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COMPARATIVE EVALUATION OF DIFFERENT BRANDS OF PARACETAMOL TABLETS 500MG

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***Abstract*:** Paracetamol is an analgesic and antipyretic drug which are generally used in reducing fever and relief in pain. Paracetamol are easily available in medical shops, because it is without prescription drugs. In this time all the pharmaceutical companies produce various brands of paracetamol tablets by various technique and manufacturing process. The aim of the study is to compare and evaluate different brands of paracetamol tablets of 500mg. In this study we selected four different brands of paracetamol tablets 500mg from local markets in Dehradun and check their quality control parameters like weight variation, hardness, friability, disintegration and dissolution test.
We found that all the test results of different brands of paracetamol tablets are obtained within acceptable limits, weight variation for all four different brands of paracetamol tablets within ±5% of the their average weight and friability is not more than 1%, disintegration time for all paracetamol tablet within 15 minutes, percentage release of all brands of paracetamol tablets was found not less than 85% according IP specification limit within 30 minutes. Therefore we concluded that all the tablets of paracetamol of different brands are safe and effective for use except the pricing.

***IndexTerms* - Paracetamol, analgesic and antipyretic, quality control.**

INTRODUCTION – Paracetamol is a non-steroidal anti-inflammatory drug (NSAID) and commonly used as analgesic and antipyretic agent in the relief of fever, headaches, other minor aches and pains.[1] It is commonly used for severe pain condition such as cancer pain and pain after surgery in combination with opioid pain medication[2].Chemically, It is 4-hydroxy acetanilide [3] and word paracetamol is from a chemical name for para-acetyl aminophenol and it consists of a benzene ring center, substituted by one hydroxyl group and the nitrogen atom of an amide group in the para (1, 4) pattern as indicated in figure (1) below [4]

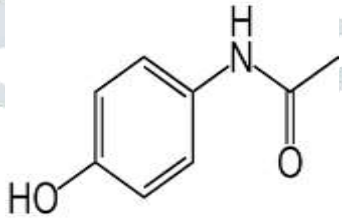

Figure 1. Chemical structure of Paracetamol

It is better tolerated than aspirin in patients in whom excessive gastric acid secretion or prolongation of bleeding time may be a concern [5]. The Paracetamol are available without prescription in markets, and it has few anti-inflammatory effects in comparison to NSAIDs. However, aspirin, paracetamol and other NSAIDs all act by the same mechanism (inhibition of prostaglandin synthesis by inhibiting cyclooxygenase (COX)) and all show varying levels of analgesic, anti-inflammatory, antipyretic and antiplatelet actions[6].
Several brands of paracetamol tablets are available in markets with different-different strength. Paracetamol is generally safe for human use at recommended dose. But overdoses of Paracetamol can cause potentially fatal liver damage and in rare individual, a normal dose can do the same. [7].

MATERIAL AND METHODS

MATERIAL:

Chemicals –

1. Pure Paracetamol powder for standard solutions.
2. Four different brands of paracetamol tablets 500mg
3. Potassium dihydrogen orthophosphates for buffers solution.
4. Sodium Hydroxide

Glassware – Beakers, test tubes. Volumetric flask, measuring cylinder, pipette, funnel, etc.
Instruments – Weighing balance, Monsanto hardness tester, Vernier Caliper, Disintegration machine, Dissolution machine, UV spectrophotometer etc.

METHODS:

Weight Variation Test – Twenty tablets from each brands of paracetamol were weighted individually with the mentioned analytical balance and average weight and the percent deviation was determined for each brand of paracetamol tablets [8]. The weight variation limits show in tablet 1.
Hardness Test – The tablet hardness was measured with a Monsanto hardness tester. The force to break the tablet was diametrically applied, by placing the tablet between the anvil and spindle of the tester, and the knurled knob turned until the tablet fits into space and adjusted to zero. The pressure was applied by turning the knurled knob until the tablet breaks; the force (kg) was read and the mean of triplicate determinations of each brand was recorded [9]
Friability Test: 10 tablets of each brand of paracetamol tablets were weighed and placed in Roche friabilator that rotated at 25 rpm for 4 minutes. Then the tablets of paracetamol were dedusted and weighed again. The percentage of weight loss was calculated again, the percentage of weight loss was calculated using the formula [10].

