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# 2.9.7. FRIABILITY OF UNCOATED TABLETS[(1)]

PURPOSE

This general chapter provides guidelines for the friability determination of compressed, uncoated tablets. The test procedure presented in this general chapter is generally applicable to most compressed tablets. The measurement of tablet friability supplements other physical strength tests, such as tablet breaking force.

EQUIPMENT

Use a drum, with an internal diameter of 283.0-291.0 mm and a depth of 36.0-40.0 mm, made of transparent synthetic polymer with polished internal surfaces, and subject to minimum static build-up (see Figure 2.9.7.-1). One side of the drum is removable. The tablets are tumbled at each turn of the drum by a curved projection with an inside radius of 75.5-85.5 mm that extends from the middle of the drum to the outer wall. The outer diameter of the central ring is 24.5-25.5 mm. The drum is attached to the horizontal axis of a device that rotates at 24-26 r/min. Thus, at each turn the tablets roll or slide and fall onto the drum wall or onto each other.

PROCEDURE

For tablets with a unit mass equal to or less than 650 mg, take a sample of whole tablets corresponding as near as possible to 6.5 g. For tablets with a unit mass of more than 650 mg, take a sample of 10 whole tablets. Carefully dedust the tablets prior to testing. Accurately weigh the tablet sample, and place the tablets in the drum. Rotate the drum 100 times using a speed of 24-26 r/min, and remove the tablets. Remove any loose dust from the tablets as before, and accurately weigh.

Generally, the test is run once. If obviously cracked, cleaved or broken tablets are present in the tablet sample after tumbling, the sample fails the test. If the results are difficult to interpret or if the weight loss is greater than the target value, repeat the test twice and determine the mean of the 3 tests. A mass loss from a single test or the mean of 3 tests of not more than 1.0 per cent is considered acceptable for most products. Friability specifications may typically be different for effervescent and chewable tablets.

If tablet size or shape causes irregular tumbling, adjust the drum base so that the base forms an angle of about 10° with the horizontal and the tablets no longer bind together when lying next to each other, which prevents them from falling freely.

In the case of hygroscopic tablets, an appropriate humidity-controlled environment is required during testing.

A drum with dual scooping projections, or an apparatus with more than one drum, designed to test multiple samples at the same time, are also permitted.

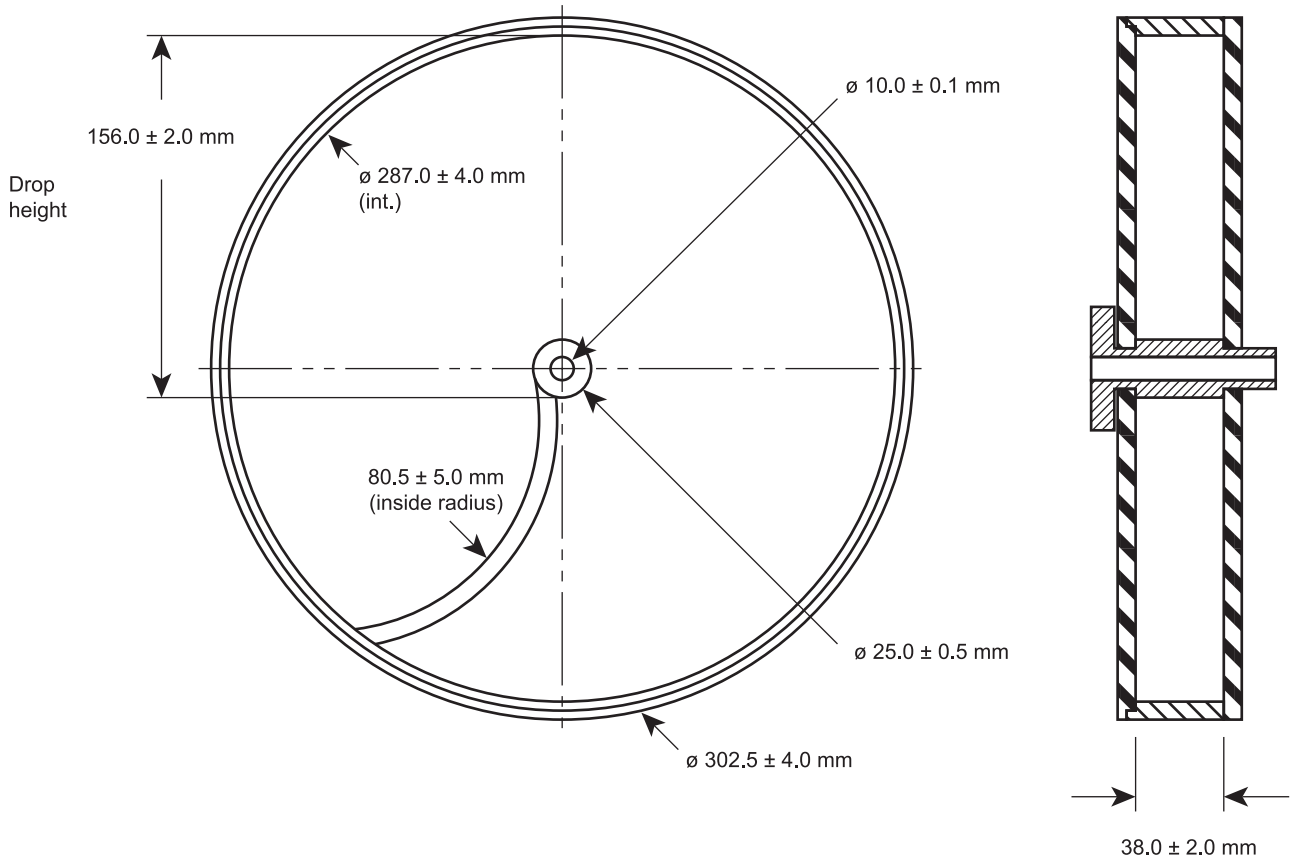


Figure 2.9.7.-1. – *Tablet friability apparatus*

(1) This chapter has undergone pharmacopoeial harmonisation. See chapter *5.8. Pharmacopoeial harmonisation.*