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Comparative evaluation of brand and generic medicine of mefenamic acid and dicyclomine hydrochloride

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ABSTRACT:- This study presents a comparative evaluation between brand and generic formulations of mefenamic acid and dicyclomine hydrochloride tablets. The research aims to assess the pharmaceutical equivalence, in vitro dissolution profiles, and in vivo bioavailability of the brand andgeneric drugs. Methods included in vitro dissolution testing following pharmacopeial guidelines and in vivo bioavailability studies in human subjects. Results revealed differences in dissolution profiles and bioavailability parameters between brand and generic formulations. These findings underscore the importance of evaluating generic drug quality and bioequivalence to ensure therapeutic efficacy and patient safety. Mefenamic acid and dicyclomine hydrochloride tablets are commonly prescribed for the treatment of pain and spasms associated with various gastrointestinal disorders. This study aimed to comprehensively evaluate the pharmaceutical attributes, including physical characteristics, drug content uniformity, dissolution profiles, and stability, of mefenamic acid and dicyclomine hydrochloride tablets. The tablets were subjected to various quality control tests according to pharmacopeial standards. Physical evaluation included tests for appearance, dimensions, hardness, friability, and weight variation. Drug content uniformity was assessed using a validated high-performance liquid chromatography (HPLC) method. Dissolution studies were conducted using USP dissolution apparatus to determine the release profile of the active ingredients under simulated gastric conditions. Stability studies were performed to assess the shelf-life of the tablets under different storage.

KEYWORDS:- Mefenamic acid,Dicyclomine hydrochloride,comparative study.

INTRODUCTION:-

In the pharmaceutical world, the debate between brand and generic medicines continues to be relevant. This review aims to provide a comparative evaluation of brand and generic formulations of two commonly prescribed medications: mefenamic acid and dicyclomine hydrochloride. These drugs are widely used to treat various conditions, including pain, inflammation, and gastrointestinal disorders.

1. Background on Mefenamic Acid and Dicyclomine Hydrochloride:

- Mefenamic Acid: A nonsteroidal anti-inflammatory drug (NSAID) used to relieve mild to moderate pain, inflammation, and menstrual cramps.

- Dicyclomine Hydrochloride: An antispasmodic agent primarily used to treat irritable bowel syndrome (IBS) and gastrointestinal spasms.

2. Brand vs. Generic Medicines:

- Brand Medicines: Developed and marketed by pharmaceutical companies who hold patents for the original drug formulation. They undergo extensive research, development, and clinical trials before approval.

- Generic Medicines: Produced after the patent for the brand-name drug expires. Generic drugs must demonstrate bioequivalence to the brand-name drug in terms of dosage, safety, strength, quality, performance, and intended use.

3. Comparative Evaluation:

a. Efficacy:

- Studies have shown that both brand and generic formulations of mefenamic acid and dicyclomine hydrochloride exhibit comparable efficacy in relieving pain and gastrointestinal symptoms.

b. Safety:

- Adverse effects such as gastrointestinal irritation, nausea, and dizziness are reported with both brand and generic versions. However, the incidence and severity of side effects may vary among individuals.

c. Cost:

- Generic drugs are generally more affordable than their brand-name counterparts, making them accessible to a wider population. Cost-effectiveness is a significant factor, especially in healthcare systems with limited resources.

d. Quality:

- Regulatory agencies such as the FDA (U.S. Food and Drug Administration) ensure that generic medications meet strict quality standards. Generic drugs must undergo rigorous testing to demonstrate bioequivalence to the brand-name drug.

e. Patient Preference:

- Some patients may have a preference for brand-name medications due to factors such as perceived efficacy, familiarity, or marketing influence. However, studies suggest that the majority of patients are willing to use generic drugs if they are deemed equivalent in effectiveness and safety.

4. Regulatory Considerations:

brand and generic medications. Stringent approval processes and post-marketing surveillance help monitor and evaluate the performance of these drugs in real-world settings.

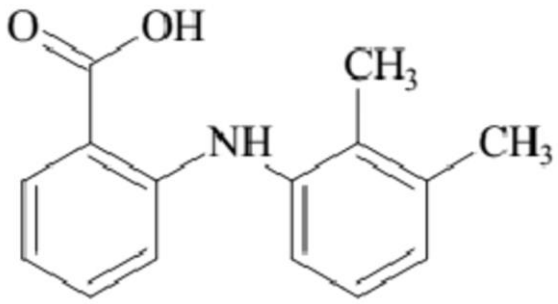
MEFENAMIC ACID:-

Mefenamic acid is a nonsteroidal anti-inflammatory drug (NSAID) used to relieve pain and inflammation. It's commonly prescribed for conditions like menstrual cramps, arthritis, and mild to moderate pain. However, it can have side effects like stomach irritation and increased risk of bleeding. Always follow your doctor's instructions when taking it.

