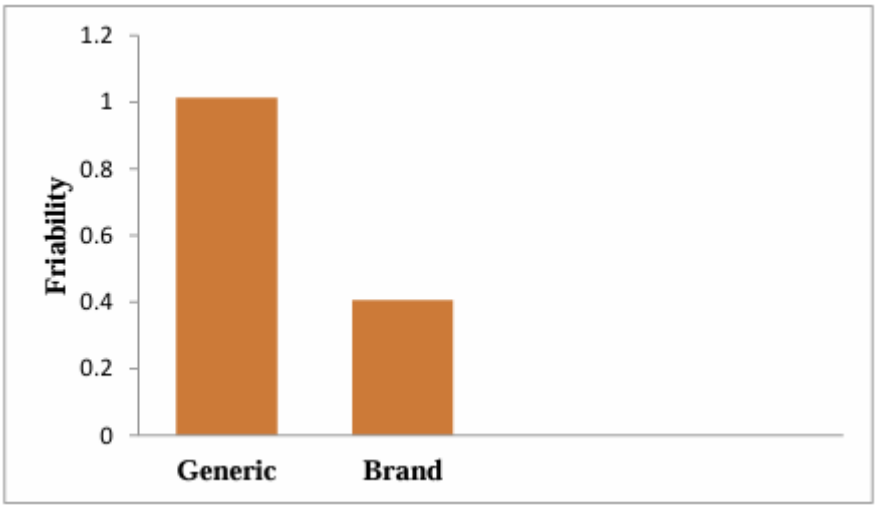

Fig. 5. Friability of frusemide tablets

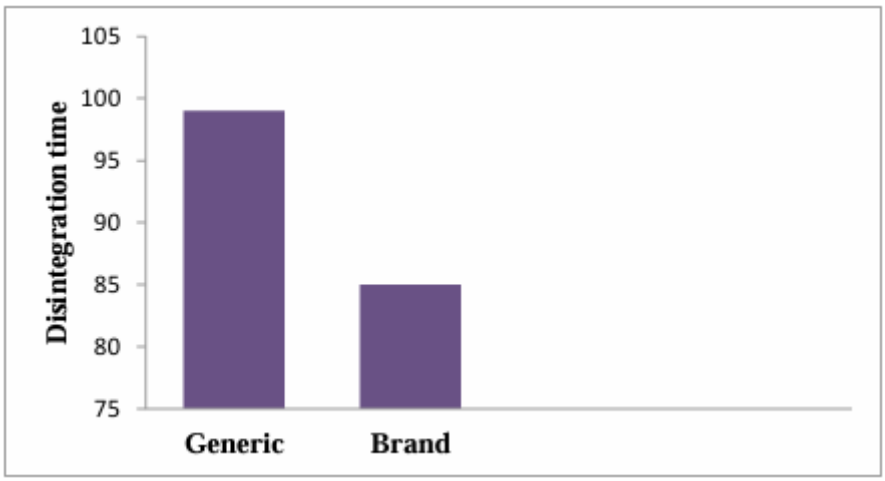

Fig. 6. Disintegration time of frusemide tablets

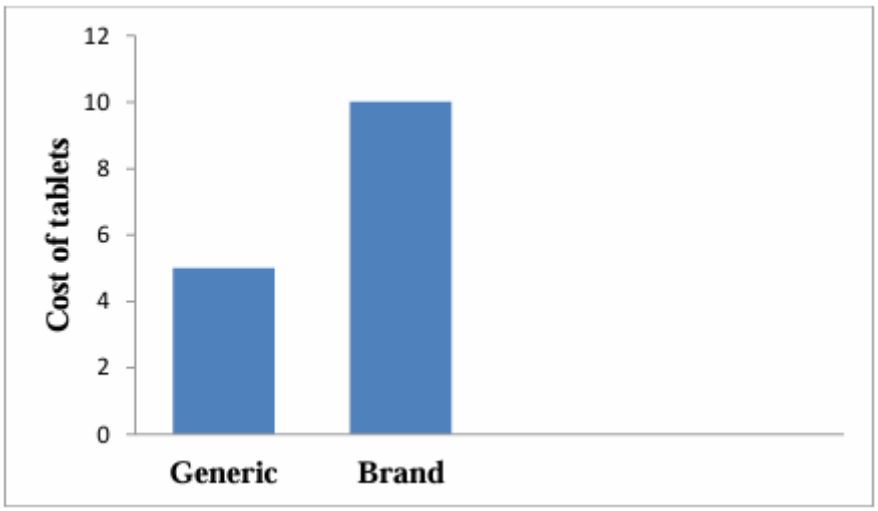

Fig. 7. Cost of frusemide tablets

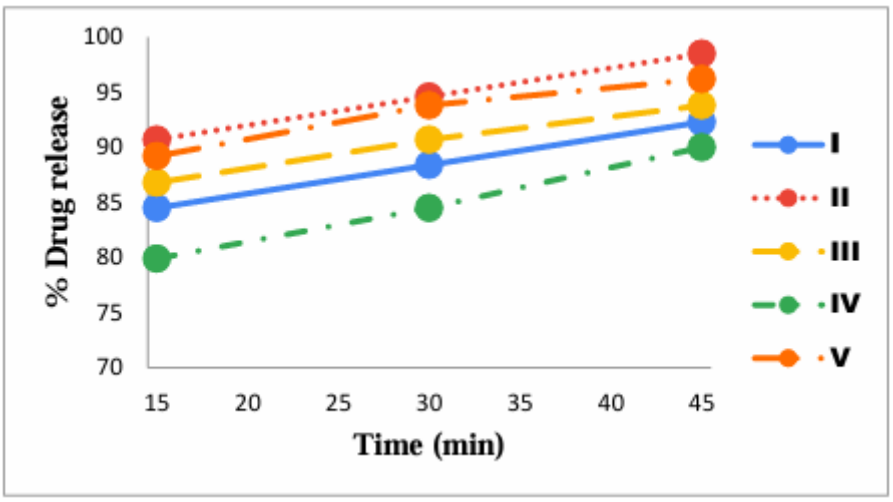

Fig. 8. Dissolution profile for generic drug

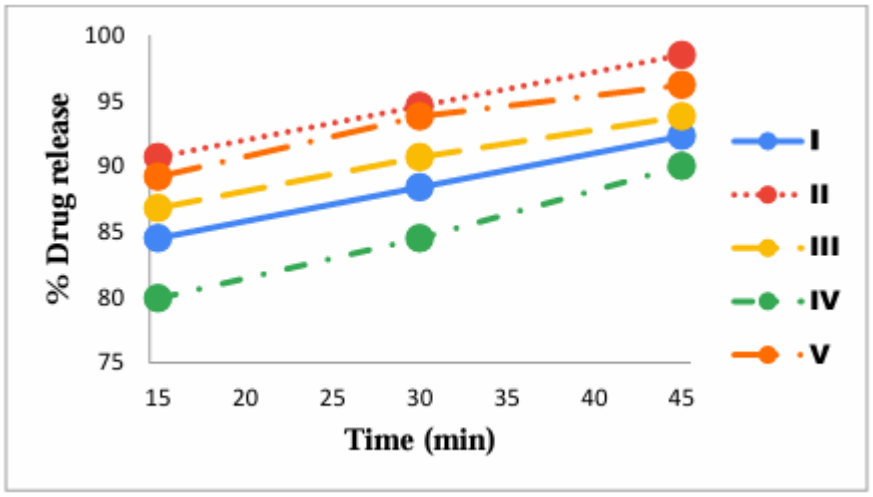

Fig. 9. Dissolution profile of branded drug

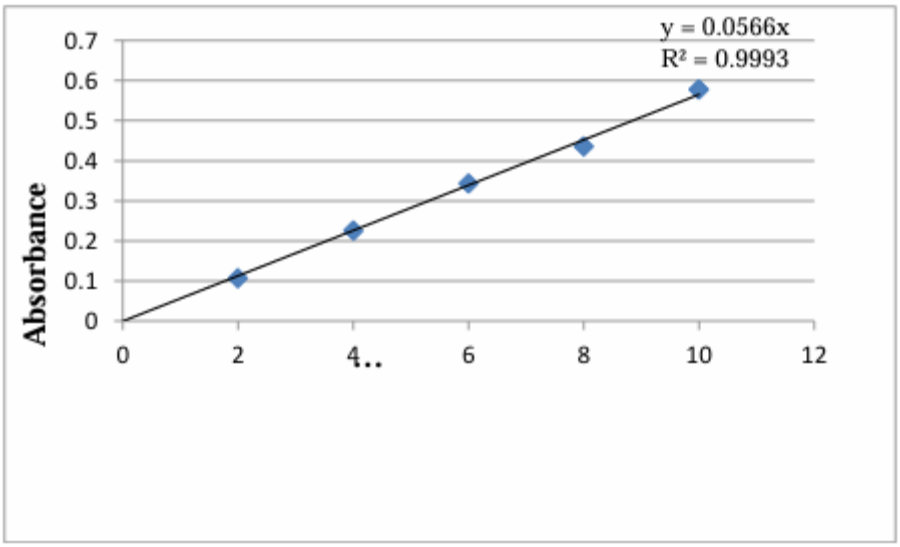

Fig. 10. Calibration curve of frusemide drug

5. CONCLUSION

In conclusion, both generic and branded loop diuretic frusemide tablets exhibit comparable therapeutic efficacy, safety, and clinical outcomes when manufactured in accordance with regulatory standards. The bioavailability, patient response, and diuretic action of generic frusemide are identical. They are cost-effective and dependable for the treatment of edema and hypertension. Patients may favor branded tablets because of their improved quality, superior packaging, and greater recognizability. However, these do not reduce the clinical efficacy. Generic frusemide tablets are advantageous from both a public health and pharmacoeconomic standpoint, as they reduce treatment costs and improve accessibility while maintaining quality. As a result, it is imperative to expand their application in therapeutic settings.

REFERENCES

