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IN-VITRO EVALUATION OF DIFFERENT MARKETED BRANDS OF PARACETAMOL TABLETS USING QUALITY CONTROL TESTS

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ABSTRACT

Paracetamol is an active ingredient in the antipyretic and pain relievers class. Various brands of certain formulations are available on the market. The primary goal of the study was to compare 500 mg paracetamol tablet brands in vitro. In vitro evaluation guarantees quality, bioavailability and optimal therapeutic activity.

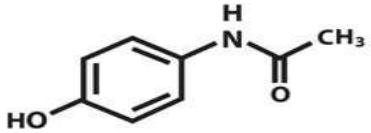
The active metabolite of phenacetin, paracetamol, is widely used for headaches and pains and is one of the main ingredients in many cold and flu remedies.

In the study, 500mg of paracetamol were selected from 5 different manufacturer's standard tablets. The study was purely experimental and used in vitro testing (IP) and other official literature to evaluate the in vitro quality of paracetamol tablets using various analytical methods and procedures. In the post-evaluation phase, the following post-evaluation parameters were observed: Weight variation, Friability, Hardness, Content uniformity Within the prescribed limit

KEYWORDS: *Paracetamol, Comparative, Quality control parameters, Evaluation*

INTRODUCTION

Paracetamol or acetaminophen is active metabolites of Phenacitin. It is a widely used over-the-counter analgesic and antipyretic. Chemically, it is 4-hydroxy acetanilide (acetaminophen). Paracetamol is approved for reducing fever in people of all ages. 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.



Paracetamol

FIG 1

This drug which has well-established metabolic and pharmacokinetic (pKa) profiles is a universally accepted analgesic and antipyretic drug. It is poorly aqueous soluble and its frequency of administration is high due to low bioavailability.

Paracetamol is used for the relief of pains associated with many parts of the body. It has analgesic properties comparable to those of aspirin, while its anti-inflammatory effects are weaker. It is better tolerated than aspirin in patients in whom excessive gastric acid secretion or prolongation of bleeding time may be a concern. Available without a prescription, it has in recent years increasingly become a common household drug.

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MATERIALS AND METHODS

TABLE 1 : LIST OF INSTRUMENTS USED

Evaluation methods	Instruments
Weight variation test	Analytical balance
Friability test	Roche friabilator
Disintegration test	Disintegration apparatus
Dissolution test	Dissolution tester (USP) *Electrolab tdt-08l*
Content uniformity test	UV-visible spectroscopy *Jasko v-530*

To perform the study paracetamol tablets of five different manufacturers were purchased from the drug store. Both the tablet brands of paracetamol were labeled to contain 500 mg of paracetamol per tablet. The shelf life of the given tablets were from 2-4 years from the date of manufacturing.

Sample to be Identified

The tablet was named as Brand1, Brand2, Brand3, Brand4, Brand5 for paracetamol tablets of different manufacturer. And then the tablet was taken for evaluation.

Procedure of Evaluation

Different analytical methods and tests methods are necessary for pharmaceutical formulation.
For the evaluation there are official and non official tests

- Non official tests:
  a) Friability
  b) Hardness
  c) Thickness
- Official tests:
  a) Weight variation
  b) Dissolution
  c) Content uniformity
  d) Disintegration

1. Weight Variation:
   20 tablets was taken and weighed individually there average was been note down. For all brands percent variation was been calculated.
2. Hardness:
   10 tablets were taken and they were placed individually in Monsanto hardness tester.
   The load required to break the tablet was noted down.
3. Friability
   Roche Friabilator was been used. Now rotate the drum at 25 rpm per min or 100 rpm for 4 mins.
   And then calculate the weight of tablets and take its % using following formula.