MECHANISUM OF ACTION:-

Mefenamic acid works by inhibiting the production of prostaglandins, which are substances in the body that cause inflammation, pain, and fever. By blocking the action of the enzyme cyclooxygenase (COX), which is involved in the production of prostaglandins, mefenamic acid helps to reduce pain and inflammation. This

mechanism of action is similar to other nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and naproxen



PHARMACOLOGY OF MEFENAMIC ACID:-

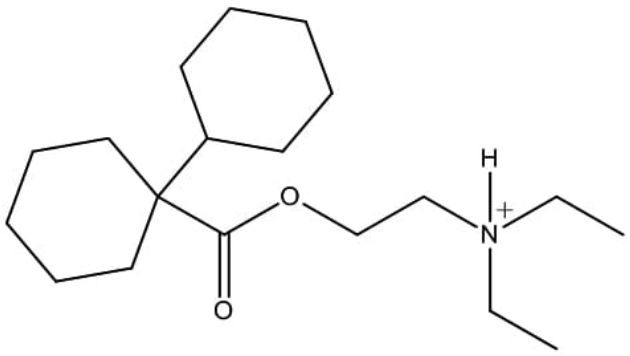
Mefenamic acid is classified as a nonsteroidal anti-inflammatory drug (NSAID) with analgesic, antipyretic, and anti-inflammatory properties. Its primary pharmacological action is the inhibition of cyclooxygenase (COX) enzymes, specifically COX-1 and COX-2. By blocking these enzymes, mefenamic acid reduces the production of prostaglandins, which are lipid compounds involved in inflammation, pain, and fever. This leads to decreased pain perception, alleviation of inflammation, and reduction of fever.

DICYCLOMINE HYDROCHLORIDE:-

Dicyclomine hydrochloride is an anticholinergic medication used to treat symptoms of irritable bowel syndrome (IBS), such as abdominal cramps and discomfort. It works by relaxing the muscles in the stomach and intestines, which helps to reduce spasms and relieve symptoms. Dicyclomine hydrochloride should be taken exactly as prescribed by a doctor, as it can cause side effects such as dry mouth, blurred vision, and constipation. It's important to discuss any concerns or potential interactions with other medications with your healthcare provider.

MECHANISUM OF ACTION:-

Dicyclomine hydrochloride works by blocking the action of acetylcholine, a neurotransmitter that plays a role in stimulating muscle contractions in the gastrointestinal tract. By inhibiting the effects of acetylcholine on smooth muscle, dicyclomine helps to relax the muscles in the stomach and intestines, reducing spasms and alleviating symptoms of irritable bowel syndrome (IBS) such as abdominal cramps and discomfort.



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PHARMACOLOGY OF DICYCLOMINE HYDROCHLORIDE:-

Dicyclomine hydrochloride is a synthetic antispasmodic medication that acts primarily on the gastrointestinal (GI) tract. Its pharmacological action involves antagonizing the effects of acetylcholine at muscarinic receptors, specifically the M1 and M3 subtypes, in smooth muscle cells of the GI tract.By inhibiting the action of acetylcholine, dicyclomine reduces smooth muscle contractions and spasms in the GI tract, particularly in the intestines. This leads to relaxation of the muscles and alleviation of symptoms associated with irritable bowel syndrome (IBS), such as abdominal cramping and discomfort.

EVALUATION PARAMETER:-

1)GENERAL APPERANCE:-

The formulated tablets were assessed for its general appearance and observations were made for Shape, Colour, Diameter, Thickness and Odour.Weight Variation Individually weighed 20 tablets and calculated the average weight not more than two of the individual weights deviate from the average weight by more than the percentage deviation shown in more deviated by more than twice that percentage.

2)THICKNESS:-

Thickness mainly depends up on die filling, physical properties of material to be compressed under compression force. The thickness of the tablets was measured by using Digital Vernier Callipers.Desired thickness: 2.0 - 4.0 mm.

3)HARDNESS:-

Hardness of the tablet is defined as the force required in breaking a tablet in a diametric compression test. In this test, a tablet was placed between two anvils, force was applied to the anvils and the crushing strength that just causes the tablet to break is recorded.

4)Friability :-Friability is defined as the loss in weight of tablet in the container due to removal of fine particle from their surface. It is expressed in percentage (%). A pre weighed tablet sample (20 tablets) was placed in the friabilator chamber and rotated for 10 revolutions. In each revolution the tablets are carried up and are allowed to freely fall from a height of 6 inches. After 100 revolutions the tablets are removed from the chamber, dusted and reweighed. When capping is observed during friability test, tablets should not be considered acceptable, regardless of percentage weight loss.

