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COMPARATIVE STUDIES OF DIFFERENT MARKETED BRANDS OF PARACETAMOL: AN OVERVIEW

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ABSTRACT

Paracetamol is an analgesic and antipyretic drug which are generally used in reducing fever and relief in pain. Paracetamol are easily available in medical shops, because it is without prescription drugs. In this time all the pharmaceutical companies produce various brands of paracetamol tablets by various technique and manufacturing process. The aim of the study is to compare and evaluate different brands of paracetamol tablets of 500mg. In this study we selected four different brands of paracetamol tablets 500mg from local markets and check their quality control parameters like weight variation, hardness, friability, disintegration and dissolution test. We found that all the test results of different brands of paracetamol tablets are obtained within acceptable limits, weight variation for all four different brands of paracetamol tablets within ±5% of their average weight and friability is not more than 1%, disintegration time for all paracetamol tablet within 15 minutes, percentage release of all brands of paracetamol tablets was found not less than 85% according IP specification limit within 30 minutes. Therefore, we concluded that all the tablets of paracetamol of different brands are safe and effective for use except the pricing.

KEYWORDS: Paracetamol, analgesic and antipyretic, quality control.

INTRODUCTION

Two official names of the same chemical compound derived from its chemical name are paracetamol (an international name used in Europe) and acetaminophen (an international name used in the USA): N-acetyl-par aminophenol. Paracetamol (acetaminophen) has one of the most commonly used non-prescription medications in the world, from cradle to grave. It's available and it's cheap. Paracetamol is tolerated better than non-steroidal anti-inflammatory drugs (NSAIDs), but it may be less effective.[1] World Health Organization has an established guideline which addresses issues relating to drug stability with special focus on countries in the tropical climate zones [Zones III (hot and dry) and IV (hot and humid) according to W.H.O. classification] where drug stability constitutes a serious threat to drug product stability. This is why drug stability test is a necessary procedure for registration of new drug substances and products during development as outlined by W.H.O.[2] Evaluations of different parameters like, hardness, friability, weight variation, disintegration time dissolution profile were performed. Therapeutic effectiveness and bioavailability of tablet depends on these parameters. Depending on these facts the present study was conducted to compare the quality standards of different commercially available paracetamol 500 mg tablets.[3]

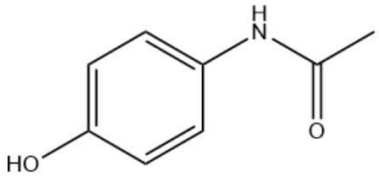

Figure 1: Chemical structure of N-(4- hydroxyphenyl) acetamide (acetaminophen, C8H9NO2).

A UV-Visible spectrophotometer is proven as a fundamental tool for many pharmaceutical drug analyses. This is due to its wide utilization in the identification, quantification, and purity measurement of the Active Pharmaceutical Product (API) in the raw materials, manufacturing processes, and final formulation.[4] Paracetamol or acetaminophen is a common analgesic and antipyretic drug used for the solace of fever, headaches and other minor aches. It is a highly recommended medicine for several types of flu, cold and body pains. It is very applicable and secure drug for living being in adequate quantity but deliberate or accidental overdose is often observed due to its wide availability. It is also a commonly used analgesic compound combined with centrally acting compounds such as caffeine, codeine and dextropropoxyphene as well as with oral decongestants in a variety of formulations for the relief of the symptoms of common

