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COMPARATIVE STUDIES OF DIFFERENT MARKETED BRANDS OF PARACETAMOL

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ABSTRACT

The study objective is to contrast and assess several 500mg Paracetamol tablet brands. In this study, we choose four brands of 500mg Paracetamol tablet from the local market and evaluate them for weight variation, hardness, friability, disintegration, and dissolution test, among other quality control measures. The weight variation for all four brands of Paracetamol tablet is within ±5% of their average weight, and friability is not more than 1%. All paracetamol tablets disintegrate within 15 minutes, and the maximum percentage limit for all brands of Paracetamol tablets was discovered to be not less than 85% according to IP specifications limit within 30 minutes. We therefore came to the conclusion that all Paracetamol tablets from various manufacturers are safe and useful to use, with the exception of the cost. Although brand specific variations in physio-chemical tests such as weight variation, friability, disintegration, dissolution, and assay were observed, these tests were determined to be adequate to set limits. Despite being an over-the-counter medication, too much paracetamol is being used. The authenticity, quality, and marketing of each brand are so crucial. Therefore, further investigation into the quality of paracetamol is necessary to ensure its safety for human ingestion.

KEYWORDS: Different brands of paracetamol, Analgesics, Antipyretics, Comparative Analysis, Quality control test.

INTRODUCTION

Tablets are solid a solid dosage form for medications that prepared by compression method that may or may not contain excipients. Tablets are solid, flat, or biconvex unit dosage form

of a medication alone or a medication coupled with excipients that are made using the compression technique, according to the Indian Pharmacopoeia. Depending on the medication and the method of administration, they may differ in size, shape, and weight. Due to their numerous benefits, tablets are thought to be the most often used conventional dosage form, according for 70% of all medications administered.[1] The active metabolite of phenacetin is paracetamol or acetaminophen (figure 1). It is a popular antipyretic and analgesic available over the counter. It is 4-hydroxy acetanilide, often known as acetaminophen. All ages of people can reduce fevers using paracetamol. It is frequently used to treat headaches and other mild aches and pains, and it is a key component of many over-the-counter cold and flu medications.[2]

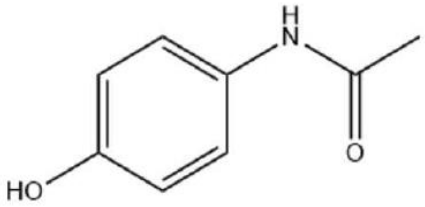

Fig. 1: Chemical structure of paracetamol.

A non-steroidal anti-inflammatory medication is Paracetamol. Evaluations of various criteria, including hardness, friability, weight variation, and dissolution profile disintegration time, were carried out. These factors affect the tablet's bioavailability and therapeutic effectiveness.[3] Warfarin and acenocoumarol anticoagulant actions are amplified by paracetamol, increasing the risk of bleeding.[4] For the treatment of the symptoms of the common cold, the flu, and sinusitis, it is also a frequently used analgesic chemically mixed with centrally acting substances like caffeine, codeine, and dextropropoxyphene as well as with oral decongestants in a variety of formulations. Along with treating headaches and other mild aches and pains, it is also used in conjunction with opioid analgesics to treat cancer pain episiotomy pain, and pain following surgery.[5] Additionally, according to data from numerous research, Paracetamol tablets were selected as the model drug since they were readily available, often eaten by people, and had notable price variations between brands.[6] When a patient's high gastric acid output or prolonged bleeding time may be a problem, it is more well tolerated than aspirin.[7]

MATERIALS AND METHODS

Materials

Preparation of buffer solution pH 5.8

For a pH of 5.8 dissolve 8.1654gm of sodium hydrogen ortho phosphate and 0.4gm of sodium hydroxide in enough distilled water to fill a volumetric flask with a 1000ml capacity.

Instruments

Analytical balance, UV-Spectrophotometer, Tablet hardness tester, Dissolution test apparatus, Disintegration test apparatus, Friability test apparatus.

Reagents

Standard Paracetamol, Sodium hydroxide (NAOH), Potassium Dihydrogen orthophosphate (KH_2PO_4).

