ION LABS	Standard Operating Procedure Friability Testing	SOP Number D-705	Revision 4
		Effective Date 11/01/22	Page Page 1 of 4

Written by/ Date	Reviewed by/ Date	Approved by/ Date
09/30/22	10/03/22	10/03/22
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1.0 Purpose

The purpose of this procedure is to give instruction on how to perform tablet friability testing and where to document results.

2.0 Scope

This procedure meets the requirements of USP <1216> Tablet Friability. This procedure specifically applies to compressed, uncoated tablets. This procedure applies to all friabulators that meet the equipment configuration specifications described in section 6.1.

3.0 Responsibility

4.1 It is the responsibility of QC inspectors to follow this procedure.

4.2 It is the responsibility of QC Management to implement this procedure and to ensure that the procedure is being followed.

4.3 It is the responsibility of QC Laboratory or Analytical Development personnel to calibrate the friabulators.

4.4 It is the responsibility of QC Laboratory Management and/or Analytical Development to keep this procedure current with Ion Labs practices.

4.0 Definitions

4.1 **QC** – Quality Control

4.2 **BPR** – Batch Production Record

4.3 **RPM** – Rotations per minute

4.4 **Mm –** Millimeters

4.5 **Friability** – The tendency of a tablet to crumble, chip or break. It is an important characteristic on the tablets' ability to withstand chipping, cracking or "dusting" during the packaging operations and shipping. Measurement of tablet friability supplements other physical strength measurements, such as tablet crushing strength.

5.0 References

5.1 USP <1216> Tablet Friability

5.2 G-201, SOP, Calibration Program

6.0 Procedure

6.1 Friabulator configuration

6.1.1 Drum with an internal diameter between 283 and 291 mm and a depth between 36 and 40 mm, of transparent synthetic polymer with polished internal surfaces, and not subject to static build up.

6.1.2 Tablets are tumbled at each turn of the drum by a curved projection with an inside radius between 75.5 and 85.5 mm that extends from the middle of the drum to the outer wall.

6.1.3 The drum is attached to a horizontal shaft and rotates at a velocity of 25 RPM.

6.2 Calibration

6.2.1 The friabulator is calibrated yearly as per SOP G-201 Calibration Program to a specification of 25RPM +/- 1.

6.3 Testing Procedure

6.3.1 For tablets with a unit weight equal or less than 650mg use a sufficient quantity of tablets to meet or exceed 6.5 grams. For tablets with a unit weight of more than 650mg use 10 tablets.

6.3.1.1 The tablets should be carefully de-dusted prior to testing.

6.3.2 Accurately weight the tablet sample to the nearest 0.01g +/- 0.002.

6.3.2.1 Place the tablets in the drum.

6.3.3 Start the test cycle.

6.3.3.1 A cycle is 100 rotations at 25RPM.

6.3.4 At the end of the cycle remove the tablets from the drum.

6.3.4.1 Remove any loose dust from the tablets as before.

6.3.4.2 If obviously cracked, cleaved, or broken tablets are present in the tablet sample after the cycle, the sample automatically fails the test.

6.3.5 Accurately weigh the sample and record.

6.3.6 Calculate the % Loss using the equation:

6.3.6.1 % Loss = ((Initial weight – Final weight) / Initial weight) * 100

6.3.7 Unless otherwise stated in the product specifications a maximum weight loss of not more than 1.0% of the tablets being tested is considered acceptable for most products. Chewable tablets are not more than 5.0% unless otherwise indicated.

6.3.8 If the results are doubtful or if the weight loss is greater than the targeted value, the test should be repeated twice and the mean of the three tests determined.

6.3.9 The calculations and results are recorded in the BPR.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	Original	-	-
1	02/15/13	Reformatted and reorganized in a more readable manner, added instruction on documentation.	13-089	B. Johns
2	09/09/15	Biennial review: Added G-201 Calibration Program reference. Added equipment configuration. Updated for clarity and accuracy.	15-0566	B. Johns
3	02/04/19	Scheduled review: Changed responsibility.	19-0115	J. Maignan
4	09/30/22	Scheduled review: Updated logo and format.	CC-22-0370	K. Burris