DISSOLUTION CHECKLIST

Batch ID DISL-MA-170118-1 **Test Sample ID** SS29888

Active Ingredient Weight: 1209.4 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-HCL-170116-03, ①
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 18JUN17
Shaft Center Check Performed:	Initials: DMS Date: 18JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30201, SS30202	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.3 °C
2	36.7 °C	37.3 °C
Sample number:	SS30201, SS30202	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.3 °C
4	36.7 °C	37.3 °C
Sample number:	SS30201, SS30202	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.2 °C
6	36.7 °C	37.3 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	DMS 18JUN17 °C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # ~~004026~~ ② 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 05/5°C Expiration Date: —

Dissolution performed by DMS on 18JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① DISL-HCL-170116-02 also used. DMS 18JUN17

② 2 E DMS 18JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** 55209888

Active Ingredient Weight: 1209.4 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170110-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45-um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 12JAN17
Shaft Center Check Performed:	Initials: DMS Date: 12JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

(1)

Sample number:	~~55302303~~ 55302303	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.2°C
2	36.6 °C	37.2°C
Sample number:	55302033	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.1 °C
4	36.8 °C	37.2 °C
Sample number:	55302033	
Vessel #	Start Temp.	End Temp.
5	36.7°C	37.1 °C
6	36.6 °C	37.1 °C
~~Sample number:~~		
Vessel # DMS 12JAN17	~~Start Temp.~~	~~End Temp.~~ °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 1040216

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: _____

Dissolution performed by DMS on 12Jan17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

(1) R.F. DMS 12Jan17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** 55298889

Active Ingredient Weight: 1688.4 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-CB-170110-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 12 JAN 17
Shaft Center Check Performed:	Initials: DMS Date: 12 JAN 17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530209	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.4 °C
2	36.8 °C	37.3 °C
Sample number:	5530209	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	37.3 °C
4	36.5 °C	37.1 °C
Sample number:	5530209	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.3 °C
6	36.7 °C	37.3 °C
~~Sample number:~~		
Vessel # DMS 12JAN17	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65 / 5°C Expiration Date: NA

Dissolution performed by DMS on 12 JAN 17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170118-1 **Test Sample ID** 55298589

Active Ingredient Weight: 1688.4 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec1
Dissolution Media (Lot/PN)	DISL-HCL-170116-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 18JUN17
Shaft Center Check Performed:	Initials: DMS Date: 18JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530207, 5530208	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.5 °C
2	36.9 °C	37.5 °C
Sample number:	5530207, 5530208	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.5 °C
4	36.5 °C	37.4 °C
Sample number:	5530207, 5530208	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.5 °C
6	36.6 °C	37.5 °C
~~Sample number:~~		
Vessel # DMS	~~Start Temp.~~ 18JUN17	End Temp.
	°C	~~°C~~
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Room 65 Expiration Date: ~~_____~~

Dissolution performed by DMS on 18JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529889

Active Ingredient Weight: 1688.4 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01714
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☐ No
Withdraw Volume (mL)	

Sample number:	S530206	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.2 °C
2	37.2 °C	37.2 °C
Sample number:	S530206	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.2 °C
4	37.1 °C	37.2 °C
Sample number:	S530206	
Vessel #	Start Temp.	End Temp.
5	37.1 °C	37.2 °C
6	37.1 °C	37.2 °C
~~Sample number:~~		
Vessel # 09JAN17 DMS	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets are completely disintegrated.

Storage Location/Condition: Probe 65/5C Expiration Date: —

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 55 2 9890

Active Ingredient Weight: 1586.5 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530210	
Vessel #	Start Temp.	End Temp.
1	36.6 °C	37.3 °C
2	36.5 °C	37.3 °C
Sample number:	5530210	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	37.3 °C
4	36.5 °C	37.2 °C
Sample number:	5530210	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.2 °C
6	36.6 °C	37.2 °C
~~Sample number:~~ DMS 09JAN17		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes, the tablets are completely disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170118-1 **Test Sample ID** 55299890

Active Ingredient Weight: 1586.5 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DSL-HCL-170116-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 18JUN17
Shaft Center Check Performed:	Initials: DMS Date: 18JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530211, 5530212	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.5 °C
2	36.7 °C	37.4 °C
Sample number:	5530211, 5530212	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.5 °C
4	36.7 °C	37.5 °C
Sample number:	5530211, 5530212	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.5 °C
6	36.6 °C	37.5 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	DMS 18JUN17 °C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 0155806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated

Storage Location/Condition: Probe 60/5°C Expiration Date: —

Dissolution performed by DMS on 18JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** SS 29890

