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Research

A comparative study on the in-vitro performance of uncoated generic and branded Isoxsuprine Hydrochloride tablets

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Abstract

The primary intension of the present work is to execute "The comparative study on the in-vitro performance of uncoated generic and branded Isoxsuprine hydrochloride tablets". Here, we compare the 4 distinct brands of branded tablets with 1 generic tablet. The main purpose of the comparative study is to compare their stability, efficacy and other evaluation parameters with different marketed Isoxsuprine HCl tablets. Isoxsuprine hydrochloride tablets acts as beta-2 adrenergic agonist (parasympathomimetic), peripheral vasodilator, uterine relaxant (tocolytic agent). In this comparative study, we determined their efficacy and effectiveness of the tablets on the basis of various in-vitro tests like weight variation, friability, hardness, dissolution and disintegration. It can be concluded that both branded and generic isoxsuprine hydrochloride tablets meet the pharmacopoeial quality standards.

Keywords: Isoxsuprine Hydrochloride, Generic vs Branded Tablets, In-vitro Evaluation, Pharmaceutical Quality Control, Dissolution and Disintegration Tests, Drug Content Assay

INTRODUCTION

Comparative study and quality control (QC) are fundamental components in the pharmaceutical industry, ensuring that medications are safe, effective and of consistent quality. These processes not only safeguard patient health but also uphold the integrity of pharmaceutical companies and ensure compliance with regulatory standards. Thus, minimizing risk of adverse reactions and treatment failure. This unwavering commitment to quality fosters trusts between healthcare providers, patients and pharmaceutical companies, reinforcing the industry's dedication to delivering safe and effective medications.[1]

Branded drug

A brand-name drug is a tiny medication which a pharmaceutical company has discovered, developed and selling. When the new medication is discovered, that company applies for the approving patent to prevent another business from duplicating and dispose of the medication. The FDA approves brand-name medications through the submission of a New Drug Application that includes information about the chemistry of the product, efficacy and safety of the dosage form, manufacturing of drug, dosage form of drug, packaging and labeling of the product characteristics that must be proven. Only with FDA approval can the creative company use this brand name during the specified patent protection period.[2]

Generic drugs

A generic drug contains the same active ingredient in identical strength as the original brand-name medication. Generic medications can only be introduced to the market after the patent on the innovator drug has expired. They are produced, following the same international quality standards and GMP regulations as brand-name counterparts. Since clinical trial data on the safety and effectiveness of the active ingredient is already established by the innovator, generic drugs do not require expensive and costly clinical studies. [3,4]

Isoxsuprine Hydrochloride IP

Isoxsuprine (ISX) is a synthetic compound classified as β_2-adrenergic receptor agonist. It's a medication that's been around for decades, quietly playing a role in treating conditions tied to blood flow and uterine activity primarily recognized for its vasodilatory and smooth muscle relaxant properties. Specifically, it's a beta-2 agonist, meaning it targets receptors primarily found in smooth muscle tissues, like those lining blood vessels and the uterus. When it binds to these receptors, it triggers and relaxing a bit like telling tense muscles to take a deep breath and loosen up. Chemically, it's known as Isoxsuprine Hydrocloride. The structure features a phenol linked to a hydroxylamine chain and a phenoxyethyl moiety, which facilitates its interaction with beta-2 adrenergic receptors. [5,6]

IUPAC Name: 4-hydroxy-α-[1-(1-methyl-2-phenoxy-ethyl)amino] ethyl benzenemethanol
Molecular formula: $C_{18}H_{23}NO_3$. HCl
Molecular weight: 337.84 g/mol[7]
Molecular structure:

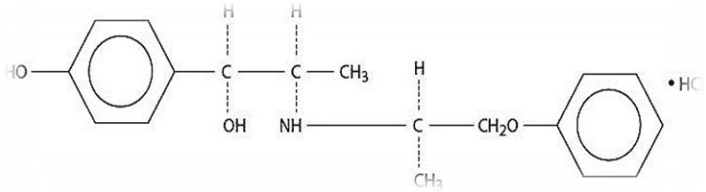

Fig 1: Structure of Isoxsuprine Hydrochloride

Mechanism of action

Isoxsuprine binds to beta-2 adrenergic receptors in the blood vessels and uterus

↓

Binding activates adenylate cyclase, which increasing intracellular cyclic adenosine monophosphate (cAMP) levels.