5)Disintegration Test :-The process of breakdown of a tablet into smaller particles is called as disintegration. The in vitro disintegration time of a tablet was determined using disintegration test apparatus as per IP specifications. Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus by using Water, 0.1N HCl, Phosphate buffer pH - 6.8 as the immersion liquid and maintained a temperature at 37o ± 2 oC. The time in seconds/minutes taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded. TABLE 4. Disintegration testing condition and interpretation (IP)

6)Content Uniformity :-

(a) Content uniformity for Weigh and powder 20 tablets .Weigh accurately a quantity of the powder containing about 0.1gms of METFORMIN shake with 70ml of water for 15minutes, dilute to 100ml with water and filter. Dilute 10ml of the filtrate to 100ml with water. Further dilute 10ml to 100ml with water and measure the absorbance of the resulting solution at the maximum at about 322nm.calcutate the absorbance at 322nm.

(b) Content uniformity for Metformin HCl Weigh and powder 20 tablets .Weigh accurately a quantity of the powder containing about 0.1gms of Metformin Hydrochloride, shake with 70ml of water for 15minutes, dilute to 100ml with water and filter. Dilute 10ml of the filtrate to 100ml with water. Further dilute 10ml to 100ml with water and measure the absorbance of the resulting solution at the maximum at about 232nm.calcutate the absorbance at 232nm

In-Vitro Drug Release study :-

Dissolution studies:-

The drug release rate of Ranitidine and Metformin HCl tablets were determined by using United States Pharmacopeia (USP) dissolution testing apparatus type 2 (paddle method).The dissolution test was performed by using 900 ml of Dissolution medium at 37± 0.50 C and 50 rpm. In specified time intervals an aliquot of 5ml samples of the solution were withdrawn from the dissolution apparatus and with replacement of fresh fluid to dissolution medium. The samples were filtered through filter paper of 0.45 µ m. Absorbance of these solutions were measure at λmax 322 nm for Ranitidine and 232nm for Metformin HCl by using UV/Visible Spectrophotometer. The drug release of tablet was plotted against time to determine the release profile of selected

generic and branded drugs. The % drug release of the formulation can be calculated by % drug release = (At/As)×Cs× (Dt ×Vm/Wd×1000) ×100 Where At is the Sample (test) Absorbance. As is the Standard Absorbance, Cs is the standard concentration of drug, Dt is the Dilution factor, Wd is the Weight of the drug, Vm is the volume of the dissolution.

Result :Quality control test

1. Discription of generic and branded mefenamic acid and dicyclomine hydrochloride tablet

Description	Generic	Brand
Colour	Tartrazine	Tartrazine
Shape	Oval	Oval
Smell	Faint odor	Faint odor
Coat	Uncoated	Uncoated
Content	Mefenamic Acid = 250mg Dicyclomine Hydrochloride =10mg Excipients = q.s	Mefenamic Acid = 250mg Dicyclomine Hydrochloride =10mg Excipients = q.s
Brand Name	Delta	Nemi
Mfg by	Sotach pharma.pvt.ltd	Samsonlaboratories pvt.ltd

2.Average Weight-

Tablet No	Generic	Brand
10	3.885gm	4.825gm
Average weight	3.885gm	4.825gm

3.Uniformity weight-

Tablet No	Generic	Brand
1	390	483
2	383	483
3	387	483
4	387	480
5	390	494
6	386	473
7	393	483
8	391	482
9	387	486
10	392	485
Average weight	388.6	483.2

4.Thickness of tablet

Tablet No	Generic	Brand
1	0.12	0.14
2	0.12	0.14
3	0.12	0.15
4	0.12	0.14
5	0.11	0.15
6	0.11	0.14
7	0.12	0.14
8	0.11	0.14
9	0.12	0.15
10	0.11	0.16
Average weight	0.11mm	14mm