Active Ingredient Weight: 1586.5 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170110-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 12Jan17
Shaft Center Check Performed:	Initials: DMS Date: 12Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30213	
Vessel #	Start Temp.	End Temp.
1	36.8 °C	37.2 °C
2	36.6 °C	37.1 °C
Sample number:	SS30213	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.7 °C	37.2 °C
Sample number:	SS30213	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.1 °C
6	36.7 °C	37.1 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe US/5°C Expiration Date: ———

Dissolution performed by DMS on 12Jan17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 55 2 9891

Active Ingredient Weight: 991.0 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530215	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3 °C
2	37.0 °C	37.2 °C
Sample number:	5530215	
Vessel #	Start Temp.	End Temp.
3	36.9 °C	37.2 °C
4	36.9 °C	37.2 °C
Sample number:	5530215	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.2 °C
6	36.8 °C	37.2 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: ———

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** SS29891

Active Ingredient Weight: 991.0 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL_CB-170110-02, DISL_CB-170110-03
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 12JAN17
Shaft Center Check Performed:	Initials: DMS Date: 12JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30218	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3°C
2	37.0 °C	37.3°C
Sample number:	SS30218	
Vessel #	Start Temp.	End Temp.
3	36.8 °C	37.2°C
4	36.5 °C	37.1 °C
Sample number:	SS30218	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.3°C
6	36.9 °C	37.2 °C
~~Sample number:~~	~~SS3~~ ①	
~~Vessel #~~	Start Temp.	End Temp.
	°C	°C
	DMS 12JAN17	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes the tablets are disintegrated.

Storage Location/Condition: Probe 05/5°C Expiration Date: ———

Dissolution performed by DMS on 12JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① R.F. DMS 12JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170118-1 **Test Sample ID** SS298911

Active Ingredient Weight: 991.0 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	011565
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-HCL-170116-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 18JUN17
Shaft Center Check Performed:	Initials: DMS Date: 18JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS302161, SS30217	
Vessel #	Start Temp.	End Temp.
1	37.5 °C	37.5 °C
2	37.4 °C	37.3 °C
Sample number:	SS30216, SS30215	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.4 °C
4	37.1 °C	37.4 °C
Sample number:	SS30216, SS30217	
Vessel #	Start Temp.	End Temp.
5	37.3 °C	37.5 °C
6	37.2 °C	37.4 °C
Sample number:		
Vessel # DMS	Start Temp.	End Temp.
	°C 18JUN17 °C	°C
		°C

① R.E. 18 JUN 17 DMS

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 6S/5°C Expiration Date: —

Dissolution performed by DMS on 18JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** 55298 92

Active Ingredient Weight: 1577.5 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170110-03
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 1L
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 12 JUN 17
Shaft Center Check Performed:	Initials: DMS Date: 12 JUN 17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530224	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.2 °C
2	37.1 °C	37.1 °C
Sample number:	5530224	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.2 °C
4	37.1 °C	37.1 °C
Sample number:	5530224	
Vessel #	Start Temp.	End Temp.
5	37.1 °C	37.1 °C
6	37.1 °C	37.1 °C
Sample number:		
Vessel # DMS	Start Temp. 12 JUN 17 °C	End Temp. °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 6S/5°C Expiration Date: —

Dissolution performed by DMS on 12 JUN 17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** 5529892

Active Ingredient Weight: 1577.5 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01741
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-HCL-170116-02, DISL-HCL-170116-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 um nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19Jan17
Shaft Center Check Performed:	Initials: DMS Date: 19Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530221, 5530222	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.2 °C
2	36.7 °C	37.2 °C
Sample number:	5530224, 5530227	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.6 °C	37.2 °C
Sample number:	5530221, 5530222	
Vessel #	Start Temp.	End Temp.
5	36.7 °C	37.3 °C
6	36.7 °C	37.2 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 19Jan17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** SS298093

Active Ingredient Weight: 1556.2 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-HCL-170116-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19JUN17
Shaft Center Check Performed:	Initials: DMS Date: 19JUN17
Auto sampler used?	☐ Yes ☑ No
Withdraw Volume (mL)	10

Sample number:	SS30226, SS30228	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.5 °C
2	37.0 °C	37.5 °C
Sample number:	SS30226, SS30228	
Vessel #	Start Temp.	End Temp.
3	36.9 °C	37.5 °C
4	36.7 °C	37.4 °C
Sample number:	SS30226, SS30228	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.5 °C
6	36.8 °C	37.4 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: ———

Dissolution performed by DMS on 19JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISL-MA-170112-1

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-0① **Test Sample ID** SS29893

