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Significance of Friability and Evaluation of Different Type of Tablet's For Abrasion in Packaging, Handling and Shipping

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ABSTRACT
Considering the different types of tablet and their effect on transportation study, this study was performed to analyze the friability of seven different types of tablets collected from market. A transport route profiling study is a technical study that collects temperature data to accurately represent how a product is distributed. The study's purpose is to qualify a shipping system based on how well it performs in a specific operational context. To support the transportation study of tablets friability evaluation is very important. During the transportation or shipment from one place to another place there is a chance to breakage of tablets. 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, friability apparatus and acceptance criteria along with the seven different marketed tablet (Table:1) evaluations for friability.

Keywords: Tablets, Hardness, Friability test, Fribilator

I. INRODUCTION

Friability test to support the successful transportation/shipment of tablets. Friability is the tendency of a tablet to chip, crumble, or break, and it can occur for a number of reasons, including:

Poor tablet design

Sharp edges, low moisture content, or insufficient binders can cause tablets to be weak and more prone to breaking

Mechanical shock

Tablets can experience mechanical shock during handling, packaging, and transportation

Extreme temperatures and humidity

Exposure to these conditions during storage and transportation can negatively impact a tablet's friability

Friability is an important consideration in the pharmaceutical industry because it can affect the quality of a tablet and the dose a patient receives. Tablets need to be hard enough to maintain their structure during storage and shipping, but also friable enough to break down in the gastrointestinal tract and release the active ingredients.

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.

DEFINITIONS[1]

Tablets: Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. 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 excipents, 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).

Single drum friability apparatus

Double drum friability apparatus

Coated tab. Chewable Tab. Effervescent Tab. Uncoated Tab. Bilayer Tab. Sublingual Tab.

SIGNIFICANCE OF FRIABILITY TEST

This test is a method to determine physical strength of uncoated tablets upon exposure to mechanical shock, attrition and to conclude the transportation study of tablets. The friability test ensures that tablets can withstand forces during: Manufacturing, Distribution, and Handling by customers.

II. METHODOLOGY:

The friability procedure for tablets as per the USP (United States Pharmacopeia) involves:

Preparing the sample:

- Ensure the tablets are uniform in size and weight
- Store the tablets under the same conditions
- Accurately weigh the sample

Placing the sample in the friabilator:

- Place the tablets in the friabilator's rotating drum
- Ensure the drum is level and rotating smoothly

Running the test:

- Rotate the drum at 25 revolutions per minute (rpm) for a minimum of 4 minutes (100 revolutions)

Weighing the sample again:

- Remove any loose dust from the tablets
- Accurately weigh the tablets again

Calculating the weight loss:

- Calculate the weight loss as a percentage of the original sample weight

Checking the results:

- A maximum weight loss of 1% or less is

generally considered acceptable.

- If the results are doubtful or the weight loss is greater than the targeted value, repeat the test twice and calculate the mean
- If the sample contains obviously cracked, cleaved, or broken tablets, the sample fails the test

To calculate the friability of a tablet follows below formula.

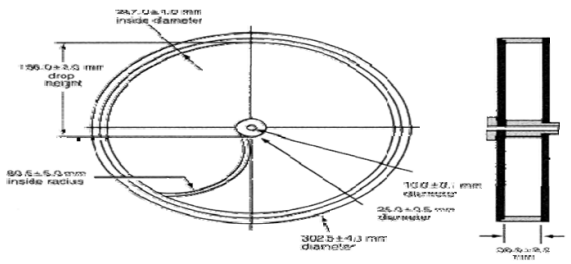
$F=(W1-W2)\times100\div W1$

Where W1 is initial weight of tablet, W2 is final weight of tablet.

APPARATUS DISCRIMINATION[2]

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 291mm 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 650mg or less then approx 6.5g of total weight should be taken and for more than 650mg/tablet weight,10 tablets should be taken](3) are placed in the plastic chamber revolving at 24-25rpm for 4 min (100times) 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 13mm) 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.

Figure1: Fribilator description.



ACCEPTANCE CRITERIA[2]

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.

