

EVALUATION OF TABLETS BY FRIABILITY APPARATUS

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ABSTRACT

Tablet design and post-formulation quality monitoring requires quantitative evaluations and assessments of tablet's chemical, physical and bioavailability properties. The tablets were subjected to various post-production tests such as hardness, friability and dissolution rate following standard pharmacopeia such as USP, BP and Indian pharmacopeia procedures. In this we study definitions, instrument of friability and acceptance criteria. The purpose of this article was to study detailed information about friability test along with apparatus which were compiling with standard specifications.

Keywords: Tablets, Hardness, Friability, Abrasion Drum.

INTRODUCTION

Friability (the condition of being Friable) testing is a method, which is employed to determine physical strength of compressed and uncoated tablets upon exposure to mechanical shock and attrition. In simple words, friability test tells how much mechanical stress tablets are able to withstand during their manufacturing, distribution and handling by the customer. Throughout pharmaceutical industry, friability testing has become an accepted technology and the instrument used in to perform this process is called Friabilator or Friability Tester.

The mechanical strength of tablet or granules can be determined by its hardness and through friability test. The strength of a tablet plays a very important role in its marketing and dissolution.

DEFINITIONS¹

Tablets: Tablets are solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volumes of particles. Tablets are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are

retained in the mouth where the active substance is liberated.

Un Coated Tablets: These are a single layer or more than one layer tablet consisting of active ingredient with the excipients, no additional cover is applied on to it after the compression. It means they are core tablets.

Chewable Tablets: Disintegrate rapidly when chewed for patients with swallowing difficulty (children, elderly) and when there is no access to water. Most commonly used for multiple vitamins and antacids.

Effervescent Tablets: In addition to the active, this product form contains sodium bicarbonate and citric acid. When water is added the ensuing chemical reaction forms carbon dioxide, which acts as a disintegrate and produces effervescence that hastens dissolution (antacids).



Effervescent tablets



Chewable tablets



Uncoated Tablets



Single drum friability apparatus



Coated Tablets



Double drum friability apparatus

PURPOSE OF THE TEST

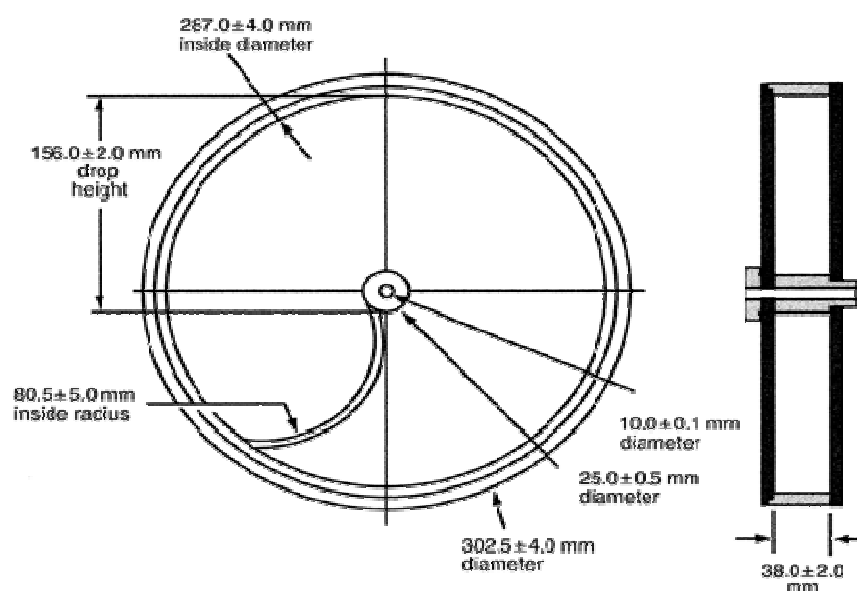
This test is a method to determine physical strength of uncoated tablets upon exposure to mechanical shock and attrition.

APPARATUS DISCRIMINATION²

This instrument consists of a plastic chamber for placing the tablets which is attached to a horizontal axis. The drum has an inside diameter of 283 to 291 mm USP and is about 36 to 40 mm USP in depth, made of a transparent synthetic polymer with polished internal surface.

