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A STUDY ON GENERIC AND BRANDED PHARMACEUTICAL MEFENAMIC ACID AND PARACETAMOL SUSPENSION AS PER I.P.

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Abstract: One significant class of pharmaceutical dosage forms is suspensions. A coarse dispersion of finely divided insoluble material suspended in a liquid medium is known as a pharmaceutical suspension. Suspensions should have the following desirable qualities: uniform particle size distribution, ease of re-dispersion of settled solid particles, resistance to microbial contamination, good organoleptic properties, good pour ability that facilitates easy dose removal from the container, and physical and chemical stability. Mefenamic acid and paracetamol are the two medications found in Mefenamic Acid + Paracetamol. The cyclo-oxygenase (COX) enzyme, which is a chemical messenger and produces other chemical prostaglandins, is inhibited by Mefenamic Acid + Paracetamol. Less prostaglandin is produced because of the COX enzymes' function being blocked. This aids in lowering the injured or damaged site are mild to moderate pain and inflammation. Mefenamic acid suspension is put through a series of tests to determine its quality; these tests are used to compare the two generic and branded suspensions. Initially, the pH of the suspensions was measured. Next, the sedimentation rate was calculated using a 100 ml measuring cylinder. Finally, spectrophotometer analysis was carried out.

Index Terms - : Suspension; Mefenamic Acid; Paracetamol; Quality control tests;

I. INTRODUCTION

Generic Drugs: according to the FDA" a drug product comparable to a branded product is a dosage form strength route of administration, quality and performance, characteristics, and intended use. It is a copy of a branded drug whose patent has expired and has no longer exclusive rights to produce and distribute medicines.

Branded Drugs: it is the original product that has been developed by a pharmaceutical company. It has the sole right to manufacture and distribute for some time (patent). A brand-name drug is a small medicine that is discovered developed and marketed by a pharmaceutical company. Once a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drugs. At this point, the drug has two names - a generic name and a brand name to make it stand out in the marketplace.

Similarities between generic and branded drugs

- It must contain the same active ingredients.
- It must have the same dosage form.
- They must have the same route of administration.
- They both are equally safe.

Difference between generic and branded drugs

- It must contain different inactive ingredients.
- Generic drugs are cheaper than branded ones.

- They look different due to different shapes, sizes, colors, and markings.
- Branded drugs have the sole right (patent) to manufacture and distribute for a while generic drugs do have not any patent on their manufacturing and distribution.[1]

Suspension

Suspensions are those course dispersions in which the internal phase i.e., coarse powder is dispersed into the external phase i.e., liquid vehicle. An internal phase consists of solid particles that are uniformly suspended in a sufficient amount of vehicle by the addition of individual or combined forms of suspending agents. Vehicles in the external phase are commonly aqueous in an oral preparation, on the other side organic and oily liquids are used in non–oral preparations[2]. In these preparations, the substance distributed is known as the 'dispersed phase' and the vehicle is termed a 'dispersion medium'[3]. The particles of the dispersed phase vary widely in size, from large, visible particles to colloidal dimensions, which fall between 1.0nm and 0.5µm in size. Coarse dispersion contains particles 10-50 µm in size and includes suspension and emulsions. Fine dispersion contains particle size particles of smaller size, 0.5-10 µm. Magmas and gels represent such fine dispersions. Most solids in dispersion tend to settle to the bottom of the container because their density is higher than the dispersion medium[4].

Suspensions have several applications in pharmacy. They are used to supply drugs to the patient in liquid form. Many people have difficulty swallowing solid dosage forms. If a drug is unstable in an aqueous medium, ester or insoluble salt that does not dissolve in water may be used in the preparation of a suspension[5].

Profile of Mefenamic Acid and PCM Suspension

Mefenamic acid + paracetamol belongs to a group of medicines called NSAIDs used for the treatment of pain, inflammation, migraine, headache, period pain, heavy bleeding during periods, muscle pain, tooth pain, joint pain, pain after surgery, ear pain, fever flu, osteoarthritis, and rheumatoid arthritis. Pain is a symptom triggered by the nervous system, causing uncomfortable sensations in the body.

Mefenamic Acid + Paracetamol contains two drugs, Mefenamic acid, and Paracetamol. They block the effect of a chemical messenger known as cyclo-oxygenase (COX) enzyme that makes the other chemical messenger known as the effect of COX enzymes, lesser prostaglandins are produced. This helps mild to moderate pain and inflammation[6].