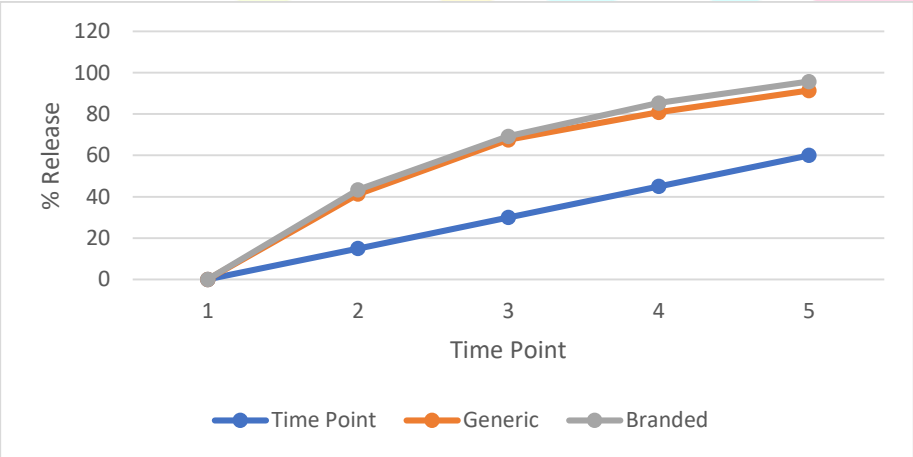
5.Diameter of Tablet-

Tablet No	Generic	Brand
1	11.6	11.2
2	11.6	11.2
3	11.6	11.2
4	11.6	11.2
5	11.7	11.2
6	11.7	11.1
7	11.5	11.1
8	11.6	11.2
9	11.6	11.2
10	11.6	11.1
Average	11.6mm	11.2mm

6.Dissolution of Tablet

Sr. No	15 (min)		30 (min)		45 (min)		60 (min)	
	G	B	G	B	G	B	G	B
1	41.26	43.56	67.77	69.23	80.33	85.72	91.52	95.91
2	41.23	43.55	67.67	69.55	80.42	85.61	91.41	95.83
3	41.45	44.44	66.52	69.61	80.36	85.59	90.29	95.21
4	40.36	43.25	67.41	68.78	81.59	85.41	91.21	95.33
5	41.28	42.36	68.53	68.92	81.72	84.33	92.38	96.49
6	42.37	43.32	67.41	69.53	80.85	85.21	91.42	95.67
Avg	41.325	43.413	67.551	69.27	80.878	85.311	91.371	95.74

Time Point	Generic	Brand
0	00	00
105	41.325	43.41
30	67.55	69.27
45	80.87	85.31
60	91.37	95.74



Conclusion:

The comparative evaluation of brand and generic formulations of mefenamic acid and dicyclomine hydrochloride underscores the importance of balancing efficacy, safety, cost, and quality considerations. While brand-name medications may offer certain advantages, generic drugs provide a cost-effective alternative without

compromising therapeutic outcomes. Healthcare providers should consider individual patient needs and preferences when prescribing medications, taking into account the available evidence and regulatory standards.

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REFERENCE:-

1.Xhafaj D, Malaj L, Mileti M. A comparative quality control study of cetirizine hydrochloride 10 mg tablets on the Albanian pharmaceutical market. Int J Pharm Pharm Sci. 2015;7(1):504- 7.

2.Hasan A, Dewan SA, Ahamed SK, Kai MM. Quality control studies on cetirizine hydrochloride tablets available in Bangladesh drug market. Int J Pharm Biol Sci. 2013;3(1):349-54.

3.Remington HS. The Sci Pract Pharm, volume I and volume II. 22nd ed. J Med Libr Assoc. 2014 Jul;102(3):220-1.

4.Gupta MM, Gupta M. Comparative pharmaceutical quality control testing of different brands of paracetamol tablets available in Trinidad and Tobago, West Indies. Int J Pharm Sci Res. 2016;7(7):2830-6.

5.Ramakrishna S, Mihira V, Raja Vyshnavi K, Ranjith V. Design and evaluation of drug release kinetics of meloxicam sustained release matrix tablets. Int J Curr Pharm Res. 2012;4:90-9.

6.Uddin MS, Mamun AA, Tasnu T, Asaduzzaman M. In-process and finished products quality control tests for pharmaceutical tablets according to pharmacopoeias. J Chem Pharm Res. 2015;7(9):180-5

7.Shah MR, Nasiri MI, Anwer S, Ali T, Zaheer K, Ahmed K. Pharmaceutical quality assessment of different brands of moxifloxacin 400 mg tablets available in Pakistan. RADS. J Pharm Pharm Sci. 2019;7(1):2-8.

8.Kumar S, Parkash C, Kumar P, Singh SK. Application of some novel techniques for solubility enhancement of mefenamic acid, A poorly water-soluble drug. Int J Pharm Sci Drug Res. 2009;1(3):164-71.

9.Neamah AJ, Hasan A-GKM, Talib Khudhair AHK. Design and characterization of candesartan cilexetil oral nanoemulsion containing garlic oil. Int J Appl Pharm. 2019;6:116- 24.

10.Parrot EL, Saski W. Solid pharmaceuticals. In: Experimental pharmaceutical technology. 3rd ed. Minneapolis: Burgess Publishing Co; 1971. p. 58-106

11.Lachman L, Lieberman HA, Kanig JL. Theory and practice of industrial pharmacy. New Delhi: CBS Publishers and Distributors Pvt, Ltd; 2009. p. 229-345.