A set of pre weighed tablets [if one tablet weigh 650 mg or less then approx 6.5 g of total weight should be taken and for more than 650 mg/tablet weight, 10 tablets should be taken] (3) are

placed in the plastic chamber revolving at 24-25 rpm for 4 min (100 times) USP. The tablets are subjected to combined effects of abrasion and shock. The tablets are dropped at a distance of six inches on each revolution. The tablets are tumbled at each turn of the drum by a curved projection with an inside radius between 75.5 to 85.5 mm (USP) that extends from the middle of the drum to the outer wall. If the tablet size or shape becomes irregular (diameter of tablets is greater than 13 mm) adjust the drum so that base forms an angle of about 10 degrees with bench top and the tablets fall freely when drum is rotated.



ACCEPTANCE CRITERIA²

Conventional compressed tablets that lose less than 0.5% to 1% of weight are considered acceptable.

Generally the test is run once. If obviously cracked cleaved or broken tablets present in the tablet sample after thumbing, the sample fails the test. If the results are doubtful or if the weight loss is greater than the targeted value, the test should be repeated twice and mean of the three tests are determined so the result should be less than 1% of weight loss is considered acceptable for most product.

If the tablets were not reaching above criteria those tablets are considered unfit for commercial use

Special Precautions

1. In case of hygroscopic tablets a humidity-controlled environment (relative humidity less than 40%) is required for testing.
2. Most effervescent tablets and some chewable tablets undergo high friability weight loss which is an indication for the special stack packing that is required for these types of tablets.

REASONS FOR FRIABILITY TEST FAIL

1. Punches that are in poor condition or worn at their surface edges, resulting in 'whiskering' at the tablet edge and show higher than normal friability values.
2. Friability test is influenced by internal factors like the moisture content of tablet

granules and finished tablets. Moisture at low and acceptable level acts as a binder

FRIABILITY TEST FOR PELLETS

There is no standard method established for evaluating friability of pellets. The friability of pellets was determined using a rotating drum like apparatus (Roche friabilator). But due to the low weight of pellets the mechanical stress applied is less. This can be corrected by adding glass or steel balls to increase stress.

AIR STREAM METHOD FOR PELLETS³

In this method the fines were removed through sieving and approximately 8g (W (initial)) of pellets were filled in glass apparatus. The apparatus was closed using a sieve lid and the pellets were subjected to air stream. After 16 min the pellets were removed and reweighed (W (Final)). Each batch was tested 3 times. The friability was calculated as percentage weight loss according to the equation:

$$F = \frac{W(\text{initial}) - W(\text{Final})}{W(\text{initial})} \times 100$$

A MODIFIED USP FRIABILITY TESTER WAS AN ABRASION DRUM⁴

This drum can generate two different types of motion depending on how the abrasion drum is mounted to the friabilator arm.

One motion generates cascading movement from one lamella to other, while the other motion raises and drops the spheres from a distance approx 200mm.

This method was made more effective by adding 1mm glass beads to the pellets in order to increase stress level on pellets (Generally 10g of pellets and 25g of glass sphere are taken and rotated for 25rpm for 10 min).

FRIABILITY TEST IS REQUIRED FOR TABLETS EVEN AFTER COMPLETING THE HARDNESS TEST BECAUSE

Measuring the hardness of a tablet is not a reliable indicator for tablet strength as some formulations when compressed into very hard tablets tend to 'cap' or lose their crown portions on attrition. Such tablets tend to powder, chip and fragment. The friability test is closely related to tablet hardness and is designed to evaluate

the ability of the tablet to withstand abrasion in packaging, handling and shipping.

Following different models for friability apparatus

The commonly used friabilator in laboratories is the Roche friabilator

COMAPANY: PANOMEX INC.

Model: PX/FTA-201 – Two drums

Model PX/FTA-202 - One drum

COMAPANY: Atlas Brand

Model: AF-2000 2 Drum

Model: AF-1000 1 Drum

And other manufacturing companies are Copley Scientific Friabilator, Distek DF-3 Automated Friabilator and veego friability test apparatus

The study was carried on friability test requirement, its apparatus along with acceptance criteria.

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