$$\% \text{ Friability} = \frac{W1 - W2}{W1} \times 100$$

4. Tablet Disintegration
   It was performed in disintegration ip apparatus. 6 tablets were placed in the apparatus containing simulated gastric fluid (0.1N HCl) and temperature was maintained to 37ºC. now note down the time taken by tablets to disintegrate.
5. Dissolution
   For the test, IP type 1 paddle apparatus was used. Phosphate buffer solution of pH 5.8 (900ml) is measured and transferred into the dissolution flask and the temperature was maintained at 37 ± 0.5^0c.
   The paddle was rotated at 50 rpm and after an interval of 5min ,5ml was withdrawn and replaced with the phosphate buffer. And this was continued for 1hrs. All samples are filtered using Wattman filter paper. The absorbance at 249 nm is measured in UV-spectrometer using the phosphate buffer solution as a blank.
6. Content uniformity

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Weigh and powdered 20 tablets accurately a quantity of powder equivalent to 0.15 grams of paracetamol and 50 ml of 0.1m NaOH, diluted with 100 ml of water Shaked for 15 minutes add sufficient water to produce 200 ml mixed and filtered and diluted 10 ml of filtrate to 100 ml with water. To 10 ml of resulting solution add 10 ml of 0.1 m NaOH dilute to 100 ml with water And measure the absorbance of the resulting solution at about 257 nm. Calculate the contents by taking A (1%, 1cm) as 715 at the maximum 257 nm.

RESULTS AND DISCUSSION

1. Weight variation
   The weight variation test of taken paracetamol tablets of all the brands have passed the test and within the specified given limits as per IP that is, with not more than ± 5% deviation for tablets above 250 mg.
2. Hardness
   In the study, it was found that all the brands of paracetamol tablets have passed the test and is within the limit specified in IP, that is 5-8 kg/cm^2
3. Friability
   % friability should be up to 0.5 to 1% for all standard compressed tablets & the results were found to be in a specified limit.
4. Disintegration test
   The Disintegration time for all the brands of paracetamol tablets must be within 5 mins. The overall disintegration time of all brands of paracetamol is in the range from 1-4 mins.
5. Dissolution
   At different time intervals, drug release at 10 min was from 17.9 to 63.07 % and at 18 mins 85.7 to 100.78 % and the values for the Same is shown in the table no 2.
6. Content uniformity
   All the tablet brands of paracetamol contained the paracetamol with in 100 ±5 % of the labelled claim. The IP specifications for assay are that the paracetamol contents should not be less than 95 % and not more then 105.

TABLE 2: EVALUATION OF DIFFERENT QUALITY CONTROL PARAMETERS

Sample	Weight variation (mg)	Hardness (kg/cm^2)	Friability (%)	Disintegration Time (sec/min)	% Drug Content Release	Concentration (%)
1	673.2	4.09	0.447	3	106.69	99.16
2	601.8	4	0.664	3	108.1	98.5
3	569.1	4.98	0.150	4	109.64	98.88
4	597.7	4.03	0.795	2	109.03	98.42
5	640.5	4.99	0.799	1	103.47	98.56