1. Petrova E. Innovation in the pharmaceutical industry: The process of drug discovery and development. InInnovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies 2013 Oct 26 New York, NY: Springer New York. 2013;19-81.
2. Allen L, Ansel HC. Ansel's pharmaceutical dosage forms and drug delivery systems. Lippincott Williams & Wilkins; 2013.
3. Rägo L, Santoso B. Drug regulation: history, present and future. Drug benefits and risks: International Textbook of Clinical Pharmacology. 2008;2:65-77.
4. Ashlesha G, Atakale M, Shinde A, Yedge V. Generic drugs vs branded drugs: view of public. Current Trends in Pharmacy and Pharmaceutical Chemistry. 2020;2(2):33-8.
5. Singal GL, Nanda A, Kotwani A. A comparative evaluation of price and quality of some branded versus branded–generic medicines of the same manufacturer in India. Indian Journal of Pharmacology. 2011;43(2):131.
6. Colgan S, Faasse K, Martin LR, Stephens MH, Grey A, Petrie KJ. Perceptions of generic medication in the general population, doctors and pharmacists: A systematic review. BMJ Open. 2015;5(12): e008915.
7. Khan AN, Khar RK, Udayabanu M. Pilot research of quality of diclofenac generic products in-house regulatory Applied method: concern. using Indian Journal Pharmaceutical validated drug of Science. 2015;5(12):147-53.7) Greene JA. Generic: The unbranding of modern medicine. JHU Press; 2014.