% friability = [(W1-W2)100]/W1

W1 refers initial weight of tablet, while W2 refers final weight of tablets.

Disintegration Test – Six tablets of each sample were placed in disintegration apparatus, where the volume of disintegration medium was 900 ml of water maintained at 37±1°C. The time taken to break each tablet into small particles and pass through the mesh was recorded and average time was calculated [11].
Dissolution Test: The dissolution was carried out by using medium 900ml of phosphate buffer (ph 5.8), Apparatus no. 1 , speed and time 50rpm and 30 minutes.
Withdraw a suitable volume of the medium and filter and dilute a suitable volume of the filtrate with the same solvent. Measure the absorbance of the resulting solution at the maximum at about 243 nm. Similarly measure the absorbance of a solution of known concentration of paracetamol RS, calculate the content of C8H9NO2 [12].
Assay Test: Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing about 0.15g of paracetamol add 50ml of 0.1 M sodium hydroxide , dilute with 100ml of water, shake for 15 minutes and add sufficient water to produce 200ml. Mix , filter and dilute 10 ml of the filtrate to 100ml with water. To 10 ml of the resulting solution add 10ml of 0.1M sodium hydroxide , dilute to 100ml with water and mix, Measure the absorbance of the resulting solution at the maximum at about 257nm Calculate the content of paracetamol taking 715 as the specific absorbance at 257nm[13].

RESULTS AND DISCUSSION

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.
Hardness test – Hardness always influence the friability and disintegration time. In this study the hardness result of all the different brand of paracetamol found satisfactory.
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%.
Disintegration - According IP uncoated tablet disintegration time within 15 minutes. In this study all the tablets of different brand of paracetamol was completely disintegrated within 15 minutes which is show by the graph (figure 2).
Dissolution – According the IP the % release of drug is not less than 85% and in this study we found that the % release all different brands of Paracetamol above 85 %. The result obtained satisfactory.
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 limits according IP/BP

IP/BP	LIMITS
80 mg or less	±10%
More than 80 mg or less than 250mg	±7.5%
250mg or more	±5%

Table 2. Weight variation, hardness, friability, disintegration, % release of paracetamol, assay of paracetamol tablets.

Brand (Cost in Rs.)	Mean Weight in gm ±SD	Hardness in kg/cm^2	Friability %	Disintegration time in minutes	% release of Paracetamol at 30 minutes	Assay %
Dolo (Rs.25)	0.598±0.003	12.28±0.25	0.27	7.15	87.45%	98.56%
Paracip (Rs.08)	0.593±0.003	7.86±0.41	0.51	5.22	89.56%	99.45%
Calpol (Rs.68)	0.642±0.002	8.34±0.34	0.34	7.38	90.04%	99.76%
Asmol (Rs.22)	0.545±0.001	7.06±0.29	0.44	4.55	90.32%	98.65%

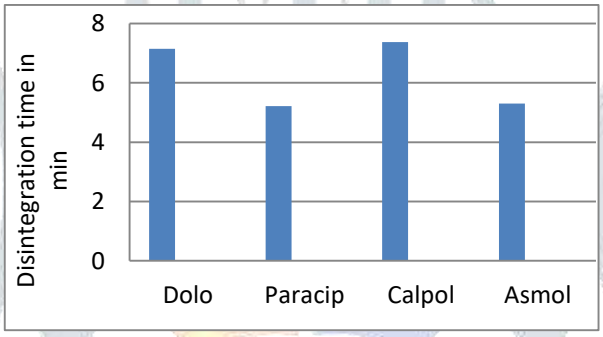

Fig 2 Disintergration time for test product

CONCLUSION: On the basis of present research it can be concluded that the various marketed brands of paracetamol taken up in the present study, showed all the studied parameters under the specified limit which makes them pharmacologically equivalent. Hence one brand can be taken as a substitute of another based on its variability in price and self-life. We also observed that the brand Paracip had the minimum price which was only 08 rupees for a pack of ten tablets each and its evaluation parameters are reported with in the specific limit, hence it can be preferred as the cheapest desirable medicine after prescription by the physician.

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