Batch ID: DI	51-MA-180305-1	Test sample ID 7020676
	ent used is certified by the manufactun testing.	rer to be capable of meeting all USP requirements for
 Verify that the instrument is 		JSP specification of 37° \pm 2°C on each day that the
the bottom o		specifications for cycle frequency and distance, and that from both the bottom of the immersion beaker and the
*	Uncoated Plain-coated/Film-coated Tablet Enteric-coated Tablet	~ Hard shell Capsule ~ Soft shell Capsule
Applicable USP	or other test procedure: ~ <701> 😺	<2040> ~
Disintegration To	est System: Tracking #: <u> ชูโดโฮโฮ</u> โ	
Bath Temperatu	re: <u>36-9</u> (Specification: 37º ±2	P°C) Thermometer #: <u>020</u> 11년
Disk used: N	0	Tablet floated: No
Media: FDA	-WP-09	Wire mesh used:
	YesXNo if yes, give th	
Comments on v	visual observation:	
would like this a At the end of 30 1. Tablet/capsul	e very helpful details that you've been dditional information: min agitation, please describe: e is still in one piece: VN v close it is to the original size/shape	sending us in the lab sheets (comments section), we

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

Batch ID:	DIST-MH-180305-1	Test sample ID 7 0 2 0 6 7 7
	iment used is certified by the matter tion testing.	anufacturer to be capable of meeting all USP requirements for
	t the waterbath temperature me t is used	ets the USP specification of 37° ± 2 °C on each day that the
the botton		hin USP specifications for cycle frequency and distance, and that 2.5 cm from both the bottom of the immersion beaker and the ration.
Type (√):	Plain-coated/Film-coated TaEnteric-coated Tablet	blet ~ Hard shell Capsule Soft shell Capsule
Applicable US	SP or other test procedure:	701><2040> ~
Disintegration	n Test System: Tracking #:	17415
Bath Tempera	ature: <u>36.2</u> (Specification	n: 37° ±2°C) Thermometer #: _020114
Disk used:	les	Tablet floated: № 0
Media: Fb	A-WP-09	Wire mesh used: Y < 5
Pre-immersio	n? XYesNo if yes	s, give the time: <u>5:00</u> min
Comments o	on visual observation:	
would like this At the end of 1. Tablet/caps	the very helpful details that you additional information: 30 min agitation, please describule is still in one piece: YN now close it is to the original size	

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 OTMARIS

@ Both procedure <7017 and <20407 were used for analysis. CMK 22 Mar18

Batch ID:	DIST-MA (180305-1	Test sample ID_ 7 0 20 67 8
	ument used is certified by the manufacturer ation testing.	to be capable of meeting all USP requirements for
	t the waterbath temperature meets the USP it is used	specification of 37 $^{\circ}$ ±2 $^{\circ}$ C on each day that the
the botton		ecifications for cycle frequency and distance, and that both the bottom of the immersion beaker and the
Type (√):	~ Uncoated ✓Plain-coated/Film-coated Tablet ~ Enteric-coated Tablet	~ Hard shell Capsule ~ Soft shell Capsule
Applicable US	SP or other test procedure: ~ <701> ~<20	40> ~
Disintegration	n Test System: Tracking #: 017615	
Bath Temper	ature: <u>36.2</u> (Specification: 37° ±2°C)	Thermometer #: 020114
Disk used:	Yes	ablet floated: No
Media: FDF	4-W8-09 W	/ire mesh used:
Pre-immersio	on? XYesNo if yes, give the tire	ne: <u>5'00</u> min
Comments o	on visual observation:	
would like this At the end of 1. Tablet/cap	the very helpful details that you've been sets additional information: 30 min agitation, please describe: sule is still in one piece: Y/N how close it is to the original size/shape?	nding us in the lab sheets (comments section), we

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 both temperature, Should read "36.80" CMR OSMARIS