Active Ingredient Weight: 1556.2 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	DIL565
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-CB-170110-03
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 12 JAN 17
Shaft Center Check Performed:	Initials: DMS Date: 12 JAN 17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30229	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.3 °C
2	37.2 °C	37.3 °C
Sample number:	SS30229	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.2 °C
4	36.9 °C	37.1 °C
Sample number:	SS30229	
Vessel #	Start Temp.	End Temp.
5	37.2 36.9① °C	37.3 °C
6	37.1 °C	37.1 °C
~~Sample number:~~		
Vessel # DMS	~~Start Temp.~~ 12 JAN 17	~~End Temp.~~ °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 605/5°C Expiration Date: ____

Dissolution performed by DMS on 12 JAN 17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① R.E. DMS 12 JAN 17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** 5529894

Active Ingredient Weight: 1601.1 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	30 017191
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-HCL-170116-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	0.45um NYLON
Filter (syringe filter)	60
Sample Times (minutes)	Initials: DMS Date: 19JUN17
Height Check Performed:	Initials: DMS Date: 19JUN17
Shaft Center Check Performed:	☐ Yes ☑ No
Auto sampler used?	10
Withdraw Volume (mL)	

Sample number:	S530231, S530232	
Vessel #	Start Temp.	End Temp.
1	36.8 °C	37.2 °C
2	36.7 °C	37.1 °C
Sample number:	S530231, S530232	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	37.0 °C
4	36.7 °C	37.1 °C
Sample number:	S530231, S530232	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.0 °C
6	36.6 °C	37.1 °C
Sample number:		
Vessel # DMS	Start Temp. 19JUN17 °C	End Temp. °C ~~°C~~

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 6S/5°C Expiration Date: _____

Dissolution performed by DMS on 19JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

O.R.E. DMS 19JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 5529894

Active Ingredient Weight: 1601.1 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170110-03, DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45-um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13JAN17
Shaft Center Check Performed:	Initials: DMS Date: 13JAN17
Auto sampler used?	☐ Yes ☑ No
Withdraw Volume (mL)	10

Sample number:	5530233	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.2 °C
2	36.9 °C	37.1 °C
Sample number:	5530233	
Vessel #	Start Temp.	End Temp.
3	36.9 °C	37.1 °C
4	36.9 °C	37.1 °C
Sample number:	5530233	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.1 °C
6	36.8 °C	37.1 °C
~~Sample number:~~ DMS 13JAN17		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 13JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 5529895

Active Ingredient Weight: 1572.1 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13JAN17
Shaft Center Check Performed:	Initials: DMS Date: 13JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530237	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.2 °C
2	37.0 °C	37.2 °C
Sample number:	5530237	
Vessel #	Start Temp.	End Temp.
3	36.8 °C	37.1 °C
4	36.7 °C	37.0 °C
Sample number:	5530237	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.2 °C
6	37.0 °C	37.2 °C
~~Sample number:~~		
Vessel # ~~DMS~~	Start Temp.	End Temp.
	13JAN17 °C	°C
		~~°C~~

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 13JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** SS298795

Active Ingredient Weight: 1572.1 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	011SUS
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	DISL-HCL-170116-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um NYLON
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19JAN17
Shaft Center Check Performed:	Initials: DMS Date: 19JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS302235, SS302236	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.3 °C
2	36.7 °C	37.2 °C
Sample number:	SS302235, SS302236	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	37.1 °C
4	36.5 °C	37.1 °C
Sample number:	SS302235, SS302236	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.1 °C
6	36.5 °C	37.1 °C
Sample number:		
Vessel # DMS	Start Temp. 19JAN17 °C	End Temp. °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # ~~00~~ 01 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: _____

Dissolution performed by DMS on 19JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

Q.R.F. DMS 19JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** SS298960

Active Ingredient Weight: 1526.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	~~DISL-HCL-170116~~ ①
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19Jan17
Shaft Center Check Performed:	Initials: DMS Date: 19Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30240, SS30241	
Vessel #	Start Temp.	End Temp.
1	36.6 °C	36.9 °C
2	36.5 °C	36.8 °C
Sample number:	SS30240, SS30241	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	36.8 °C
4	36.5 °C	36.9 °C
Sample number:	SS30240, SS30241	
Vessel #	Start Temp.	End Temp.
5	36.5 °C	36.8 °C
6	36.5 °C	36.8 °C
Sample number:		
Vessel # DMS	~~19Jan17~~ °C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # ~~0040210~~ ⑪ 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 19Jan17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① R.E. should be DISL-HCL-170116-01. pms 19Jan17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 55298896

