IJPSR (2012), Vol. 3, Issue 09 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 19 May, 2012; received in revised form 25 June, 2012; accepted 27 August, 2012

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

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Keywords:
Paracetamol,
Comparative,
Quality control parameters,
Evaluation

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ABSTRACT

Paracetamol is a widely used non-prescription analgesic and antipyretic medicine. The study was conducted to assess the comparative *in-vitro* quality control parameters through the evaluation of weight variation, hardness, friability, disintegration time and dissolution profile between the commercially available tablet brands of paracetamol. Tablets of two manufacturers of the formulation were evaluated in two groups A and B. The similarities were found between both the groups. Both tablet brands of paracetamol (1.0 to 1.6%) showed acceptable weight variation and friability (below 1%). Both tablet brands were somewhat different in their hardness, disintegration time and dissolution profile. It can be concluded that standard quality control parameters always should be maintained not for paracetamol but also for all kinds of medicine for getting better drug products.

INTRODUCTION: Paracetamol (INN) or acetaminophen (USAN) is a widely used over-the-counter analgesic (pain reliever) and antipyretic (fever reducer). It is commonly used for the relief of fever, headaches, and other minor aches and pains, and is a major ingredient in numerous cold and flu remedies [1].

The clinical effectiveness exerted by tablet formulation depends on at least two factors such as, the drug must be present in the labeled amount and its availability to the body. The main objective of an oral tablet is to deliver the drug to the human body at certain and defined amount through the gastro-intestinal system for producing therapeutic effect. The formulation of the drug product can have a significant effect on the quality parameters such as weight variation, hardness, friability, disintegration time, dissolution profile etc. This also includes the physiochemical properties of the active ingredients and excipients as well as the procedures used in the manufacturing process.

Moreover, quality control parameters also or physical properties of tablet are useful tools for maintaining consistency in batch-to-batch manufacturing and it should be performed for every drug product.

All of these parameters are closely related to each other and have effect on drug absorption, bioavailability etc. The aim of the study was to evaluate the comparative quality control parameters between the tablets of two brands of a formulation because standard quality parameters are essential for better quality of medicine [2].

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MATERIALS & METHODS [2-5]:

TABLE 1: LIST OF EQUIPMENT USED

Equipment Name	Maker
High Precision Balance	Globus
Roche Friabilator	UTS
Monsanto Hardness Tester	Zineo Scientific Instruments
Dissolution Apparatus (6 Paddle)	Model no.- TDT-68L Elecrolab
U.V. Spectrophotometer	Model no. – U.V.1650 Shimadzu

TABLE 2: LIST OF CHEMICAL USED

S. No.	Chemical Name
1.	0.1M Sodium Hydroxide
2.	0.1N Hydrochloric Acid
3.	Distilled Water

Study design: Comparative *in-vitro* quality control parameters between the commercially available tablet brands of paracetamol were studied through the evaluation of weight variation, hardness, friability, disintegration time, dissolution profile and pharmacopeial assay. The study was done by performing various test procedures associated to assess the quality of tablets.

Sample collection: To perform the study paracetamol tablets of two different manufacturers were purchased from the drug store. Both the tablet brands of paracetamol were labeled to contain 600 mg of paracetamol per tablet. The labeled shelf life of all of the tablets was three years from the date of manufacturing and was taken for the evaluation before two years of the labeled expiry date.

Sample identification: After purchasing, tablets of both the brands were coded as A and B for paracetamol tablets of two different manufacturers. Finally the coded samples were separated as the same manufacturer and taken for evaluation.

Procedure of evaluation: Various analytical methods and tests are important for the development and manufacture of pharmaceutical formulations. For the evaluation, following quality control tests were performed for both the tablet brands in the study.

1. **Weight Variation:** 10 tablets were taken and were weighed using globus high precision weighing machine. Their average weight and standard deviation were noted down.
   a) Then each tablet was weight and their % difference from the average weight was determined.

2. **Hardness Test:**
   a) A tablet was placed vertically on the Monsanto hardness tester.
   b) The load was then applied along the radial axis of the tablet.
   c) The weight or load required for breaking the tablet was noted down.
   d) Similarly it was done for 10 tablets.

3. **Friability:**
   a) It was performed using Roche Friabilator.
   b) 5 tablets were weighed and placed in apparatus.
   c) The apparatus was rotated at a speed of 25 rpm.
   d) The apparatus was made to rotate for 4 min.
   e) The tablets were then weighed and the weights were compared with the initial weights.
   f) The % age friability was calculated using the formula.

$$\% F = [1 - (W/W_o)] \times 100$$

Where, % F = Friability in % age, W_o = Initial weight of tablets, W = Weight of the tablets after revolution.