Batch ID:	DIST-MA-180307-	2	Test sample ID 7020679
	ument used is certified by tation testing.	he manufacturer to	be capable of meeting all USP requirements for
	at the waterbath temperaturnt is used	e meets the USP s	specification of 37° \pm 2°C on each day that the
the botto		least 2.5 cm from	sifications for cycle frequency and distance, and that both the bottom of the immersion beaker and the
Type (√):	~ Uncoated ✔Plain-coated/Film-coate ~ Enteric-coated Tablet	ed Tablet	~ Hard shell Capsule ~ Soft shell Capsule
Applicable U	SP or other test procedure:	: ~ <701> <204	0> ~
Disintegratio	n Test System: Tracking #	019659	
Bath Temper	rature: <u>37. 7°</u> (Specifi	ication: 37° ±2°C)	Thermometer #: ozou4
Disk used:	Yes	Та	blet floated: No
Media: FI	DA-WP-09	Wir	re mesh used:
Pre-immersion	on? <u>V</u> YesNo	if yes, give the tim	e: min
Comments	on visual observation:		
would like th	the very helpful details that is additional information: 30 min agitation, please d	_	ding us in the lab sheets (comments section), we

Pictures:

- For obvious pass: a picture of the tubes after removing them from the media.
 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. Tablet/capsule is still in one piece: Y/N

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

Batch ID: DIST-MA-180307-2	Test sample ID 70206 80
The instrument used is certified by the manufacture disintegration testing.	r to be capable of meeting all USP requirements for
 Verify that the waterbath temperature meets the US instrument is used. 	P specification of 37° ± 2 °C on each day that the
 Verify that the instrument is operating within USP sp the bottom of the basket remains at least 2.5 cm fro surface of the immersion fluid during operation. 	m both the bottom of the immersion beaker and the
Type (√): ~ Uncoated	~ Soft shell Capsule
Applicable USP or other test procedure: <701>	2040> ~
Disintegration Test System: Tracking #: 019659	
Bath Temperature: <u>37.7°</u> (Specification: 37° ±2°C	C) Thermometer #: <u>020114</u>
Disk used: Yes	Tablet floated: No
Media: FDA-wP_001	Nire mesh used: Yes
Pre-immersion? XYesNo if yes, give the t	time: min
Comments on visual observation:	
In addition to the very helpful details that you've been so would like this additional information: At the end of 30 min agitation, please describe: 1. Tablet/capsule is still in one piece: If so, how close it is to the original size/shape?	ending us in the lab sheets (comments section), we

- 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.

Batch ID: DIST-MA-180307 · 2	Test sample ID 7020683
 The instrument used is certified by the manufact disintegration testing. 	curer to be capable of meeting all USP requirements for
 Verify that the waterbath temperature meets the instrument is used. 	USP specification of 37° $\pm 2^{\circ}\text{C}$ on each day that the
	P specifications for cycle frequency and distance, and that from both the bottom of the immersion beaker and the
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 #:	0
Bath Temperature: <u>37.4°</u> (Specification: 37° ±	E2°C) Thermometer #: OZOIY
	Tablet floated: No
Media: FDH_WP_D9	Wire mesh used: Y/5
Pre-immersion? <u>Yes</u> No if yes, give t	the time: min
Comments on visual observation:	
In addition to the very helpful details that you've bee would like this additional information: At the end of 30 min agitation, please describe: 1. Tablet/capsule is still in one piece: YN If so, how close it is to the original size/shap	en sending us in the lab sheets (comments section), we

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

Batch ID:	DIST-MA-180307-2	Test sample ID
	ument used is certified by the manufacture ation testing.	er to be capable of meeting all USP requirements for
	at the waterbath temperature meets the US nt is used	SP specification of 37° ± 2 °C on each day that the
the bottor	at the instrument is operating within USP sp m of the basket remains at least 2.5 cm fro of the immersion fluid during operation.	pecifications for cycle frequency and distance, and that om both the bottom of the immersion beaker and the
Type (√):	~ Uncoated ✓Plain-coated/Film-coated Tablet ~ Enteric-coated Tablet	~ Hard shell Capsule ~ Soft shell Capsule
Applicable US	SP or other test procedure: ~ <701> 🗸 <	2040> ~
Disintegration	n Test System: Tracking #: 017615	0
	rature: <u>36.7°</u> (Specification: 37° ±2°0	
Disk used:	ies	Tablet floated: No
	4-WP-09	
Pre-immersion	on? YesNo if yes, give the	time: min
Comments of	on visual observation:	
would like this At the end of 1. Tablet/cap	o the very helpful details that you've been s is additional information: f 30 min agitation, please describe: osule is still in one piece: Y/N how close it is to the original size/shape?	sending us in the lab sheets (comments section), we

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