Active Ingredient Weight: 1526.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13JAN17
Shaft Center Check Performed:	Initials: DMS Date: 13 JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530243	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.2 °C
2	36.7 °C	37.1 °C
Sample number:	5530243	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.7 °C	37.1 °C
Sample number:	5530243	
Vessel #	Start Temp.	End Temp.
5	36.5 °C	37.1 °C
6	36.6 °C	37.1 °C
~~Sample number:~~		
~~Vessel #~~ DMS	~~Start Temp.~~ 13JAN17 °C	~~End Temp.~~ °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60. minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 6S/5°C Expiration Date: —

Dissolution performed by ~~DMS~~ ① on 13 JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① marked paper with pen unintentionally. DMS 13 JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529896

Active Ingredient Weight: 1526.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31 DEC17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530238	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.4 °C
2	36.9 °C	37.3 °C
Sample number:	5530238	
Vessel #	Start Temp.	End Temp.
3	36.8 °C	37.3 °C
4	36.7 °C	37.2 °C
Sample number:	5530238	
Vessel #	Start Temp.	End Temp.
5	36.7 °C	37.3 °C
6	36.9 °C	37.3 °C
Sample number:		
Vessel # DMS	Start Temp.	End Temp.
	09JAN17 °C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: _____

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** 5529897

Active Ingredient Weight: 1133.0 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011505
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL_HCL-170116-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19JUN17
Shaft Center Check Performed:	Initials: DMS Date: 19JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530246, 5530247	
Vessel #	Start Temp.	End Temp.
1	36.7 °C	36.9 °C
2	36.6 °C	36.9 °C
Sample number:	5530246, 5530247	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	36.8 °C
4	36.5 °C	36.8 °C
Sample number:	5530246, 5530247	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	36.8 °C
6	36.5 °C	36.8 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 19JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170125-3 **Test Sample ID** SS29897

Active Ingredient Weight: 1133.0 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-HCL-170119-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45-um nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 25JUN17
Shaft Center Check Performed:	Initials: DMS Date: 25JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30246	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.3 °C
2	37.1 °C	37.3 °C
Sample number:	SS30246	
Vessel #	Start Temp.	End Temp.
3	37.1 °C	37.3 °C
4	36.9 °C	37.2 °C
Sample number:	SS30246	
Vessel #	Start Temp.	End Temp.
5	37.1 °C	37.1 °C
6	37.0 °C	37.2 °C
~~Sample number:~~		
Vessel #	~~Start Temp.~~ DMS 25JUN17	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # ~~004026~~ ① 005993

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: ———

Dissolution performed by DMS on 25JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① R.E. DMS 25JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 5529897

Active Ingredient Weight: 1133.0 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13 JUN17
Shaft Center Check Performed:	Initials: DMS Date: 13 JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530249	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3 °C
2	36.9 °C	37.2 °C
Sample number:	5530249	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.6 °C	37.0 °C
Sample number:	5530249	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	~~37.0 °C~~ 37.2
6	36.9 °C	37.2 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
~~DMS 13 JUN17~~	°C	°C
		°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5° C Expiration Date: _____

Dissolution performed by DMS on 13 JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

DMS 13JUN17

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DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529898

Active Ingredient Weight: 1258.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01714
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530251	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3 °C
2	37.0 °C	37.3 °C
Sample number:	5530251	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.2 °C
4	36.9 °C	37.3 °C
Sample number:	5530251	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.2 °C
6	36.9 °C	37.2 °C
Sample number:		
Vessel # DMS	Start Temp. 09JAN17 °C	End Temp. °C
		°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170119-1 **Test Sample ID** 5529898

Active Ingredient Weight: 1258.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01714
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	~~DISL-HCL-170119-01~~ ①
Media Delivery Tracking #	NA
Media Vol. (mL) / Apparatus	NA
Stirring Speed (rpm)	900 / 6
Sinkers (Type)	75
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19JUN17
Shaft Center Check Performed:	Initials: DMS Date: 19JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530252, 5530253	
Vessel #	Start Temp.	End Temp.
1	36.7 °C	36.8 °C
2	36.6 °C	36.7 °C
Sample number:	5530252, 5530253	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	36.8 °C
4	36.6 °C	36.8 °C
Sample number:	5530252, 5530253	
Vessel #	Start Temp.	End Temp.
5	36.5 °C	36.7 °C
6	36.5 °C	36.7 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	DMS 19JUN17 °C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 05/5°C Expiration Date: —

Dissolution performed by DMS on 19JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① R.E. should be DISL-HCL-170116-01