Precautions during performing friability test:

- **Cleanliness:** Ensure the apparatus and sample holder are clean & free of dust before starting the test.
- **Calibration**: Regularly calibrate the machine to maintain accuracy.
- **Temperature and humidity:** Conduct the test in a controlled environment to avoid variations in tablet behavior.
- **Drum base angle:** Adjust the drum base to 10° to prevent irregular tumbling.
- **Tablet condition:** Remove any cracked, cleaved, or broken tablets from the sample before testing.
- **Weight:** Accurately weigh the tablet sample.
- **Repeat test:** If the results are difficult to interpret or the weight loss is greater than the targeted value, repeat the test twice and determine the mean of the three tests.
- **Electrical safety:** Use a three-wire outlet with a ground connection that is rated for the load. Make sure the operating voltage is correctly set for the outlet.
- **Punches:** Use punches that are not worn or in poor condition.
- In case of hygroscopic tablets a humidity-controlled environment (relative humidity less than 40%) is required for testing.
- 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.

Friability testing is often required by regulatory bodies like the FDA and EMA to ensure compliance with quality control standards.

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 PELLETS[3]

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= {W(initial)–W (Final)/ W(initial)}*100

A MODIFIED USP FRIABILITY TESTER WAS AN ABRASION DRUM [4]

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.

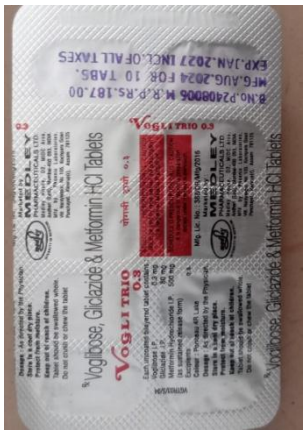
This method was made more effective by adding 1mm glass beads to the pellets in order to increase stress level on pellets (Generally 10g of pellets and 25g of glass sphere are taken and rotated for 25rpm for 10 min). For this study we collect different type of tablets from market and evaluated for friability test. details are mentioned below.

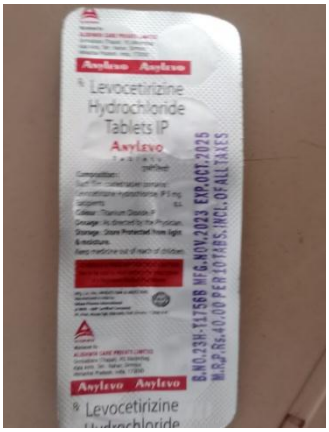
Table 1: Marketed Sample details.

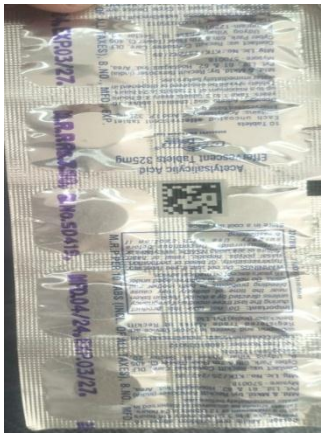
Types of Tablet	Brand	Code
Uncoated	CALPOL 500	Sample A
Uncoated	SARIDON	Sample B
Coated	PROXIDIL D	Sample C
Bilayered	VOGLI TRIO 0.3	Sample D
Effervescent	DISPRIN	Sample E
Uncoated	AXYLEVO	Sample F
Sublingual	SORBITRATE	Sample G

Figure 2: Visual appearance of Samples.

Figure 3: Intact pack of purchased Samples from market.







Sampling methodology:
The number of tablets used in a friability test depends on the unit weight of the tablets:

