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COMPARATIVE *IN VITRO* QUALITY EVALUATION OF SOME PARACETAMOL TABLETS, COMMERCIALLY AVAILABLE IN BANGLADESH DRUG MARKET

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Abstract:

Paracetamol is a widely used non-prescription analgesic and antipyretic medicine. It is one of the most commonly used drugs worldwide with non-prescription sales exceeding 25 thousand million doses per year in the United States of America. 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 among the commercially available tablet brands of paracetamol. To assess the quality, Seven different marketed Paracetamol 500 mg tablet were selected and in-vitro dissolution test, potency, disintegration time was carried out. Other general quality parameters of these tablets like weight variation, hardness, friability were also determined according to established protocols. All the brands comply the requirements of ''United State Pharmacopoeia'' as they showed acceptable weight variation range. Friability of all brands was less than 1%. No significant differences were founding disintegration time as they disintegrated within 5 minutes. In case of dissolution profile all brands showed better dissolution time as they released more than 60% of drug in 40 minute. The hardness of one brand was within the range 6 kg/cm^2 to 10 kg/cm^2. The limitation of the potency must be within 95-105%. All three brands meet this specification. This study suggested that most commercially available Paracetamol tablet in Bangladesh maintain the quality and comply with the USP specifications. 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.

Key words: *Paracetamol, Comparative, Quality control parameters, Evaluation, Potency, Dissolution profile*

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INTRODUCTION:

Quality control is a process that is carried out to ensure a desired level of quality in a product or service. It might include whatever actions a business deems necessary to provide for the control and verification of certain characteristics of a product or service [**1].** Most often, it involves thoroughly examining and testing the quality of products or the results of services. ISO 8402-1986 standard defines that quality is the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implicated needs **[2].**

Paracetamol or acetaminophen 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 **[3].**

It is an antipyretic, non-opioid analgesic and non-steroidal anti-inflammatory drug (NSAID), and is one of the most commonly used medications worldwide. Paracetamol was first used clinically in 1893, then avoided for more than 60 years due concerns about paracetamol induced methaemoglobinaemia **[4].** Subsequently, three separate research groups disproved the toxicity theory **[5, 6, 7]** and paracetamol was released in the United States in 1950 as an oral formulation. It is now used ubiquitously in both prescription and over-the-counter formulations with over 200 million prescriptions annually in the USA, and non-prescription sales exceeding 25 thousand million doses per year, making it the most commonly dispensed pharmaceutical in America **[8].**

This study is conducted to obtain a brief idea about physico-chemical parameters of those brands and to make a comparison in quality among the sample brands.

MATERIALS AND METHODS:

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

The marketed samples of seven brands of paracetamol 500 mg tablet were purchased at M.R.P from different Retail pharmacy at Rajshahi in Bangladesh. These tablets of seven brands were coded as T1, T2, T3, T4, T5, T6 and T7. The samples were properly checked for their physical appearance, name of manufacturer, batch number, and manufacturing date, expiry date, manufacturing license number, D.A.R. number & maximum retail price at the time of purchase.

Procedure for evaluation

Weight variation test

For each brand, 20 tablets were randomly and weighted individually using an analytical balance (TE214S, sartorius Germany). The average weights were determined using the following formula.

X= (X1+X2+X3+……+Xn)/10

Then the percentage weight deviations were determined by using the following formulas.

% of Deviation (+) = (maximum weight- average weight)/average weight ×100.