Mechanism of Action

They belong to the NSAIDs class like other members of anthranilic acid derivatives. They tend to inhibit both COX-1 and COX-2 enzymes. They play a key role in pain sensitivity, mild to moderate inflammation, fever, hemostasis, kidney function, sustaining the pregnancy, and protection of gastric mucosa[6, 7].

Pharmacokinetics

It is rapidly absorbed from the gut and reaches the highest concentration in the blood plasma after one to four hours. When in the bloodstream, over 90% of the substances are bound to plasma proteins. It probably crosses the placenta, and is found in breast milk in small amounts.

It is metabolized by the liver enzyme CYP2C9 to the only weakly active 3'- carboxymefanamic acid and is also identified as a metabolite. The parent substance has a biological half-life of two hours; the half-life of its metabolites may be longer[7].

Drug-Drug Interactions: MEFENAMIC ACID+PARACETAMOL may interact with pain killers (aspirin, ibuprofen, celecoxib, diclofenac, naproxen), anti-gout (probenecid), immunosuppressant's (cyclosporine, tacrolimus), anticoagulants (warfarin, heparin), anti-rheumatoid (methotrexate), anti-HIV (zidovudine), anti-depressant (duloxetine, lithium, fluoxetine, sertraline), steroid medication (mifepristone), anti-emetic (metoclopramide, domperidone), anti-cancer (imatinib), and bile acid sequestrants (cholestyramine).

Drug-Food Interactions: Avoid alcohol consumption while taking MEFENAMIC ACID+PARACETAMOL as it might cause increased dizziness and risk of stomach bleeding.

II. SAMPLE COLLECTION

Mefenamic acid and Paracetamol branded suspension is purchased from Shiv Medical Store, Iglas, U.P., and Mefenamic acid and Paracetamol generic drug suspension is purchased from Pradhan Mantri Bharatiya Janaushadhi Pariyojana Shop at Mangalayatan University Campus.

Table1: List of materials used in the evaluation tests

S.No.	Name of material	Generic or branded
1	Mefenamic acid & paracetamol suspension (50mg/125 mg/5ml)	Generic
2	Dolopar-M suspension	Branded
3	Nobel- Plus	Generic
4	Nimebest- MF	Branded

Figure 1- Suspension sample used

Table 2: List of Equipment used

S.No.	Instruments/Equipment	Use
1.	Optical microscope	Particle size measurement
2.	pH meter	Determination of pH
3.	Electronic weighing balance	Weight per ml

III. METHODOLOGY

All evaluation tests were conducted as per Indian Pharmacopeia.

Evaluation parameters

Appearance of suspension

All four suspensions were inspected visually for their appearance.

Taste Characterization

The taste was evaluated by human volunteers. The study protocol and result consent were explained and obtained from volunteers. Each volunteer held suspensions (equivalent to 50mg) of mefenamic acid and Paracetamol in the mouth for 15s. The bitterness level was compared with each other.

Particle size measurement

Optical microscopy was carried out to study the size of suspended particles. The optical microscope is used to analyze particles within a size range of 0.5 – 150 microns. Start the experiment by cleaning the microscope thoroughly. Then calibration of the eyepiece micrometer. First, adjust the light, mount the stage micrometer, and observe the scale under a microscope. Then you can observe two scales- one is the eyepiece micrometer scale showing values of 0 to 100 and the other one is the stage micrometer scale. Figure out the actual value of 1 division of the eyepiece micrometer by observing two lines of eyepiece micrometer completely overlapping lines of stage micrometer and count the division of both scales between two overlapping lines. Now count the divisions covering both scales. We can calculate the value of one division using the formula

$$\frac{X \times 10}{Y}\ \mu m$$

Where, X = Number of divisions of stage micrometer coinciding
Y= Number of divisions of eyepiece micrometer coinciding

Now, start counting the particle size by controlling the movement of the slide under a view and it should follow the motion path. In this way, count less than 300 particles to get the distribution curve. Particle size range can be judged by viewing the sample, for that, we just need to figure out which particles cover minimum and maximum divisions so we can easily define our particle size ranges.

pH

pH of the suspension was determined using a pH meter. Firstly 30 ml of the sample was taken in a 50 ml clean and dry test tube. After that, the pH electrode was dispersed in a test tube and shaken gently. Observed pH after 5 minutes.