↓

And it inhibits the myosin light-chain kinase enzyme, which is essential for smooth muscle contraction

↓

Increased level of cAMP results in relaxation of the smooth muscles

↓

This relaxation effect causes vasodilation effect in blood vessel and in the uterus.[8]

Adverse effects

One of the most commonly reported side effects of Isoxsuprine Hydrochloride is dizziness or light headness. Some patients may experience nausea, vomiting or stomach pain. In rare cases, it may cause tachycardia. Allergic reactions, flushing, muscle cramps or weakness have also been reported, though these symptoms are less common.[9]

Dosage

Table 1: Dosage of Isoxsuprine HCl 10mg tablet

Indication	Dosage
Peripheral vascular disorders	10-20 mg orally, 3-4 times daily [10]
Preterm labor management	10 mg every 6 hrs (adjusted based on response) [11]
Cerebrovascular insufficiency	10-20 mg, 3 times daily [12]

MATERIALS AND METHODS

sample selection

To carry out this study, different samples of 4 branded and 1 generic isoxsuprine hydrochloride 10 mg tablets were procured from local pharmacy and health care centre.

Table 2: Different samples of Isoxsuprine HCl 10mg tablets

Sample Code	Product type	Batch No	Manufacturing Date	Expiry Date
IS001	Generic	223-770	Jul.2023	Jun.2025
IS002	Branded	W23L38	Dec.2023	Nov.2025
IS003		DAZA2027	Dec.2023	Nov.2025
IS004		B0H5W005	Nov.2023	Oct.2025
IS005		T1B796	Aug.2024	Oct.2025

Fig 2: IS001

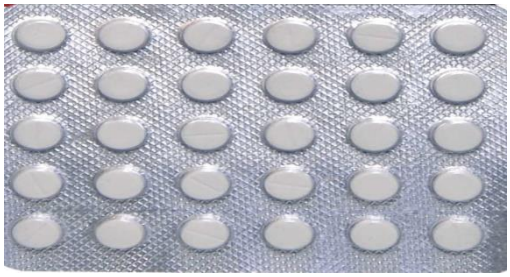

Fig 3: IS002

Fig 4: IS003

Fig 5: IS004

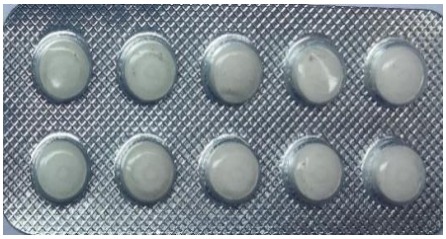

Fig 6: IS005

Chemicals
0.1M hydrochloric acid and distilled water.

Equipments
Monsanto Hardness Tester, Roche Friabilator, UV Spectroscopy,U.S.P Type 1 Dissolution Apparatus, Disintegration Apparatus, Electronic Analytical Balance.

Methods
For the comparative evaluation, following quality control test were performed for the Isoxsuprine Hydrochloride tablets.

Procedure
Visual Inspection
The tablets were visually examined, as it essential for its identity, consumer acceptance, for control lot-to-lot uniformity and tablet-to-tablet uniformity. It includes measurement of size, shape, color, texture etc. [13]

Friability Test
Friability testing evaluates the ability of the tablets to withstand mechanical stress during handling, packaging and transportation.

Table 3: Parameters of friability testing

Parameters	Specifications
Instrument	Roche Friabilator
Speed	25 rpm
Duration	4 minutes
Sample size	10 tablets

Weigh 10 tablets of isoxsuprine hydrochloride from each brand and record the initial weight (W_1). Place the tablets in the roche friabilator apparatus. Set the instrument to rotate at 25 rpm for 4 minutes, completing 100 rotations. After completion, remove the tablets, dust them and weigh again (W_2) and the weights were compared with the initial weight. The % friability was calculated by using the formula,

$$\% \text{ Friability} = \{W_1\text{-}W_2\}/\{W_1\}*100$$

Acceptance criteria: The percentage weight loss should not exceed 1%.[14]

Hardness Test
Hardness test is used to determine the crushing strength required for tablet breakage. Monsanto hardness tester is used to determine the hardness of the tablet. Place the tablet between the jaws of the tester. Apply force gradually until the tablet breaks. Record the force required to break the tablet in kg/cm^2.
Acceptance criteria: The acceptable hardness range is 4 to 8 kg/cm^2.[15]

Weight Variation Test
The weight variation test ensures uniformity in tablet dosage, which is essential for consistent drug deliver. For weight variation test, select 20 tablets randomly from each brand. Weigh each tablet individually using an electronic analytical balance. Then, calculate the average weight of the tablets. Determine the percentage deviation of each tablet from the average weight.[16]

Table 4: % Deviation Allowed Under Weight Variation Test

Average weight of Tablets	% Weight variation allowed
≤ 80 mg	±10%
80 to 250 mg	±7.5%
≥250 mg	±5%

Disintegration Test

The disintegration test determines the time taken for the tablet to breakdown into smaller particles in an aqueous medium under physiological conditions, ensuring proper drug release in the body.