8. Sweetman SC editors. Martindale, 'The Complete Drug Reference. 36th Edition. London: Pharmaceutical Press. 2009: 1292.
9. Shankar SS, Brater DC. Loop diuretics: from the Na-K-2Cl transporter to clinical use. American Journal of Physiology-Renal Physiology. 2003;284(1): F11-21.
10. Azlan NF, Koeners MP, Zhang J. Regulatory control of the Na–Cl co transporter NCC and its therapeutic potential for hypertension. Acta Pharmaceutica Sinica B. 2021;11(5):1117 28.
11. Burton RF. Ionic regulation and water balance. The Mollusca-Physiology. 1983: 293-350.
12. Sappani HK, Karthikeyan S. 4-Chloro-2 ((furan-2-ylmethyl) amino)-5 sulfamoylbenzoic Acid (FSM) and N (Isopropylcarbamoyl)-4-(m-tolylamino) Pyridine-3-sulfonamide (TSM) as Potential Inhibitors for Mild Steel Corrosion in 1 N H2SO4 Medium. Part I. Industrial & Engineering Chemistry Research. 2014;53 (9):3415-25.

13. Brater DC, Ellison DH, Emmett M. Causes and treatment of refractory edema in adults. Up to date; 2022.
14. Indian Pharmacopoeia. 8th edition. 2018; 299-309 & 2135-2136).
15. Elghnimi T, Benamer W, Walli R, Benshaban M, Comparative in-vitro Benashour Evaluation M. of Some Desloratadine Tablets Marketed in Tripoli Libya. AlQalam Journal of Medical and Applied Sciences. 2022:556 64.
16. United State Pharmacopoeia27/ National Formulary 22. Asian Edn., United state Pharmacopeial Convention Inc., Rockville. 2004;2622.