4. **Tablet Disintegration:**
   a) It was performed using USP disintegration device.
   b) 6 tablets were placed in disintegration test apparatus.
   c) It was maintained at 37 ± 0.2^{o}C containing simulated gastric fluid (0.1N HCl).
   d) Noted down the time taken for tablets to disintegrates.

5. **Tablet Dissolution:**

For this test U.S.P. Type- 1 (Basket), 6 Paddle Apparatus was used.

Gastric Fluid as Dissolution Medium: The tablets formed were immersed into 900 ml. of Dissolution medium, simulated gastric fluid (0.1N HCl).

The temperature of the dissolution medium was maintained at 37 ± 0.2^{o}C.

The basket was rotated at a speed of 150 rpm.

After an interval of every 15 minutes, 2 ml. of the medium was Pipette out and replaced with fresh medium (0.1N HCl).

This was continued all along for 2 hours.

The pipetted out samples were then diluted to 10 ml. with fresh dissolution medium and were then filtered.

The absorbances of the filtered samples were determined using U.V. Spectroscope at λ_{max} 222 nm.

6. **Pharmacopoeial Assay (I.P.):** Weigh & powdered 20 tablets. Then weighed accurately a quantity of powder equivalent to about 0.15 gm of paracetamol. Then add 50 ml 0.1M NaOH & 100 ml. of distilled water. Shake the contents for 15 minutes & then add sufficient water to produced 200 ml. Then filtered & diluted 10 ml of filterate to 100 ml. with water. Then again to 10 ml of resulting solution, add 10ml. of 0.1M NaOH & again diluted to 100 ml with water & mix thoroughly. Then note down the absorbance of resulting mixture at maximum at 257nm & calculate the contents by taking A (1%, 1cm) as 715 at the maximum 257 nm.

RESULT & DISCUSSIONS:

Weight Variation: During the study, at first the weight variation which is the key to controlling crushing strength and friability of tablet was assessed. The test stated that both the samples of paracetamol coded A and B have passed the weight variation uniformity test as specified in the Indian Pharmacopoeia (not exceed 5% deviation) (Indian Pharmacopoeia, 2007).

Hardness: Hardness is the second most important physical feature for assessing tablet. In the study, it was found that both A and B brands of paracetamol group passed the test of tablet crushing strength or hardness. Both these brands have acceptable crushing strength of between 4 kg/cm^2 to 10 kg/cm^2.

Friability: In the friability test, both tablet brands showed impressive friability values. The friability values for both paracetamol tablet brands were ranged from 0.1 to 0.2%. In both formulations the percent (%) friability was less than 1% which ensures that all the tablets of both brands of formulation were mechanically stable.

Disintegration Time: The disintegration time of both tablet brands of paracetamol A and B was satisfactory as uncoated USP tablets have disintegration time standards as low as 5 minutes. The overall disintegration time for paracetamol tablet brands was in the ranged from 24 seconds to 4 minutes 52 seconds.

Results of weight variation, hardness, friability and disintegration tests are shown in **Table 3**.

Table 3: Evaluation of different quality control parameters of paracetamol tablets.

Sample (Tablet Brands)	Weight (mg)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (sec/min)	% Drug Content Release	Concentration (%)
A	1.6%	9	0.1	1 min 38 sec	93.06	104
B	1.0%	10	0.2	1 min 12 sec	85.69	103

Dissolution: Dissolution was another studied important quality control parameters directly related to the absorption and bioavailability of drug. The study revealed that at different time intervals drug release rate was better.

After 10 minutes, the release rate of both tablet brands of paracetamol was 43.96 to 45.60%. Finally after 120 minutes, 85-95% drug release was observed in A and B for paracetamol brands. Outcome of the test has been shown in **Table 4** and **Figure 1-3.**

TABLE 4: EVALUATION OF DISSOLUTION PROFILE OF PARACETAMOL TABLETS.

Sample (Tablet brands)	% Drug Content Release (5 min)	% Drug Content Release (10 min)	% Drug Content Release (20 min)	% Drug Content Release (40 min)	% Drug Content Release (80 min)	% Drug Content Release (120 min)
A	20.24	43.96	54.93	65.89	71.95	93.06
B	36.60	45.60	54.93	70.96	77.51	85.69

TABLE 5: CALIBRATION CURVE DATA OF PARACETAMOL

Concentration(µg/ml)	Absorbance
0	0
10	0.23
20	0.363
30	0.456
40	0.541
50	0.619
60	0.745
70	0.841