Table 5: Parameters of disintegration testing

Parameters	Specifications
Instrument	U.S.P Disintegration Test Apparatus
Medium	Purified water
Temperature	37 ± 2^0C
Sample size	6 tablets

It was performed by USP disintegration device. Prepare the apparatus by filling the disintegration beaker with 900 ml of purified water and maintained at 37 ± 2^0C**.** Time taken should be recorded after the complete breakdown of the tablet. Acceptance Criteria: For uncoated tablets: The tablet should disintegrate within 15 minutes.[16]

In-vitro dissolution study

The dissolution test evaluates the rate and extent of drug release in a simulated gastrointestinal environment to ensure consistent bioavailability.

Table 6: Parameters of in-vitro dissolution testing

Parameters	Specifications
Apparatus	U.S.P. Type 1 Dissolution Apparatus (Basket Method)
Medium	900 ml of water
Temperature	37 ± 0.50C
Basket Speed	100 rpm
Time interval of sampling	5,10,25,30 & 45 mins
Absorbance detection	269 nm

For dissolution purpose here U.S.P. Type1 Dissolution Apparatus used with 900 ml of water and maintains the temperature of37 ± 0.5^0C. Place one tablet in each basket and start the apparatus at 100 rpm. During the process, discard few ml of samples from medium in specific time interval such as 5, 10, 15, 30, 45 mins and filter. Replace the withdrawn volume with fresh dissolution medium to maintain constant volume. Measure the absorbance of the filtered sample at 269 nm using a UV-Visible Spectrophotometer.
Acceptance Criteria: At least 80% of the drug should be released within 30 minutes.[17]

Assay (potency test)

The Assay determine the potency of drug that is, how much drug concentration present in the tablet or formulation.[2] The assay was conducted by using UV Spectrophotometer. Weigh and powder 20 tablets. Disperse a quantity of powder containing about 20 mg of Isoxsuprine Hydrochloride, add 50 ml of 0.1M hydrochloric acid and boil on a water bath for 30 minutes. Cool, add sufficient 0.1M hydrochloric acid to produce 100 ml, mix and filter. Dilute 25 ml of the filtrate to 100 ml with 0.1M hydrochloric acid and measure the absorbance of the resulting solution at the maximum at about 274 nm.
Acceptance Criteria: The drug content should be 95% to 105% of the labeled claim.[17]

IR Procedure

Potassium thiocyanate was used as an internal standard which was preground, dried and then reground with dry KBr to make a concentration of about 0.2% by weight of thiocyanate. The final mixture was stored over phosphorous pentoxide. Five different concentration of standard and KBr-KCNS were prepared by mixing known weights of the standard substance with a known weight of KBr-KCNS mixture and then grinding using mortar & pestle. The discs were prepared by using KBr press and the infrared spectrum was recorded in the absorbance mode. The calibration curve was obtained by plotting the amplitude of the IR absorption spectra 2068 cm^{-1} against the concentration of the substance.[18]

RESULTS AND DISCUSSION

The four branded and one generic tablet of Isoxsuprine Hydrochloride 10mg tablets are successfully evaluated by weight variation test, hardness test, friability test, disintegration test, dissolution test and assay for the tablet. The results are listed below:

Results

Visual Inspection

The generic and branded Isoxsuprine Hydrochloride tablets were visually inspected and the results are presented in Table 7:

Table 7: Visual Inspection Data of Generic and Branded Isoxsuprine HCl 10mg Tablets

S.no	Product Type	Tablet Code	Color	Shape	Texture
1	**Generic**	IS001	White	Round	Smooth
2	**Branded**	IS002	White	Round	Smooth
3		IS003	White	Round	Slightly rough
4		IS004	White	Round	Smooth
5		IS005	White	Round	Smooth