% of Deviation (-) = (minimum weight- average weight)/average weight ×100. [9]

Hardness test

10 tablets were taken randomly and hardness was measured using automatic Hardness Tester (VEEGO, INDIA). The hardness of tablets, which is the force required to break a tablet in a diametric compression force. If the tablet is too hard, it may not disintegrate in the required period of time or meet the dissolution specification, if it is too soft, it will not withstand the handling during subsequent processing such as coating or packaging and shipping operations **[9].**

Friability test

Friability test should be performed to evaluate the ability of Paracetamol tablet to withstand abrasion during packaging, handling & transporting. 20 Paracetamol tablets were taken randomly & weighted together. Paracetamol tablets were then placed into the Roche friabilator & subjected to 100 rpm for 1 minute at Paracetamol tablets were re-weighted. This loss of weight indicates the friability of Paracetamol tablet. Finally the percent of weight of loss was calculated by following way **[9]**

$$\text{Loss of \% of Weight loss} = \frac{(\text{Initialweight} - \text{Finalweight}) * 100}{\text{Initialweight}}$$

Disintegration Test

Disintegration test is performed to find out that within how much time the Paracetamol tablet disintegrates. Disintegration test is very important for all coated & uncoated tablet because the dissolution rate of drug depends on the disintegration time, which ultimately affect the rate of absorption of drug. About 900ml buffer solution was taken in both 1000 ml beaker & then these beakers were placed into the

device. One Paracetamol tablet was placed in each tube of basket rack & a plastic disk was placed over each tablet & then the basket rack was accurately positioned into the beaker. The temperature was maintained as 37^0C i.e. body temperature. The time at which all the Paracetamol tablets passed through the sieve was the disintegration time & the average disintegration time were calculated**. [10]**

Potency Test

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. **[11]**

Dissolution test

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°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. **[12]**

RESULT AND DISCUSSION:

Weight variation determination

Tablet weight is mainly affected by factors such as tooling of the compression machine, head pressure, machine speed and flow properties of the powder. Inconsistent powder or granulate density and particle size distribution are common sources of weight variation during compression. The tablets of seven brands undergo this test to assure their uniformity of weight and tablet to tablet variability in weight, which should be within the limits of percentage deviation according to the USP specifications.

Table 1: weight variation profile of tested tablet

Sample	Average weight variation
T1	0.70 %
T2	1.5%
T3	1.56%
T4	1.25%
T5	1.8%
T6	2.3%
T7	0.95%

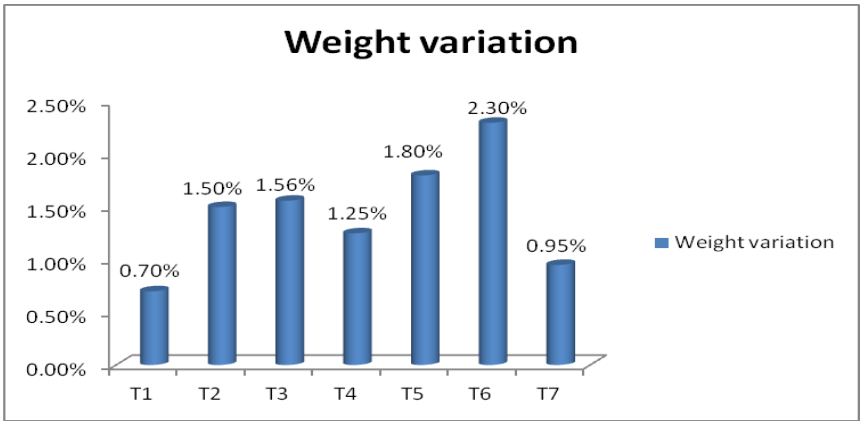

Fig. 1: Average weight variation of seven brands of Paracetamol tablet.

Table 2: Hardness profile of tested tablet

Sample	Average hardness (kg/cm^2)
T1	7.9
T2	6.48
T3	8.9
T4	8.8
T5	9.45
T6	9.85
T7	9.6