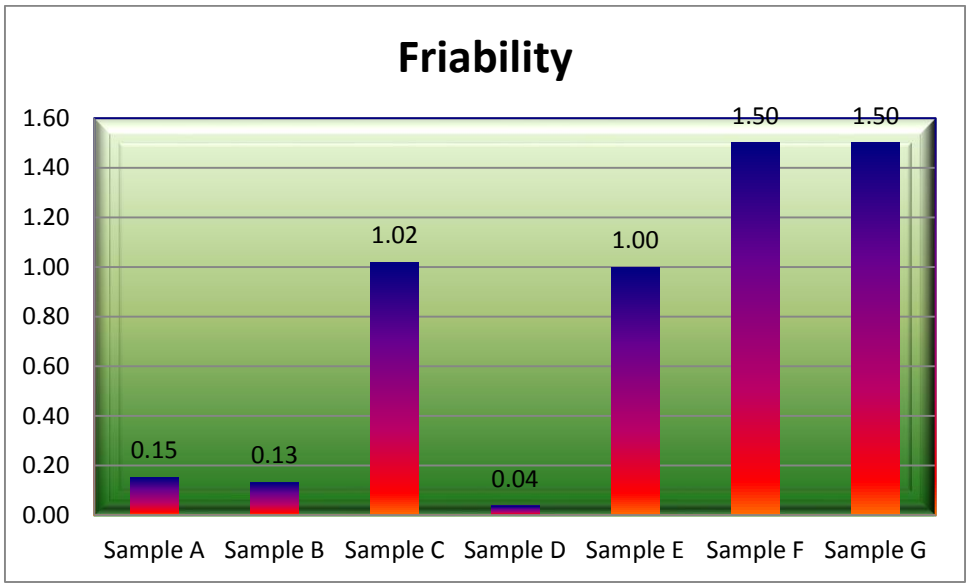
- 6.5 g: If the unit weight of the tablet is equal to or less than 650 mg, use a sample of whole tablets that corresponds to 6.5 g
- 10 tablets: If the unit weight of the tablet is more than 650 mg, use 10 whole tablets

Table 2: Weight of samples.

Sample-A		Sample-B	Sample-C	Sample-D	Sample-E	Sample-F	Sample-G
S.No.	Weight of tablet	Weight of tablet	Weight of tablet	Weight of tablet	Weight of tablet	Weight of tablet	Weight of tablet
1	660.1	660.1	890.1	550	520.1	200.1	80.2
2	667.3	667.3	889.2	551	521.4	210.2	80.3
3	660.9	668.9	889.3	550	520.1	200.3	80.4
4	667.3	667.3	887.4	551	520.5	203.7	80.3
5	668.5	668.5	888.5	550	521.5	203.8	80.2
6	668.5	668.8	888.6	551	521.5	203.9	80.1
7	668.5	668.8	887.7	550	521.5	204.0	80.1
8	670.9	670.9	885.8	551	520.5	204.1	80.1
9	670	670	887.9	550	520.5	204.2	80
10	668.2	668.2	888.9	551	520.5	204.3	80

Avg. weight of tablet	667.02	667.88	881.10	550.5	520.8	203.9	80.17
Initial weight of 10tablet's W1(gm)	6.67	6.68	8.88	6607*	6769.1**	6559.5***	6560.4****
Final weight of tablet's W2(gm)	6.66	6.67	8.88	6607	6700	6521	6500
Fribility (%)	0.15	0.13	0.04	0.00	1.02	0.59	0.92

*, indicate total weight of 12 tablet, **13 tablet, ***32 tablet, ****82 tablet of sample D, E, F & G respectively.



III. RESULT & DISCUSSION:

After collection of samples from market (Table:1), study was performed with Sample's coded as sample A, sample B, sample C, sample D, sample E, sample F & sample G. Friability of all samples checked & found within the specification limit however comparison data show the sample C, F & G is more sensitive to friability as compared to other sample. Type of Sample C, F & G is belong to Effervescent, Uncoated, Sublingual types of tablet respectively.

IV. CONCLUSION:

There may be several reason to failure of friability test. 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. 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. However during this experimentation slightly variation was observed in Effervescent, Uncoated, Sublingual tablet. Rest of all the samples found within the acceptance criteria. 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.

REFERENCES

[1]. http://www.new drug info.com/pharmacopeia/bp2003/British % 20 Pharmacopoeia% 20 Volume % 20III/Monographs/Formulated%20Preparations% 20 Genearal % 20 Monographs/Tablets.html.

[2]. http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1216.html.Pharmaceutical pelletization technology, 1st Ghebre-Selassic(ed.), Marceldekker, NewYork ,1989:261-265.
[3]. Pisek R, Korselj V and Vrecer F. Comparison of Direct Rotor Pelletization (Fluid Bed) and Hign Shear Pelletization Method for Pellet Production. Pharm and Biopharm. 2002;(53):327-333.
[4]. Lachman L, Lieberman H, Kanig J. The theory and practice of industrial pharmacy. Varghese publication house, 3rd edition, page-299.
[5]. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q4B_Annex_9/Step4/Q4B_Annex_9_R1_Step_4.pdf-ICHGUIDELINES
[6]. http://www.fda.gov/downloads/Drugs/Guidance Compliance Regulatory Information/ Guidance's.
[7]. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/01/WC500044297.
[8]. Pdf - European MEDICINES AGENCY.