Interpretation of IR Spectra

The IR spectra confirm the presence of characteristic functional groups in both generic and branded Isoxsuprine tablets. Peaks corresponding to N-H stretching (amide group), O-H stretching (hydroxyl group), C-H stretching (alkyl and alkyne) and C=O (carbonyl stretching) are observed which are mentioned in the Table:8

Table 8: Interpretation of IR Spectra of Generic and Branded Isoxsuprine Hydrochloride tablets

Reported Wave Number (cm^{-1})	Type of Vibration	Generic	Branded			
		IS001	IS002	IS003	IS004	IS005
3200-3400cm^{-1}	N-H stretch	3285	3290	3287	3289	3286
3200-3400cm^{-1}	O-H stretch	3352	3348	3350	3351	3353
3300 cm^{-1}	Alkyne C-H stretch	3302	3305	3304	3303	3301
>3000 cm^{-1}	Alkenyl C-H stretch	3055	3058	3056	3057	3054
2850-3100cm^{-1}	C─H stretch	2923	2926	2924	2925	2922
<3000 cm^{-1}	Alkyl C─H Stretch	2975	2979	2976	2977	2978

Friability Test

The tablet's good mechanical strength is revealed by the friability tester and the results are presented in Table 9:

Table 9: Friability Data of Generic and Branded Isoxsuprine HCl 10mg Tablets

S.no	Product Type	Tablet Code	Initial Weight (g)	Final Weight (g)	% Friability
1	**Generic**	IS001	2.11	2.1	0.40%
2	**Branded**	IS002	1.07	1.06	0.90%
3		IS003	2.3	2.29	0.50%
4		IS004	1.19	1.18	0.40%
5		IS005	1.27	1.26	0.70%

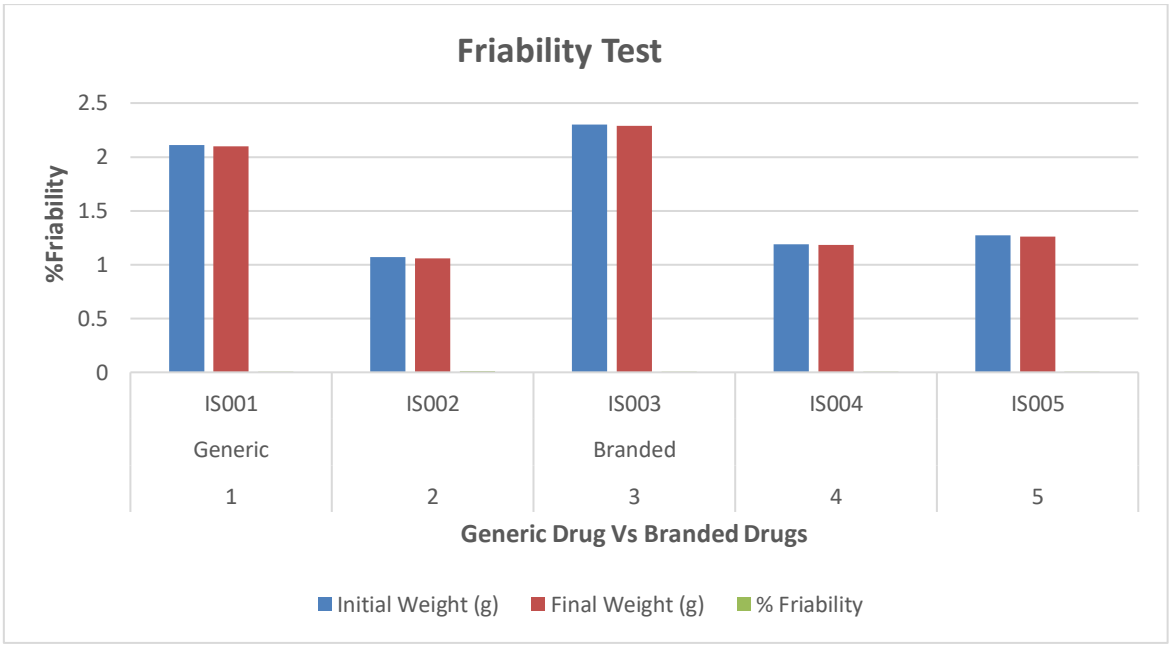

Fig 7: Comparative Analysis of Friability: Generic Vs Branded Tablets

Hardness Test

Hardness affects how things breakdown and is assessed by using Monsanto Hardness Tester. The data for generic and branded tablets are presented in Table 10:

Table 10: Hardness Data of Generic and Branded Isoxsuprine HCl 10mg Tablets

S. No	Generic	Branded			
	IS001 (kg/cm²)	IS002 (kg/cm²)	IS003 (kg/cm²)	IS004 (kg/cm²)	IS005 (kg/cm²)
1	8	5	8	8	10
2	10	6	9	10	8
3	11	5	10	11	10
4	10	6	8	10	10
5	9	5	9	9	10
6	10	6	9	10	8
7	10	5	8	10	10
8	8	6	9	8	10
9	10	6	10	10	9
10	8	5	9	9	8
Mean	9.4	5.5	8.9	8.9	9.3

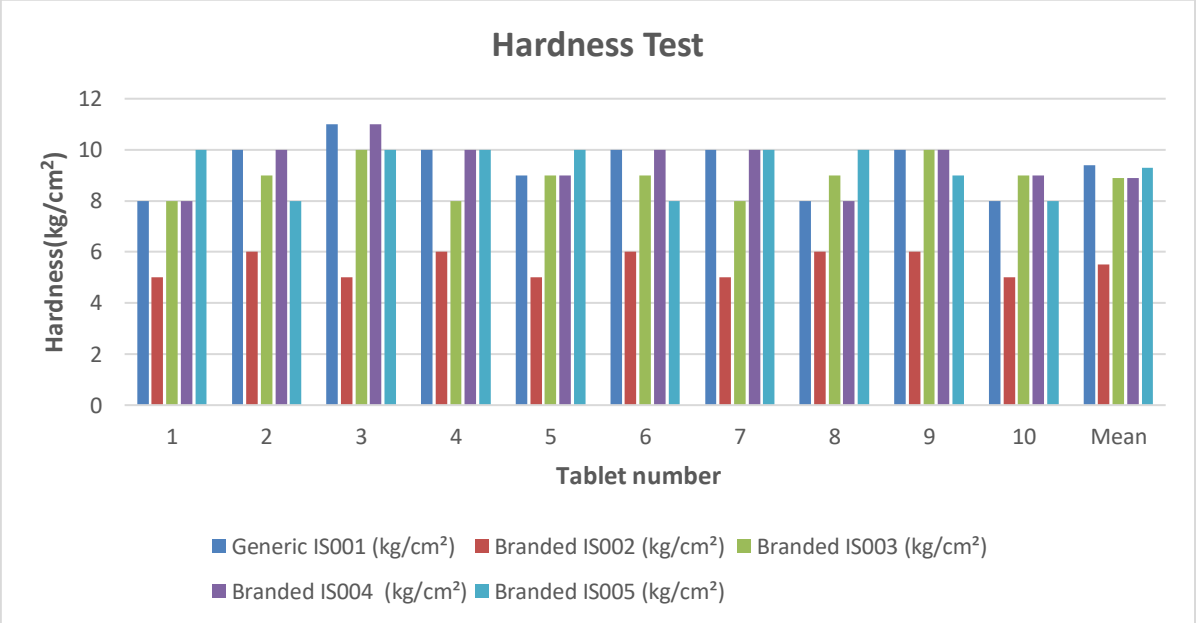

Fig 8: Comparative Analysis of Tablet Hardness: Generic Vs Branded

Weight Variation Test

Weight variation test is successfully carried out by electronic digital weighing balance. The results are presented on Table 11:

Table 11: % Weight Variation Data of Generic and Branded Isoxsuprine HCl 10mg Tablets