Evaluation tests for different brands

Weight variation test

This test was carried out to determine the whether each tablet's content was uniform and whether its shape, size, and thickness were consistent. From each brand, 20 tablets were chosen, and each one was weighed using analytical balance. It was determined what the tablet's typical weight was. The following formula is used to compute the percentage of weight variation:[8]

$$\% \text{ of weight variation} = \frac{\text{Average weight} - \text{Individual weight}}{\text{Average weight}} \times 100$$

Hardness test

Hardness is the term used to describe a tablet's capacity to withstand applied pressure. The test tablet was held between the fixed and moving jaws of the Pfizer Hardness Tester. The force applied to the edge of the tablets was steadily increased by moving the screw knob forward until the tablet broke. The reading on the scale, which indicates how much effort is required to shatter the tablet, was removed. How hard a tablet is determined by the weight of materials used, the space between the upper and lower punches during compression, and the pressure is applied during compression. The Hardness is also influenced by the kind and quantity of ingredients used during formulation. The final may not degrade in the required length of time if it is too hard, and if it is too soft, it may not withstand handling during packing and transit.[9]

Friability

Using a Roche Friabilator, 10 pills were weighed and put into the device. A 25-rpm speed was used to rotate the device. The device was designed to revolve for four minutes The weights of the tablets were then measured and contrasted with the starting weights. The formula was used to determine the percent friability.

$$\% F = \frac{W_0 - W}{W_0} \times 100$$

Where,

% F = Friability in %

W0 = Initial weight of tablets,

W = Weight of the tablets after revolution.[10]

Dissolution test

The USP Pharmacopeia was followed for conducting the dissolving test. The experiment was conducted with a potassium phosphate buffer (Ph 5.8) at a constant temperature of 37 ± 1^0C. After 5, 10, 20, 30, 45, and 60 minutes, the sample were taken out and replaced with an equivalent volume of new buffer solution. A UV spectrophotometer was used to measure the samples absorbance at 243nm and test them for the presence of drugs. As a blank, phosphate buffer was employed.[11]

Disintegration test

This test is performed to establish how long a tablet will take to dissolve. Six tablets were placed in the basket rack assembly and attached to the disintegration apparatus, after a 900ml beaker of water has been poured to a temperature of 37 ± 0.2^0C. The amount of time it took for the tablet to break down was noted.[12]

Assay

To produce the standard calibration curve,0.1gm of pure paracetamol was weighed using an analytical balance before being put into a 100ml volumetric flask to dissolve the paracetamol 10ml of 0.1m sodium hydroxide was first added, diluted and shaken with 100ml of pure water for 15min then the volume was made up to the mark with purified water to create a stock solution to create the following standard solution 1,2 and 3mg per ml, calculated volumes of stock solution were pippeted into 100ml volumetric flask. Using mixture of sodium hydroxide and filtered water as a blank, a uv/visible spectrometer was used to measure and confirm the maximum wavelength at which paracetamol absorbs light in one of

the standard solutions to analyze and determine the absorption values for all standard solutions with the same blank the wavelength was set at 243nm. By plotting the absorbance against the amounts on the calibration curve that was created, a regression equation was generated then it was utilized to calculate the concentration in each sample.[13]

RESULTS AND DISCUSSION

Calibration curve

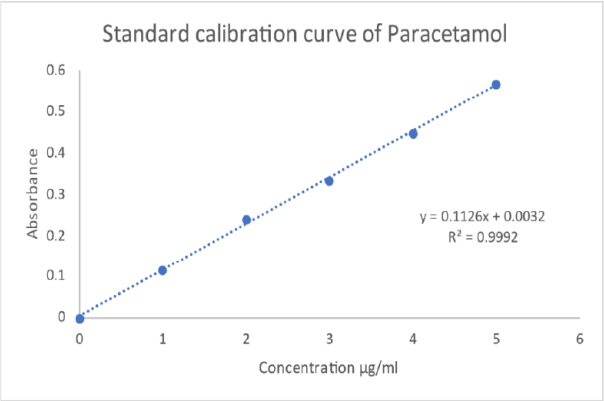

Fig. 2: Calibration curve of pure paracetamol at wavelength 243nm.

Weight variation - According IP /BP the weigh variation limits ±5% for the tablets 250mg or above 250 mg. In this study weight variation for all four different brands of paracetamol tablets within ±5% of their average weight were shown in the Table 1.

Hardness test – Hardness always influences the friability and disintegration time. In this study the hardness result of all the different bran d of paracetamol found satisfactory were shown in the Table 1.

Friability test - The limit of Friability is not more than 1% according IP/BP. In this study we found that friability of all the tablets of different brand of paracetamol less than 1% were shown in the Table 1 and Figure 4.

Disintegration - According IP uncoated tablet disintegration time within 15 minutes. In this study all the tablets of different brand of paracetamol were completely disintegrated within 15 minutes which show in Figure 3.

Dissolution – According the IP the % release of drug is not less than 85% and, in this study, we found that the % release all different brand s of Paracetamol above 85%. The result obtained satisfactory were shown in the Table 2 and Figure 5.

Assay – According to the BP the concentration of paracetamol is accepted if it is within the range of 90-110%. The assay test result for all different brands of paracetamol were found between in range 90 to 100%.

Table 1: Weight variation, Hardness, Friability, Disintegration of paracetamol.