TABLE 3 : CALIBRATION CURVE DATA OF PARACETAMOL

Concentration (µg/ml)	Absorbance
2	0.397
4	0.489
6	0.999
8	0.697
10	0.792

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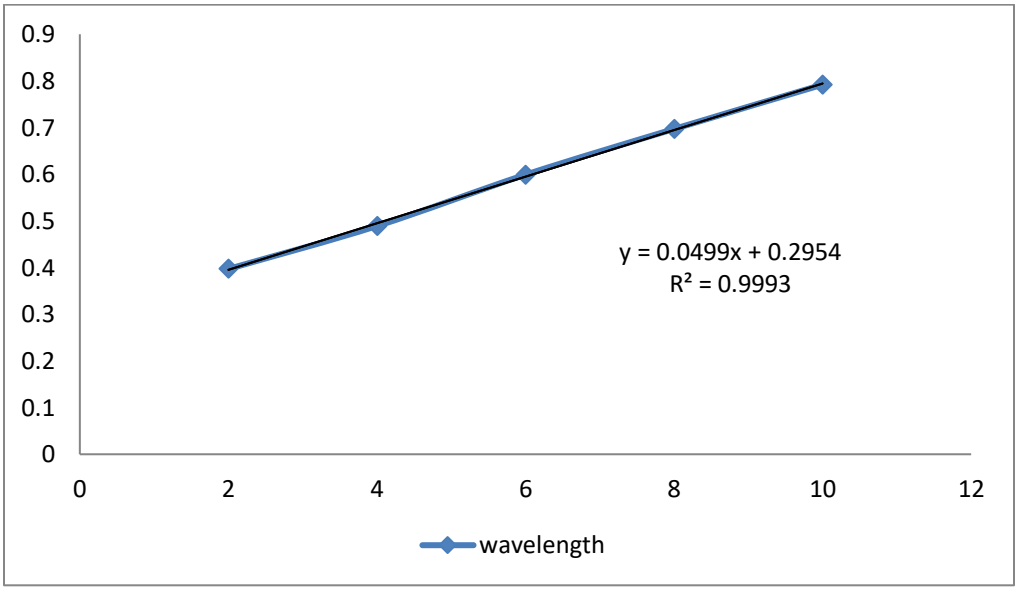

FIGURE 2: STANDARD CALIBRATION CURVE OF PARACETAMOL

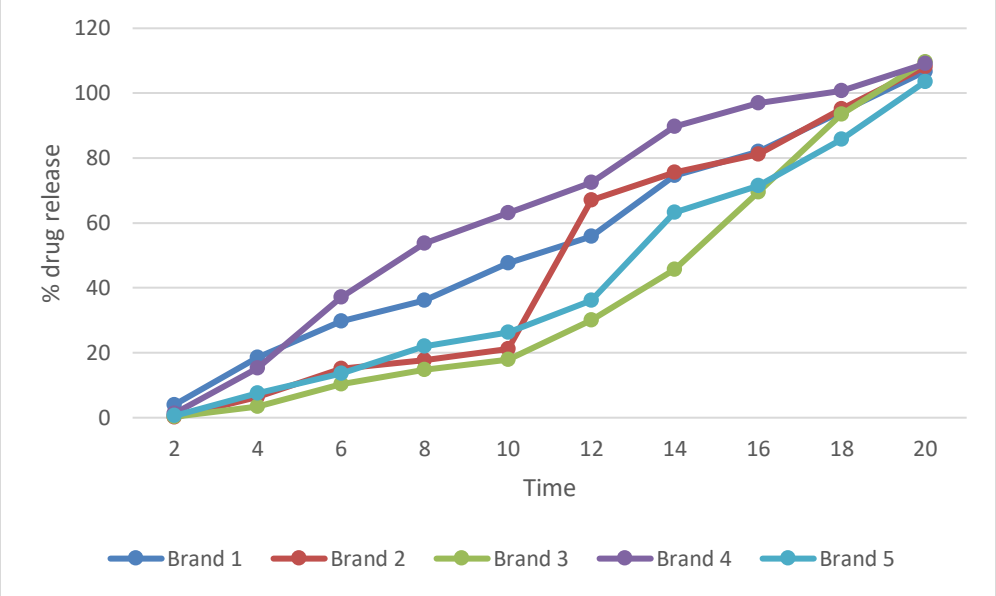

FIGURE 3: Dissolution Profile of Various Brands

CONCLUSION

This study was conducted to evaluate five different brands of Paracetamol Tablet available in market.

As a result of this study, we have concluded that all the Five brands of Paracetamol Tablet meet all the standard quality parameter for getting its desired therapeutic response. Therapeutic response of any formulation depends on its quality parameters. Various quality control parameters for tablet like weight variation, friability, disintegration time, assay, hardness, thickness and dissolution test were conducted in this work. All the drug disintegrated within a time limit of less than 15 minutes. However, despite the variation, most drugs are within the official limit. At end of this project, we noted that all quality parameters are interconnected with each other and can be alter by disturbing any of them.

So concluding, all marketed PCM tablets of 500mg were under specified IP limits.

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