

NDL Disintegration Checklist

Batch ID: DIST-MA-180305-1

Test sample ID 7020676

- 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 #: 019660

Bath Temperature: 36.9 (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114

Disk used: No

Tablet floated: No

Media: FDA-WP-09

Wire mesh used: Yes

Pre-immersion? ___ Yes X No if yes, give the time: N/A 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: Y/N
 If so, how close it is to the original size/shape?

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.

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Type (✓): ~ Uncoated
 ~ Plain-coated/Film-coated Tablet ~ Hard shell Capsule
 ~ Enteric-coated Tablet ② ~ Soft shell Capsule

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

Disintegration Test System: Tracking #: 017615

Bath Temperature: 36.2 (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114

Disk used: Yes

Tablet floated: No

Media: FDA-WP-09

Wire mesh used: Yes

Pre-immersion? X Yes ___ No if yes, give the time: 5:00 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: Y/N
If so, how close it is to the original size/shape?

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.

① Incorrect USP procedure cMR 07MAR18
② Both procedure <701> and <2040> were used for analysis. cMR 22MAR18

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- 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 #: 017615Bath Temperature: 36.2° (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114Disk used: YesTablet floated: NoMedia: FDA-W8-09Wire mesh used: YesPre-immersion? X Yes ___ No if yes, give the time: 5:00 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: Y/N
 If so, how close it is to the original size/shape?

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.

① Incorrect bath temperature, should read "36.8°" cmx 05MAR18

NDL Disintegration Checklist

Batch ID: DIST-MA-180307-2

Test sample ID 7020679

- 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
- ~ Enteric-coated Tablet

~ Hard shell Capsule

~ Soft shell Capsule

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

Disintegration Test System: Tracking #: 019659

Bath Temperature: 37.7° (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114

Disk used: Yes Tablet floated: No

Media: FDA-WP-09 Wire mesh used: yes

Pre-immersion? ☒ Yes ☐ No if yes, give the time: 5 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: Y/N

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.

NDL Disintegration Checklist

Batch ID: DIST-MA-180307-2

Test sample ID 7020680

- 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

~ Enteric-coated Tablet

~ Hard shell Capsule

~ Soft shell Capsule

Applicable USP or other test procedure: ✓ <701> ① ✓ <2040> ~ _____

Disintegration Test System: Tracking #: 019659

Bath Temperature: 37.7° (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114

Disk used: Yes

Tablet floated: No

Media: FDA-WP-09

Wire mesh used: Yes

Pre-immersion? X Yes ___ No if yes, give the time: 5 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: Y/N

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

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.

① Both procedure <701> + <2040> were used for analysis. cmk 22 Mar 18

NDL Disintegration Checklist

Batch ID: DIST-MA-180307-2

Test sample ID 7020683

- 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
- ~ Enteric-coated Tablet

~ Hard shell Capsule

~ Soft shell Capsule

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

Disintegration Test System: Tracking #: 019660

Bath Temperature: 37.4° (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114

Disk used: Yes Tablet floated: No

Media: FDA-WP-09 Wire mesh used: 4.5

Pre-immersion? ☒ Yes ☐ No if yes, give the time: 5 min

Comments on visual observation:

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At the end of 30 min agitation, please describe:

1. Tablet/capsule is still in one piece: Y/N

Pictures:

1. For obvious pass: a picture of the tubes after removing them from the media.
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NDL Disintegration Checklist

Batch ID: DIST-MA-180307-2

Test sample ID 7020685

- 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

Bath Temperature: 36.7° (Specification: $37^{\circ} \pm 2^{\circ}\text{C}$) Thermometer #: 020114

Disk used: Yes Tablet floated: No

Media: FDA-WD-09 Wire mesh used: Yes

Pre-immersion? ✓ Yes ___ No if yes, give the time: 5 min

Comments on visual observation:

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At the end of 30 min agitation, please describe:

1. Tablet/capsule is still in one piece: Y/N
 If so, how close it is to the original-size/shape?

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