Figure 2 - pH determination test

Weight per ml

Weight per ml was measured by a thoroughly clean and dry pycnometer. Fill the pycnometer with the sample, adjust the temperature of the filled pycnometer, and take the weight of the filled pycnometer. Determine the weight milliliter by dividing the weight in the air, in gm of the quality of liquid which filed the pycnometer of specified temperature, by the capacity expressed in ml, the factor is 0.995 at 27°C.

Redispersibility

The redispersibility was calculated by placing suspensions of 50 ml in a measuring cylinder and stored for 10 days. The measuring cylinder was tilted to 90° until the sediment dispersed uniformly. Suspensions without a flocculating agent had poor redispersibility while suspensions having flocculating agent had good redispersibility. However, the time required for complete dispersion was calculated.

Sedimentation Volume

All four suspensions were evaluated for physical stability by determining the sedimentation volume. Each of the suspensions was taken in a 50 ml stoppered graduated measuring cylinder. The suspension was dispersed thoroughly by moving upside down three times. Later, the suspension was allowed to settle for three minutes and the volume of sediment was noted. This is the original volume of sediment. The cylinder was kept undisturbed for 14 days. The volume of sediment read at 1 hour and on the 14 days was considered as the final volume of sediment. Their dispensability of suspensions was checked by moving the stoppered cylinder upside down till there was no sediment left at the bottom of the cylinder.

Figure 3 - Sedimentation volume test

IV. RESULTS

Appearance of suspension

By visual inspection, the suspension was 'orange' in color and viscous.

Taste characterization

Four volunteers were selected to perform an evaluation taste of the suspension. When the four samples were evaluated by human volunteers, here first one was used as a reference because of the absence of ion exchange resin polymer. After a 60s evaluation of all the samples, the result was concluded as 1st one that gives a bitter taste mefenamic acid was masked successfully. This is confirmed by the scale of marking of the volunteers.

Table 3: Taste evaluation of paracetamol and mefenamic acid suspension

Volunteers no./sample no.	**1**	**2**	**3**	**4**
1	2	2	2	2
2	0	0	1	0
3	1	2	0	1
4	0	0	2	1

Scale: 0 good, 1 tasteless, 2 slightly bitter, 3 bitter, 4 very bitter.

Determination of pH

pH of the suspension was determined using a pH meter. The results are shown in Table 4.

Weight per ml

The results of the specified test are shown in Table 4.

Redispersibility

This study was required because formulation takes how much is required for use. All the formulations showed different results, after 10 days of study. Results are noted in table no. 4.

Sedimentation

The sedimentation volume can have values ranging from less than 1. The ultimate height of the solid phase after settling depends on the concentration of the solid and the particle size. To obtain an acceptable suspension value the sample should be less than 0.9. The result is shown in table no. 4

Table 4: Evaluation parameters of paracetamol and mefenamic acid suspensions

Parameters/ sample no.	1	2	3	4
Color	orange	orange	orange	orange
Taste	Slightly bitter	Palatable	bitter	palatable
pH	6.04	6.62	6. 29	6.51
Weight per ml (mg/ml)	840	855	845	857
Redispersibility	77	82	70	83
Sedimentation	0.91	0.92	0.904	0.923

V. DISCUSSION

In the beginning, we chose drugs that had a bitter taste like mefenamic acid and paracetamol, in which two of them were generic and the other two were branded. All the samples had the same color i.e., orange. Taste-wise branded suspensions were found to be more palatable than generic ones, as they did a better job of masking the bitter taste of mefenamic acid. pH of two generic drugs was noted as 6.02 and 6.29 and two branded drugs were 6.62 and 6.51. The sedimentation rate of generic can be concluded as 0.91 and branded as 0.92.

VI. CONCLUSION

It can be concluded that

- Branded drugs are safer for use as compared to generic ones, especially for children.
- Taste masking of branded drugs was done better than generic ones.
- By visual observation colouring of the brand was also better.
- the pH of both branded and generic came in an acceptable range.
- There was a slight difference in the redispersibility of both types of drugs.
- The sedimentation range was also recorded in the acceptable range.

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