Brand (Cost in Rs.)	Mean Weight in gm ±SD	Hardness (kg) Mean±SD	Friability (%)	Disintegration time(minute)
Dolo (Rs 16.96)	0.596±0.01	12.28±0.25	0.27	7.15
Pacimol (Rs 16.94)	0.567±0.008	7.86±0.41	0.51	5.22
Crucimol (Rs 11.31)	0.582±0.01	7.06±0.28	0.44	4.55
Calpol (Rs 16.65)	0.634±0.008	8.34±0.34	0.34	7.38

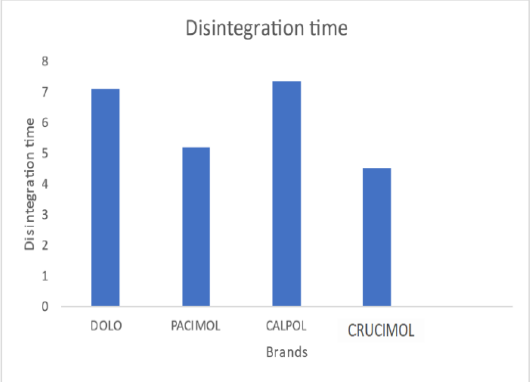

Fig. 3: Disintegration time for different brands of paracetamol.

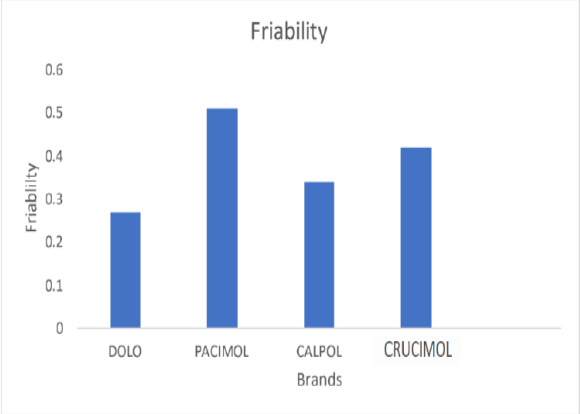

Fig. 4: Friability for different brands of paracetamol.

- **In vitro drug release study**

Table 2: *In vitro* drug release study of different brands of paracetamol in phosphate buffer.

% Drug release				
Time (minutes)	Dolo	Calpol	Pacimol	Crusimol
0	0	0	0	0

5	34.3079	36.7673	30.6189	27.9136
10	53.9827	56.4421	50.2937	47.5884
15	70.8293	73.2887	67.1403	64.435
20	83.8639	87.5529	80.1748	77.4693
25	88.6596	91.119	84.9706	82.5112
30	95.1769	97.6362	91.4879	88.7826

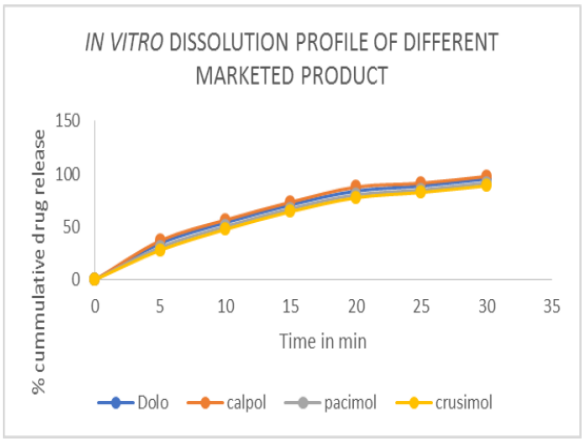

Fig. 5: *In vitro* drug release profile for different four brands of paracetamol.

CONCLUSION

The *In-vitro* physical and chemical evaluation of selected commercial brands of paracetamol available in Yemeni market proved the quality and efficacy according to the standards of USP and BP requirements. Paracetamol is a prescription drug; Hence, it is essential that it is manufactured following Good Manufacturing Practice (GMP). In this study, it was observed that all the formulation complied with the specification. It is also important that the tablets meet all the parameters because all are essential. All four brands of the paracetamol tablet comply with BP and USP specifications for in vitro quality control tests of uniformity of weight, uniformity of content, friability, disintegration time, and dissolution except hardens test. The USP and BP specification of maximum hardens value of 10 Kg/cm^2, where the lower value of hardens is 13.67 Kg/cm2 and the value is 26.075 Kg/cm^2. But Hardness is referred to as non-compendial test. If the hardness is increased, then the disintegration rate will increase and this will affect the dissolution profile. It is also necessary that the drugs disintegrate properly because this will influence the dissolution profile. Pharmaceutical equivalence can also be determined from these tests. According to my knowledge, not much work has been done to determine the quality control parameters of generic paracetamol tablet available in market. So further study needs to be conducted regarding the quality control parameters because paracetamol is widely used by people and it is necessary that the product is of good and acceptable quality.

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