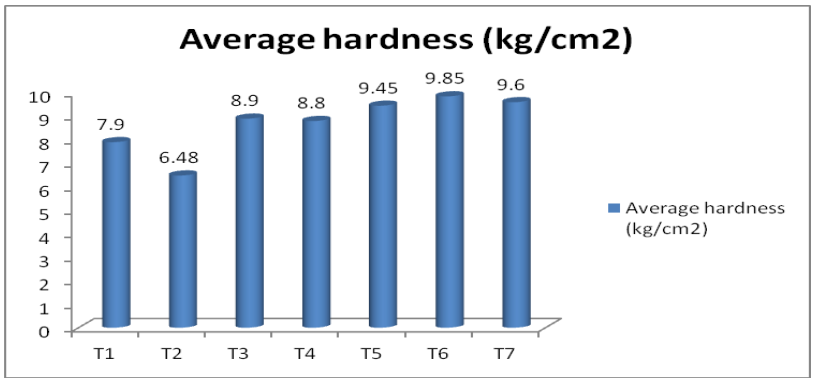

Fig. 2: Average hardness of seven brands of Paracetamol tablet

Hardness:

Hardness is the second most important physical feature for assessing tablet. In the study, it was found that all seven brands of paracetamol group passed the test of tablet crushing strength or hardness. All these brands have acceptable crushing strength of between 6 kg/cm^2 to 10 kg/cm^2.

Friability test

It is the tendency for a tablet to chip, crumble or break following compression. This tendency is normally confined to uncoated tablets and surfaces during handling or subsequent storage. The USP specification for friability test is less than 1%. It was monitored that seven different brand of Paracetamol tablets were in accordance with USP guideline.

Table 3: Friability profile of tested tablet

Sample	Friability
T1	0.586%
T2	0.509%
T3	0.39%
T4	0.13%
T5	0.61%
T6	0.14%
T7	0.12%

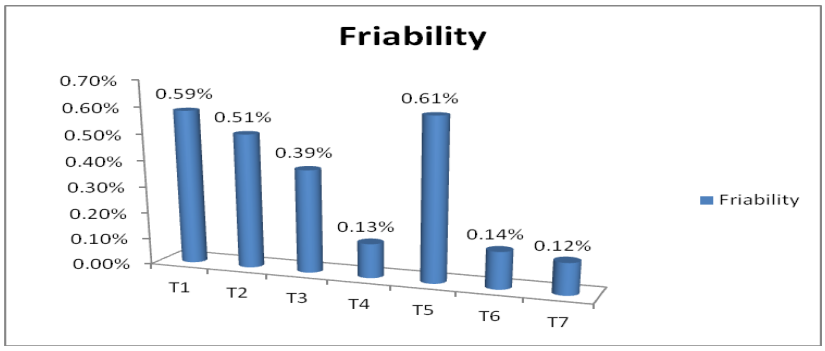

Fig. 3: % Friability of seven different brands of Paracetamol tablets

Table 4: Disintegrating time profile of tested tablet

Sample	Disintegrating time
T1	53 sec
T2	1 min 32 sec
T3	1 min 17 sec
T4	58 sec
T5	2 min 25 sec
T6	1 min 50 sec
T7	3 min 11 sec