S.No.	Generic		Branded							
	IS001		IS002		IS003		IS004		IS005	
	Individual weight `(g)	% Weight variation	Individual wt (g)	% Weight variation	Individual wt (g)	% weight variation	Individual wt (g)	% weight variation	Individual wt (g)	%weight variation
1	0.13	6.557	0.23	0.877	0.1	-6.1	0.21	-2.325	0.13	6.557
2	0.12	6.557	0.23	0.877	0.11	3.286	0.22	-2.325	0.13	6.557
3	0.12	-1.639	0.22	-3.5	0.11	3.286	0.22	2.325	0.12	-1.639
4	0.12	-1.639	0.23	0.877	0.11	3.286	0.21	-2.325	0.12	-1.639
5	0.12	-1.639	0.22	-3.5	0.11	3.286	0.21	-2.325	0.12	-1.639
6	0.12	-1.639	0.23	0.877	0.1	-6.1	0.21	-2.325	0.12	-1.639
7	0.12	-1.639	0.23	0.877	0.11	3.286	0.21	-2.325	0.12	-1.639
8	0.12	-1.639	0.23	0.877	0.1	3.286	0.22	2.325	0.12	-1.639
9	0.12	-1.639	0.23	0.877	0.11	3.286	0.21	-2.325	0.12	-1.639
10	0.12	-1.639	0.22	-3.5	0.11	3.286	0.21	-2.325	0.12	-1.639
11	0.12	-1.639	0.23	0.877	0.11	3.286	0.21	-2.325	0.12	-1.639
12	0.12	-1.639	0.23	0.877	0.11	3.286	0.21	-2.325	0.13	6.557
13	0.13	6.557	0.22	-3.5	0.1	-6.1	0.21	-2.325	0.12	-1.639
14	0.12	-1.639	0.23	0.877	0.1	3.286	0.22	2.325	0.12	-1.557
15	0.12	-1.639	0.23	0.877	0.11	3.286	0.22	2.325	0.12	-1.557
16	0.12	-1.639	0.23	0.877	0.11	3.286	0.22	2.325	0.12	-1.557
17	0.12	-1.639	0.23	0.877	0.11	3.286	0.22	2.325	0.12	-1.557
18	0.12	-1.639	0.23	0.877	0.1	-6.1	0.22	2.325	0.12	-1.557
19	0.12	-1.639	0.22	-3.5	0.11	3.286	0.22	2.325	0.12	-1.557
20	0.13	6.557	0.23	0.877	0.1	3.286	0.22	2.325	0.13	-1557
Mean	0.122		0.228		0.106		0.215		0.122	

Disintegration Test

The disintegration time of the tablets is a crucial parameter for the tablet dissolution. USP Disintegration Apparatus is used for this purpose and the results are presented in Table12:

Table 12: Disintegration Time of Generic and Branded Isoxsuprine HCl 10mg Tablets

S.No	Generic	Branded			
	IS001(min)	IS002(min)	IS003(min)	IS004(min)	IS005(min)
1	0.1	3.35	1.49	1	3
2	0.3	3.45	1.55	1	3
3	0.3	4	2.3	1.01	3
4	0.4	4	2.36	1.01	4
5	0.45	4.01	3.5	1.23	4
6	1	4.02	5.18	1.25	5

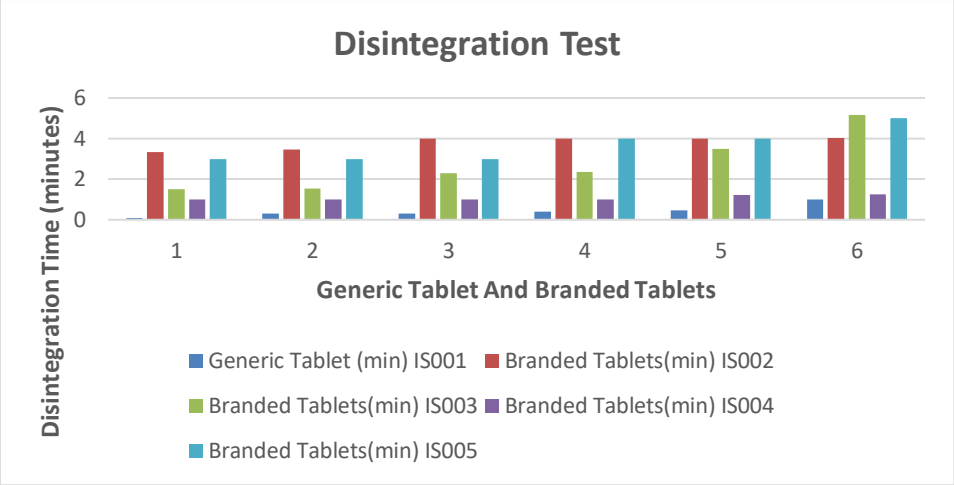

Fig 9: Comparative Analysis of Disintegration Time: Generic Vs Branded Tablets

Content Uniformity Test (Assay)

The Assay were performed to quantify active Isoxsuprine content to ensure the potency of the tablet. It was conducted using a UV Spectrophotometer. The absorbance and % drug content is mentioned in Table 13:

Table 13: Absorbance And % Drug Content of Generic and Branded Isoxsuprine HCl 10mg Tablets

