Comparative in vitro release study of some commercially available paracetamol tablets

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ABSTRACT

A tablet is a pharmaceutical dosage form. It comprises of active substances and excipients. Various brands of some dosage forms are available in the market with the common claim that they are all bioequivalent. The main objective of the present study was to conduct the comparative dissolution studies of various brands of same dosage forms to determine whether all the formulations used were equivalent or significantly different. Five different brands of Paracetamol of 500 mg conventional tablets from different manufacturers were selected in the study and dissolution testing in 7.8 pH Phosphate buffer was conducted from each brands for 30 mins. By using dissolution testing apparatus USP type-II.

INTRODUCTION

Paracetamol (Acetaminophen) is a non-steroidal anti-inflammatory drug (NSAIDS) and is prescribed most frequently. Chemically it is 4-hydroxy acetanilide. It is one of the most commonly used ‘over-the-counter’ analgesics for headache, mild migraine, musculoskeletal pain, dysmenorrheal, etc. 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.

The safety and efficacy of a pharmaceutical dosage form can guaranteed when its quality is reliable. The efficacy of a pharmaceutical dosage form generally depends on their formulation properties, and manufacturing methods, hence it is likely that the quality of dosage form may vary [1]. Dissolution test is one of the in vitro test usually employed to assess the quality of solid dosage form such as tablets and capsules. During the dissolution test the cumulative amount of drug that passes into solution is measured as function of time. The test thus describes the overall rate of all the processes involved in the release of drug into the bioavailable form [2]. In vitro dissolution tests can be used to guide formulation development, identify critical manufacturing variables.
Dissolution is defined as mass transfer from surface of dosage form to the bulk of solution [3]. Dissolution is of primary importance for all conventional, solid and oral dosage forms and can be the rated limiting step for the absorption of drugs administered orally especially for lipophilic drugs [4]. Two objectives in the development in in vitro dissolution test are to show (a) release of drug from tablet is as close as possible to 100% and (b) that the rate of drug release is uniform batch to batch [5].

Various brands of some dosage forms are available in the market with the common claim that they are all bioequivalent. The main objective of the present study was to conduct the comparative dissolution studies of various brands of same dosage forms to determine whether all the formulations used were equivalent or significantly different.

**MATERIALS AND METHODS**

**Materials**

Various brands of paracetamol tablets were taken and coded as A, B, C, D and E from local market. All Paracetamol tablets were of same manufacturing year and were recently manufactured.

**Dissolution studies**

**Preparation of 7.8 PH Phosphate Buffer:** It is prepared according to the Indian pharmacopoeia [6].

**Preparation of standard plot:** 100 mg of pure drug (paracetamol) was weighed and dissolved in 10 ml of methanol and diluted up to 100 ml with phosphate buffer in 100 ml volumetric flask. This was first stock solution and contains 1000 mcg/ml of drug. From first stock solution 10 ml was taken to another 100 ml volumetric flask and diluted up to the mark with phosphate buffer and contains 100mcg/ml of drug concentration. From this second stock various other concentrations were prepared like 2mcg/ml, 4mcg/ml, 6mcg/ml, 8mcg/ml, 10mcg/ml, 12mcg/ml. absorbance values of these concentrations were measured by UV double beam spectrophotometer and standard graph was plotted by taking absorbance values on Y-axis and concentration values on X-axis.

![Standard graph of paracetamol](image)

**Fig. 1 Standard graph of paracetamol**

**Procedure**

900 ml of Phosphate buffer pH 7.8 as the medium and rotating the paddle at 50 rpm for 30 min withdraw a suitable volume of the sample and filter promptly through a membrane filter disc with an average pore diameter not greater than 1.0mcm. Reject the first few ml of the filtrate and dilute a suitable volume of the filtrate with the same solvent [7].

Measure the absorbance by using UV spectrophotometer (UV 2203 Double beam spectrophotometer, Systronics) of the resulting solution at the maximum at 249nm.
RESULTS AND DISCUSSION

A dissolution study gives an idea of the amount of drug available absorption after oral administration. Drugs with poor dissolution profiles will not be available in the body system or target organ/tissues to elicit therapeutic effect. The in vitro dissolution profiles were found to be varying for each tablet but within the prescribed limit.

CONCLUSION

The tablet taken were within the prescribed range of limits but the in vitro dissolution studies showed that percentage drug release of ‘C’ was comparatively better than other paracetamol tablets used in experiments.

REFERENCES