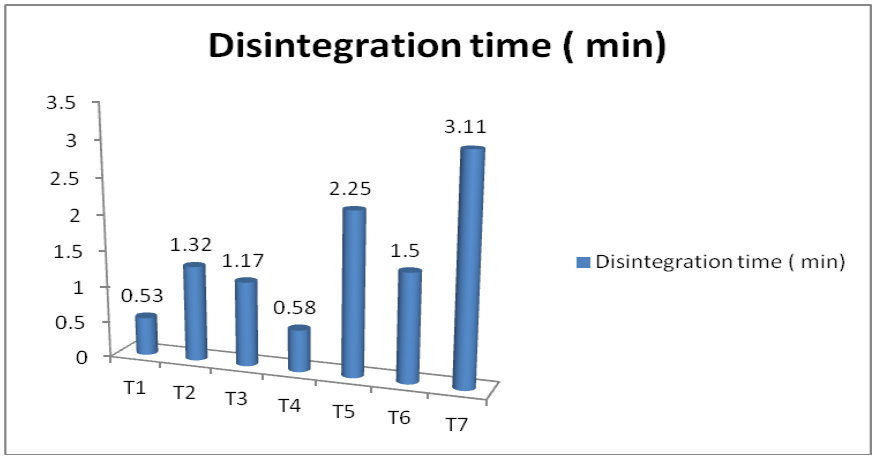

Fig. 4: Disintegration time of seven different brands of Paracetamol tablets

Disintegration Time

Disintegration tests are performed as per the pharmacopoeia standards. Disintegration is a measure of the quality of the oral dosage form like tablets and capsule pharmacopoeia like the USP, BP, IP etc. each have their own set of standards and specify disintegration tests of their own. The disintegration test is performed to find out the time it takes for a solid oral dosage form like a tablet or capsule to completely disintegrate. The time of disintegration is a measure of the quality. The disintegration time of all tablet brands of paracetamol 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 53 seconds to 3 minutes 11 seconds.

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 all tablet brands of paracetamol was 38.1% to 48.2%. Finally after 120 minutes, 82-95% drug release was observed.

Table 5: Dissolution profile of tested tablet

Sample	% DrugContent 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)
T1	34.60	48.2	56.1	72.8	79.25	94.52
T2	32.10	46.1	55.8	72.5	78.12	94.12
T3	26.60	43.60	54.93	70.96	77.51	85.69
T4	26.8	44.6	54.2	71.2	76.28	86.45
T5	22.24	40.96	50.93	65.89	71.95	83.06
T6	20.1	40.2	50.8	64.2	70.2	82.24
T7	22.8	38.1	48.8	62.25	69.14	81.92

Table 6: potency of tested tablet

Sample	Potency
T1	99.37%
T2	99.12%
T3	96.82%
T4	94.85%
T5	93.25%
T6	92.85%
T7	94.38%

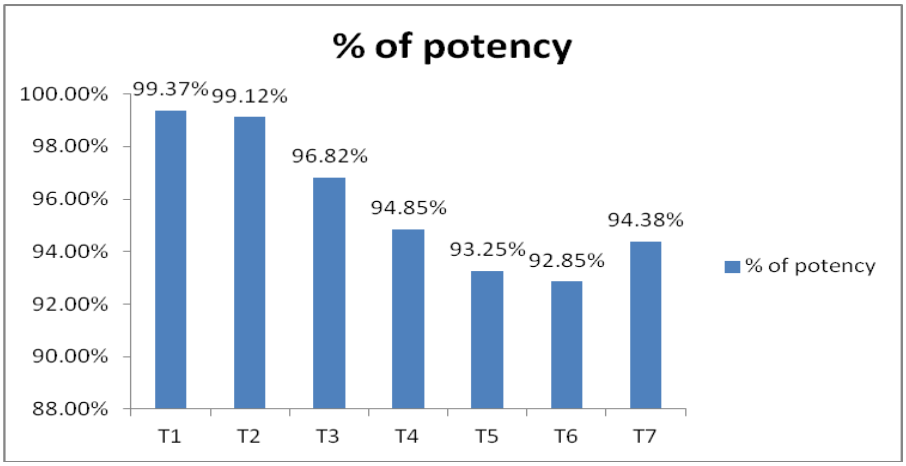

Fig. 5: Potency of seven different brands of Paracetamol tablets

Potency test

Potency of all brands was found within 92.85–99.37%.USP specification for the drugs are equivalent to not less than 95.0 percent & not more than 105.0 percent. All brands are within the limit of potency according to the USP specification.

CONCLUSION:

Paracetamol is a well established and proven analgesic and antipyretic drug. Therapeutic response of any formulation depends on its quality parameters. In this study we discussed about some quality test such as weight variation, hardness, friability, disintegration time, potency and dissolution. So the result of this quality test, which is all meets the USP specification. Paracetamol tested have uniform weight and also sufficient physical stability to maintain physical integrity over time and they will also be capable of withstanding the stiffness of mechanical shocks confrontation in its production, packaging, shipping and dispensing. From above dissolution study, our entire experimental brand meets the USP specification. 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

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