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QUALITY ASSESSMENT OF MARKETED PARACETAMOL TABLETS

Quazi Majaz Ahamad Aejazuddin *, G. J. Khan, Shirgaonkar Azim and Tajaniya Ammar

Ali Allana College of Pharmacy, Akkalkuwa, Nandurbar - 425415, Maharashtra, India.

ABSTRACT: The increasing production of cheaper and affordable generic drugs can improve the general healthcare delivery systems as well as decreasing the healthcare costs. Even though there are many generic drug brands available in the market, effective monitoring of the quality of generic drug products marketed are absent in many developing countries. This matter raises a few issues with one of it is the widespread distribution of substandard or counterfeit drug products. Substandard drug products can be defined as genuine drugs manufactured by authorized manufacturers but do not meet the quality specifications fixed for them by national standards. Also, drugs that are have three or more generic brand must be assessed and monitored to ensure its interchangeability with the innovator brand. So this study is covering the quality control tests of paracetamol tablet that are available in the local market.

Keywords: Paracetamol, Akkalkuwa, Quality assessment

Correspondence to Author:
Dr. Quazi Majaz Ahamad Aejazuddin

Ali Allana College of Pharmacy, Akkalkuwa, Nandurbar - 425415, Maharashtra, India.

E-mail: quazimajaz@gmail.com

INTRODUCTION: The increasing production of cheaper and affordable generic drugs can improve the general healthcare delivery systems as well as decreasing the healthcare costs. Even though there are many generic drug brands available in the market, effective monitoring of the quality of generic drug products marketed are absent in many developing countries. This matter raises a few issues with one of it is the widespread distribution of substandard or counterfeit drug products [1]. There are several cases that happens related to substandard and counterfeit drug products. Apart from that, a survey conducted by the World Health Organization (WHO) in 2007 found that 20 - 90% of anti-malarial and 28% of antibiotic drugs failed quality specifications.

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It is believed that substandard drugs contribute far greater threat to public health compared to counterfeit medicines. Currently, there are many kinds of literature and reports of the availability of counterfeit drugs worldwide. There are many causes and problems associated with substandard drugs such as the concentration of an active ingredient, poor quality of both excipients and active ingredients, contamination of the product, problems in packaging as well as decomposition of active ingredients [1, 2].

Thus, monitoring of generic drugs in the market is vital. WHO has issued many guidelines for global standard and requirements for the assessment, authorization, registration, marketing as well as quality assurance of the generic drug products. Monitoring marketed drugs can lessen a country's economical problem on health issues from diseases due to fraud and substandard drugs usage. Initial quality control evaluation of the generic drugs is essential, and *in-vitro* dissolution testing can be a valuable predictor of the *in-vivo* bioavailability and bioequivalence of tablet dosage forms.

Quality control methods of assessment are useful to monitor quality characteristics of various marketed brands and product consistency of batch to batch drug release. Also, drugs that have three or more generic brand must be assessed and monitored to ensure its interchangeability with the innovator brand [1, 3].

Paracetamol (an international name used in Europe) and acetaminophen (an international name used in the USA) are two official names of the same chemical compound derived from its chemical name: N-acetyl para-aminophenol[4]. It is a medicine used as a pain killer or pain relief and in case of fever treatment. Acetaminophen has weak anti-inflammatory properties and is used as a common analgesic, but may cause liver, blood cell, and kidney damage.

Key application markets for paracetamol include pharmaceuticals, dye industry, and chemical industry. Pharmaceutical was the largest application market for acetaminophen in 2014, which accounted for more than 86% share of global consumption in 2014. Rising need for medicines for pain relief and increasing health awareness are the major driving factor for the pharmaceuticals market. The increasing dominance of diseases and disorders such as swine flu, cold, fever, and arthritis and therefore need for quick pain relief, and rising demand for generic drugs is expanding the paracetamol market [5]. So this study is covering the quality control tests of paracetamol tablet that are available in the local market.

METHODOLOGY:

Collection of Sample: Different brands of paracetamol tablets with a label claim of 500 mg were collected from Akkalkuwa, Dist: Nandurbar.

General Appearance: The general appearance of tablets was determined with its shape, color, odor, taste, surface texture

Thickness and Diameter: Tablet thickness should be within a ± 5% variation of standard value. Any variation in thickness within a particular lot of tablets or between manufacturer's lots should not be clear to the unaided eye for consumer acceptance of the product. Also, the thickness should be controlled to smooth the progress of packaging. Thickness and diameter of randomly selected samples were measured using vernier calliper [6].

Hardness: The hardness of the tablet is important for drug products that have bioavailability problem or that are sensitive to altered dissolution release profiles as a function of the compressive force employed. Tablet hardness is the force necessary to break the tablet diametrically. Hardness is sometimes termed the tablet crushing strength. Tablet was placed vertically in between the jaws of hardness tester and then pressed until the tablet breaks. Reading was noted and expressed in terms of kg/cm^2. [6]

Friability: It is a measure of tablet strength. For conventionally compressed tablets, the limit is 0.5% to 1% of their weight; the chewable tablet has high friability values. When capping is observed on friability testing, the tablet should not be considered for commercials use. Friability of each formulation was measured using a Roche friabilator test apparatus. Ten pre-weighed tablets were rotated at 25 rpm for 4 min, the tablets were then re-weighed, and the percentage of weight loss was calculated [7].

$$\% \text{ Friability} = (W_0\text{-}W/ W_0) \times 100$$

Where, W_0 and W is the initial weight of tablets and the final weight of tablets, respectively.