S.no	Product Type	Tablet Code	Absorbance	% Drug Content
1	**Generic**	IS001	0.551	99.40%
2	**Branded**	IS002	0.468	93.80%
3		IS003	0.476	94.20%
4		IS004	0.472	92.10%
5		IS005	0.457	91.30%

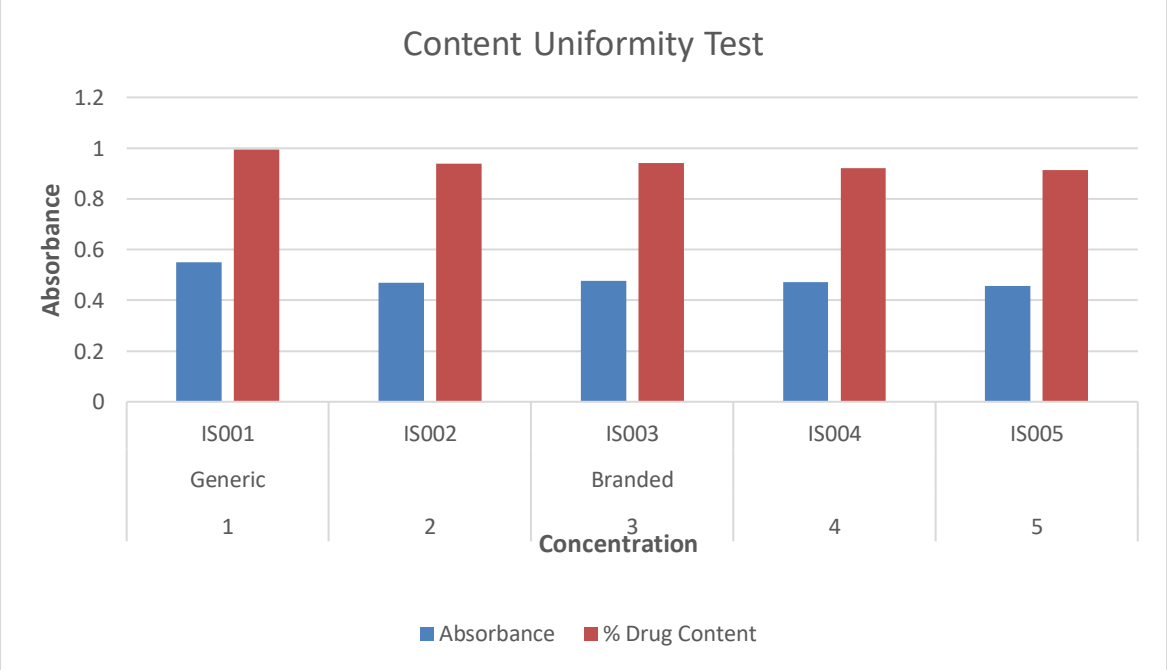

Fig 10: Comparative Analysis of Assay Values: Generic Vs Branded Tablets

Dissolution Profile

The dissolution test is a crucial parameter for evaluating the drug release profile, ensuring optimal absorption and therapeutic efficacy. The absorbance and % drug release of branded and generic Isoxsuprine HCl 10 mg tablets are mentioned in the Table 14:

Table 14: Absorbance and % Drug Release of Generic and Branded Isoxsuprine HCl Tablets

S.no	Product Type	Tablet Code	Time Interval(minutes)	Absorbance	Amount of Drug Release (mg)	%Drug Release
1	**Generic**	**IS001**	5	0.148	1.8mg	18%
2			10	0.264	3.5mg	35%
3			15	0.372	5.5mg	55%
4			30	0.502	8.0mg	80%
5			45	0.612	9.0mg	90%
1	**Branded**	**IS002**	5	0.18	1.5mg	13%
2			10	0.31	2.8mg	28%
3			15	0.432	4.3mg	43%
4			30	0.57	7.0mg	70%
5			45	0.64	8.5mg	85%
1	**Branded**	**IS003**	5	0.14	1.6mg	16%
2			10	0.252	3.2mg	32%
3			15	0.37	4.8mg	48%
4			30	0.492	7.6mg	76%
5			45	0.598	8.9mg	89%
1	**Branded**	**IS004**	5	0.158	1.5mg	15%
2			10	0.278	2.9mg	29%
3			15	0.398	4.5mg	45%
4			30	0.525	7.3mg	73%
5			45	0.622	8.8mg	88%
1	**Branded**	**IS005**	5	0.14	1.4mg	14%
2			10	0.252	2.6mg	26%
3			15	0.37	4.1mg	41%
4			30	0.492	7.2mg	72%
5			45	0.598	8.7mg	87%

