

Methods and Application of Food Composition Laboratory
Disintegration Checklist, May 2020

Batch ID: DIST-MA-200612-1

Test sample ID 9540807

- The instrument used is certified by the manufacturer to be capable of meeting all USP requirements for disintegration testing. ✓
- Verify that the waterbath temperature meets the USP specification of $37^{\circ} \pm 2^{\circ}\text{C}$ on each day that the instrument is used. ✓
- Verify that the instrument is operating within USP specifications for cycle frequency and distance, and that the bottom of the basket remains at least 2.5 cm from both the bottom of the immersion beaker and the surface of the immersion fluid during operation. ✓

Type (✓):

☒ Uncoated

☐ Plain-coated/Film-coated Tablet

☐ Hard shell Capsule

☐ Enteric-coated Tablet

☐ Soft shell Capsule

Applicable USP or other test procedure: ~ <701> <2040>

Disintegration Test System: Tracking #: 017615

Thermometer #: 020115

Start Media Temperature: 37.6°C (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$)

End Media Temperature: 37.4°C (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$)

Disk used: YES / NO

Tablet floated: YES / NO

Media: FDA-WP-16

Wire mesh used: YES / NO

Pre-immersion? Yes No if yes, give the time: NA min

Comments on visual observation:

In addition to the very helpful details that you've been sending us in the lab sheets (comments section), we would like this additional information:

At the end of 30 min agitation, please describe:

1. Tablet/capsule is still in one piece: YES / NO

If so, how close it is to the original size/shape?

2. If enough material remains, and it is cut open, is the content wet or dry inside?

NA

Pictures:

1. For obvious pass: a picture of the tubes after removing them from the media.
2. For possible fail: a picture of the 6 removed samples on the white paper
3. If any are cut open, a picture of this.

Disintegration Performed by: STG 12 Jun 2020

① completed verified by thermometer and VIMS STG 12 Jun 2020