Weight Variation Test: The weight variation test would be a satisfactory method for determining drug content uniformity of drug distribution. The weight variation test was done by weighing 20 tablets individually, calculating the average weight, and comparing the individual tablet weight to the average [7].

Disintegration Test: Disintegration is the state in which no residue of the unit under test is leftover on the screen or, if a residue remains, it consists of disintegrated parts of tablets parts such as insoluble coating of tablets or capsule shell, or any melted fatty substance from pessary or suppository. The fragmentation of a tablet into small fragments or granules is called disintegration. The first step to form a solution of the drug is disintegration. The disintegration time (DT) of the tablets was measured using a basket type disintegration test apparatus. The endpoint of the test is indicated when the tablets have passed through the screen [7].

Content Uniformity: Paracetamol tablets were weighed individually and powdered. Powdered paracetamol tablet materials equivalent to 0.15 gm of paracetamol was taken with 50 ml of 0.1 M NaOH in 250 ml volumetric flask, and the volume was made with water. The flask is well shaken, and the solution was filtered. 10 ml of filtrate was diluted to 100 ml by water. To 100 ml of the resulting solution, 10 ml of 0.1 M NaOH was added diluted to 50 ml with water and mixed thoroughly by shaking. The absorbance of the resulting solution was measured against a blank at 257 nm [7].

TABLE 1: LIST OF PARACETAMOL TABLET COLLECTED

S. no.	Brand Name	Manufacturer	Ingredient
1	Calpol	Glaxo Smith Kline Pharma Ltd	F1
2	T-98	Mankind Pharma Ltd	F2
3	Pacimol	Ipca Laboratories Ltd	F3
4	Caremol	Carezone Healthcare	F4

RESULTS AND DISCUSSION: All formulations are found to be tasteless and odorless with buff white color and disc shape with a smooth texture and do not shows capping, lamination, picking, sticking and molting, *etc*. Hardness was found to be 11.33 ± 00.57, 9.33 ± 00.57, 9.33 ± 00.57 and 7.66 ± 00.57 kg/cm2 for F1, F2, F3, and F4 respectively which indicated that the hardness of all the formulations was almost uniform and possessed good mechanical strength. The friability was found to be 0.11 ± 00.01, 0.12 ± 00.02, 0.14 ± 00.01 and 0.13 ± 00.01 % w/w for F1, F2, F3, and F4 respectively which is in standard range as per Indian Pharmacopoeia (<1%). Hence, all formulations possess good mechanical strength. The average weight of tablets was found to be 631.40 ± 03.05, 583.50 ± 02.57, 599.00 ± 02.21 and 557.50 ± 03.47 for F1, F2, F3, and F4 respectively which indicate that all formulations have weight variation less than 10% which is within the limit of Indian Pharmacopoeia (± 10 %).

The disintegration time in 0.1 N HCl using basket type disintegration test apparatus was found to be 9.67 ± 00.17, 11.42 ± 00.35, 13.83 ± 00.17 and 12.96 ± 00.28 min for F1, F2, F3, and F4 respectively which is less than 30 min. Hence all formulation complies disintegration test as per Indian Pharmacopoeia. The drug content was found to be 98.76 ± 00.23, 97.63 ± 01.21, 95.31 ± 00.73 and 92.39 ± 00.38 for F1, F2, F3, and F4 respectively which is within range for tablets more than 500 mg specified in Indian Pharmacopoeia (± 5 %). The Standard error mean for all formulation is also very small, which indicate the uniform distribution of the drug into all formulations.

TABLE 2: ORGANOLEPTIC EVALUATION OF PARACETAMOL TABLETS

S. no.	Parameter	F1	F2	F3	F4
1	Color	Buff white	Buff white	Buff white	Buff white
2	Odor	None	None	None	None
3	Taste	None	None	None	None
4	Shape	Disc Shape	Disc Shape	Disc Shape	Disc Shape
5	Texture	Smooth	Smooth	Smooth	Smooth
6	Thickness	4	4	4	4
7	Size (Diameter)	13	13	13	13
8	Hardness	11.33 ± 00.57	9.33 ± 00.57	9.33 ± 00.57	7.66 ± 00.57
9	Friability	0.11 ± 00.01	0.12 ± 00.02	0.14 ± 00.01	0.13 ± 00.01
10	Average wt (mg)	631.40 ± 03.05	583.50 ± 02.57	599.00 ± 02.21	557.50 ± 03.47
11	Disintegration time	09.67 ± 00.17	11.42 ± 00.35	13.83 ± 00.17	12.96 ± 00.28
12	Content uniformity	98.76 ± 00.23	97.63 ± 01.21	95.31 ± 00.73	92.39 ± 00.38

CONCLUSION: Paracetamol is a prescription drug. Hence, it is essential that it is manufactured following Good Manufacturing Practice (GMP). In this study, it was observed that all the formulation complied with the specification. The results meet with the specification of IP, which is required for therapeutic efficacy. It is also important that the tablets meet all the parameters because all are essential. If the hardness is increased, then the disintegration rate will increase, and this will affect

the dissolution profile. It is also necessary that the drugs disintegrate properly because this will influence the dissolution profile. Pharmaceutical equivalence can also be determined from these tests. According to my knowledge, not much work has been done to determine the quality control parameters of generic paracetamol tablet available in the market. So further study needs to be conducted regarding the quality control parameters because paracetamol, is widely used by people and it is necessary that the product is of good and acceptable quality.

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CONFLICT OF INTEREST: Nil

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