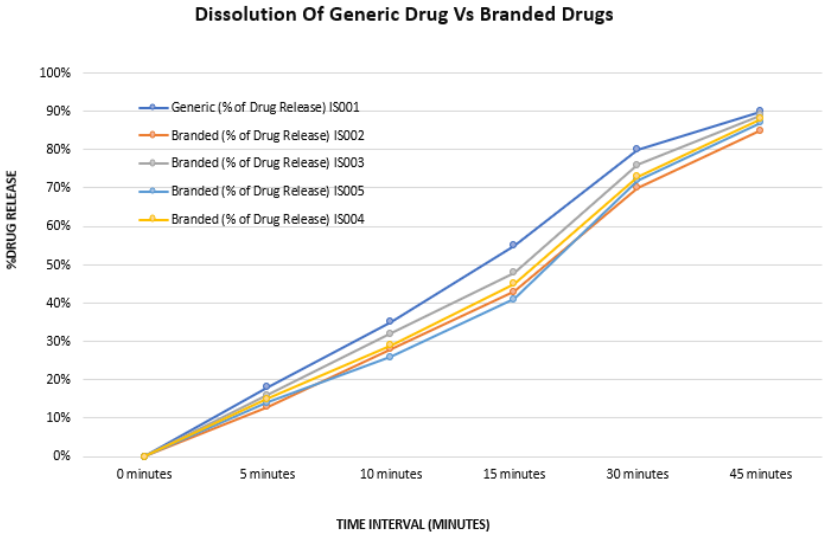

Fig 11: Comparative Dissolution Profiles of Generic tablet Vs Branded tablet

DISCUSSIONS

One generic and four branded Isoxsuprine Hydrochloride 10mg tablets which are commercially available in local retail pharmacy were subjected to a number of quality control tests in order to assess their biopharmaceutical equivalence. The assessments include, visual inspection, friability, hardness, disintegration and dissolution test as well as content uniformity tests. All the brands used were within their shelf life as at that time of study.

The friability test is mostly important criteria for uncoated tablets to examine that the tablets have a good withstand strength for transportation, packaging, shipping etc. The results showed that all selected Isoxsuprine Hydrochloride tablets met the friability criteria, with values ranging from 0.4% to 0.9%, ensuring their durability against mechanical stress.

Using Monsanto hardness tester, the strength of the tablets was tested. The results indicate that the crushing strength of all selected Isoxsuprine Hydrochloride tablets is within the acceptable range of 5 to 12 kg/cm^2, ensuring their mechanical stability.

The weight variation test of all selected tablets of Isoxsuprine Hydrochloride tablets gave values that comply with the USP specification with the deviation less than 7.5% from the mean value.

The observed disintegration times for all selected Isoxsuprine Hydrochloride tablets were disintegrated within 12 minutes, complying with the pharmacopoeial standards.

Dissolution of the tablets is an important aspect for drug bioavailability. The % drug release of isoxsuprine hydrochloride from all the tablets is 75% within 45 minutes. The similarity in dissolution rates and extent suggests that both generic and branded tablets likely exhibit similar bioavailability and therapeutic effects.

The results obtained from the content uniformity test of all selected Isoxsuprine Hydrochloride tablets showed values within the monograph specification 95% to 105%, meeting the pharmacopoeial standards.

CONCLUSION

The comparative evaluation of generic and branded Isoxsuprine HCl tablets demonstrated that both formulations meet pharmacopoeial quality standards. However, the generic tablet exhibited superior performance across multiple parameters, including drug content (99.4% vs. 91.3%– 94.2%), dissolution profile (90% drug release in 45 minutes compared to 80%-88% for branded tablets), and hardness (mean value of 9.4 kg/cm^2 compared to 5.5–9.3 kg/cm^2 for branded tablets). Additionally, the friability and disintegration tests indicated that the generic tablet maintained excellent mechanical integrity while ensuring rapid disintegration, an essential factor for bioavailability. These findings suggest that the generic Isoxsuprine tablets provide a more consistent and standardized formulation compared to branded alternatives, offering an effective and economical therapeutic option. Furthermore, this study highlights the potential of generic formulations to serve as cost-effective and high-quality alternatives to branded pharmaceuticals, promoting accessibility and affordability in health care.

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