cold, influenza and sinusitis. Besides headaches, minor aches and pains, it is also used in combination with opioids analgesics to control severe pains such as episiotomy pain, post-surgical pain and cancer pain.[5] Disintegration is the breakdown process of tablet into smaller particles and is the first step towards the dissolution. Hardness effect disintegration of tablet. It depends upon the presence of disintegrate. The hardness of tablet, binders, lubricant effect the disintegration time. Faster disintegration of tablets delivers a fine suspension of drug particles resulting in a higher surface area and faster dissolution. In 2012, comparative study of four different brands of acetaminophen was also conducted and concluded that all four-brand varying with each other but they all comply within the limit.[6] The distribution of paracetamol in the body fluid is uniform; apparent volume of distribution of paracetamol is 1 to 1.2 L/Lg. Excretion of paracetamol is observed in breast milk as it can cross the placental layer. Plasma protein binding depends upon the concentration of paracetamol, it is negligible at therapeutic concentration, however, as the concentration increases, plasma binding protein increases. Paracetamol is used for analgesia and antipyretics; its anti-inflammatory and antirheumatic activities are not sufficient to declare it as drug of choice for inflammation and rheumatic disorders.[7] It is better tolerated than aspirin in patients in whom excessive gastric acid secretion or prolongation of bleeding time may be a concern. 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.[8] Paracetamol has few anti-inflammatory effects in comparison to NSAIDs. However, aspirin, paracetamol and other NSAIDs all act by the same mechanism (inhibition of prostaglandin synthesis by inhibiting cyclooxygenase (COX)) and all show varying levels of analgesic, anti-inflammatory, antipyretic and antiplatelet actions.[9] Paracetamol is rapidly absorbed and peak serum levels usually occur 30 minutes to 2 hours after ingestion. Elimination from the body is also quick having half-life of about two hours. Paracetamol is soluble in water, alcohol, acetone, glycerol, chloroform and in solutions of alkali hydroxides. It is stable in a saturated aqueous solution having a pH of about 6 but stability decreases in acid or alkaline conditions, the paracetamol being slowly broken down into acetic acid and p-aminophenol.[10]

Evaluation Tests

Weight variation test

For each brand, 10 tablets were taken and weighed individually using the electronic weighing balance. The average weight of all the tablets was calculated and considered as the standard weight of the individual tablet. Then all the tablets were individually weighed and the percentage weight variation was calculated to determine whether the individual weight is within the range or not. The tablets meet the USP/BP test if not more than two tablets are outside the percentage limit and if no tablet differ by more than twice the percentage limit.[12]

Table 1: Weight variation limits according IP/BP.[8]

IP/BP	LIMITS
80 mg or less	±10%
More than 80 mg or less than 250mg	±7.5%
250mg or more	±5%

Hardness Test

This test was performed with twenty tablets (one tablet from each of the brands under research), the crushing strength was determined and the average was calculated using collected data. We placed every time, one tablet vertically in the hardness tester and the load applied in their radial ax, and then we noted the weight and load required to break the tablet. This operation was repeated all the time that required for each brand tablet.[13]

Thickness

During testing, thickness of ten tablets from each brand were determined by using Vernier Caliper. Place each tablet one by one in the Jaw and note the thickness reading in mm.[14]

Friability test

Friability test is essential to evaluate the ability of a tablet to withstand abrasion in packing, handling and transporting. In the study, it was determined using Electro lab EF-2 Friabilator (USP). The value of friability was expressed in percentage (%). Ten tablets for each brand were initially weighed and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes (up to 100 revolutions). The tablets were weighed again and the percent (%) friability was then calculated by using following formula (Kalakuntla et al., 2010). Generally, the considerable range of weight loss of conventional compressed tablet is less than 0.5 to 1%.[15]

$$\%\ Friability = \frac{\text{Weight before test} - \text{Weight after test}}{\text{Weight before test}} \times 100$$

Disintegration Test

At first, the disintegration tester was assembled. Then 900ml distilled water was placed in each 1000ml beaker (N.B: The volume of the liquid was such that when the assembly is in the highest position the wire mesh was at least 15mm below the surface of the liquid and when the assembly was in the lowest position the wire mesh was at least 25 mm above the bottom of the beaker and the upper open ends of the tubes remain above the surface of the liquid). The temperature was maintained at 37oC. Then one tablet was placed in each of the 6tubes and the apparatus was operated for the prescribed period. All the tablets must disintegrate within the prescribed time. If 1 or 2 tablets fail to disintegrate completely, the test must be repeated on 12 additional tablets.[16]

Dissolution Test

For this test USP Type-1 (Basket) 6 Paddle Apparatus was used. 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 ± 0.2oC. The basket was rotated at a speed of 150 rpm. After an interval of every 10 minutes, 2 ml. of the medium was pipette out and replaced with fresh medium (0.1N HCl). This was continued all along for one hour. 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. Spectroscopy at λ max 222 nm. According to USP specifications not less than 80% (Q) of the labelled amount of acetaminophen is dissolved within 30 minutes.[17]

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