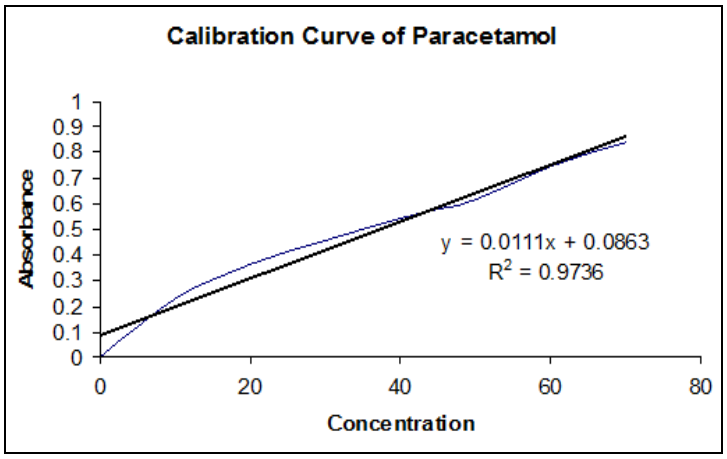

FIGURE 1: STANDARD CALIBRATION CURVE OF PARACETAMOL

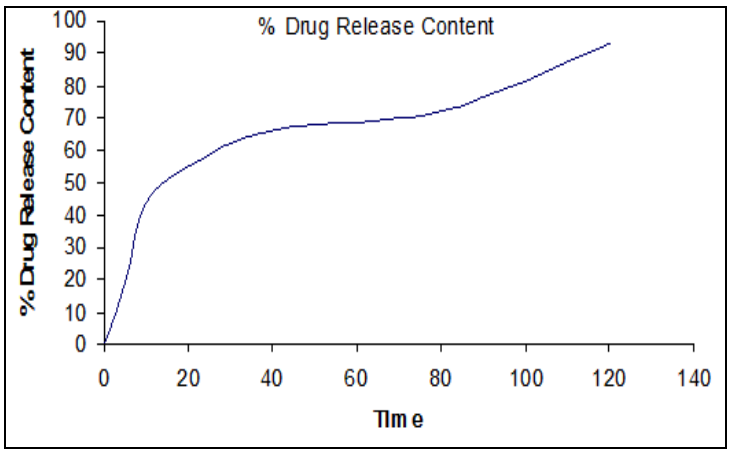

FIGURE 2: DISSOLUTION PROFILE OF PARACETAMOL TABLET (BRAND A)

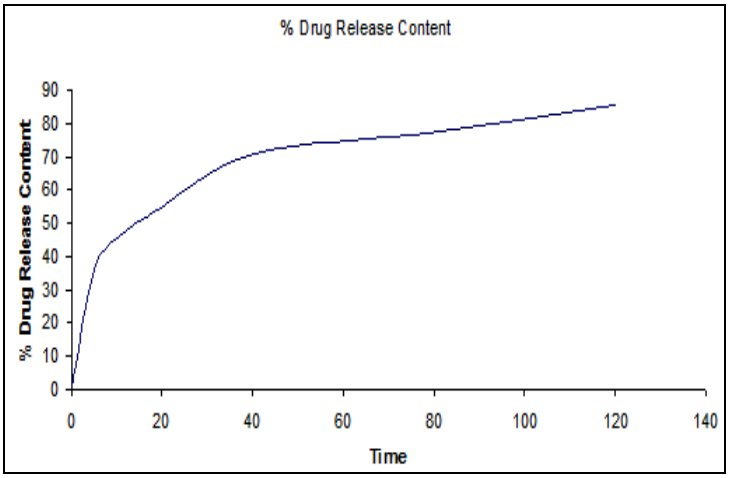

FIGURE 3: DISSOLUTION PROFILE OF PARACETAMOL TABLET (BRAND B)

Pharmacopoeial Assay: Both tablet brands of paracetamol A and B 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 then 95 % and not more then 105.

CONCLUSION: Paracetamol is a well established and proven analgesic and antipyretic drug. Therapeutic response of any formulation depends on its quality parameters. From the study it was identified that weight variation and friability test of both paracetamol tablet brands complied the specification. Variation was obtained in hardness, disintegration time and dissolution profile during the test procedure. It should be strictly considered that an ideal tablet will have sufficient hardness to maintain its mechanical stability but not more. Because harder tablet can delay disintegration time or alter dissolution profile. Finally, as quality control parameters are related to one another from initial step to pharmacological action of the drug, a high-quality tablet should meet all the standard quality parameter for getting its desired therapeutic response.

ACKNOWLEDGEMENT: The authors are thankful to Ruchika Agnihotri, Department of Pharmacy, Global College of Pharmacy, for providing her guidance to perform this research work.

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How to cite this article:
Kumar S, Shashikant and Agnihotri R: *In-Vitro* Evaluation of Two Marketed Brands of Paracetamol Tablets Using Quality Control Tests**.** *Int J Pharm Sci Res*, 2012; Vol. 3(9): 3337-3341.