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 55298 98

Active Ingredient Weight: 1258.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565 Ⓐ
Dissolution System Calibration Due:	~~31Dec16~~ 31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 2
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13JUN17
Shaft Center Check Performed:	Initials: DMS Date: 13JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530254	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.2 °C
2	36.7 °C	37.2 °C
Sample number:	5530254	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	37.2 °C
4	36.5 °C	37.1 °C
Sample number:	5530254	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.2 °C
6	36.7 °C	37.1 °C
~~Sample number:~~		
Vessel #	Start Temp.	End Temp.
~~DMS 13JUN17~~	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets were completely disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: ~~—~~

Dissolution performed by DMS on 13JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

(1) R.E. DMS 13JAN17

DISSOLUTION CHECKLIST

DISL-MA-170116-1 ①

Batch ID ~~DISL-MA-170116-1~~ **Test Sample ID** 5529899

Active Ingredient Weight: 1395.8 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	011505
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-HCL-170116-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 19JUN17
Shaft Center Check Performed:	Initials: DMS Date: 19JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530257, 5530258	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	36.8 °C
2	36.6 °C	36.8 °C
Sample number:	5530257, 5530258	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	36.8 °C
4	36.6 °C	36.7 °C
Sample number:	5530257, 5530258	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	36.8 °C
6	36.5 °C	36.8 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Prolx 65/5°C Expiration Date: —

Dissolution performed by DMS on 19JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

R.E. DMS 19JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 5529899

Active Ingredient Weight: 1395.8 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01741
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13JAN17
Shaft Center Check Performed:	Initials: DMS Date: 13JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530259	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.1 °C
2	36.7 °C	37.1 °C
Sample number:	5530259	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.1 °C
4	36.7 °C	37.1 °C
Sample number:	5530259	
Vessel #	Start Temp.	End Temp.
5	36.5 °C	37.1 °C
6	36.7 °C	37.0 °C
Sample number:		
Vessel # DMS	Start Temp. 13JAN17	End Temp. °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 0040260

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablet is completely disintegrated.

Storage Location/Condition: Probe 6S/5°C Expiration Date: —

Dissolution performed by DMS on 13JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

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DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529900

Active Ingredient Weight: 1206.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530260	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	37.4 °C
2	37.3 °C	37.4 °C
Sample number:	5530260	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.3 °C
4	37.1 °C	37.2 °C
Sample number:	5530260	
Vessel #	Start Temp.	End Temp.
5	37.3 °C	37.3 °C
6	37.2 °C	37.4 °C
~~Sample number:~~		
~~Vessel # DMS~~	~~Start Temp.~~ 09JAN17 °C	~~End Temp.~~ °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: ———

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170120-1 **Test Sample ID** SS29900

Active Ingredient Weight: 1206.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01741
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-HCL-170116-01, DISL-HCL-170119-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um NYLON
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 20Jan17
Shaft Center Check Performed:	Initials: DMS Date: 20Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	16

Sample number:	SS30261, SS30262	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.1 °C
2	37.1 °C	37.1 °C
Sample number:	SS30261, SS30262	
Vessel #	Start Temp.	End Temp.
3	37.1 °C	37.1 °C
4	37.1 °C	37.1 °C
Sample number:	SS30261, SS30262	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.1 °C
6	37.0 °C	37.1 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
DMS 20JAN17	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # ~~004 0158066~~ ① 004026 ①

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/ 5°C Expiration Date: —

Dissolution performed by DMS on 20Jan17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① R.E. DMS 20Jan17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170113-1 **Test Sample ID** 55291900

Active Ingredient Weight: 1206.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011505
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 13JUN17
Shaft Center Check Performed:	Initials: DMS Date: 13JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	55302603	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3 °C
2	37.0 °C	37.3 °C
Sample number:	55302603	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.6 °C	37.0 °C
Sample number:	55302603	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.3 °C
6	36.9 °C	37.1 °C
~~Sample number:~~		
~~Vessel #~~ DMS	~~Start Temp.~~ 13JUN17 °C	~~End Temp.~~ °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 13JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529901

Active Ingredient Weight: 1253.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 µm Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09Jan17
Shaft Center Check Performed:	Initials: DMS Date: 09Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530264	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.3 °C
2	37.3 °C	37.3 °C
Sample number:	5530264	
Vessel #	Start Temp.	End Temp.
3	37.3 °C	37.3 °C
4	37.3 °C	37.3 °C
Sample number:	5530264	
Vessel #	Start Temp.	End Temp.
5	37.2 °C	37.2 °C
6	37.2 °C	37.3 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

Storage Location/Condition: Probe 65 / 5°C Expiration Date: —

Dissolution performed by DMS on 09 Jan 17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170120-1 **Test Sample ID** 552 9901

Active Ingredient Weight: 1253.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-HCL-170119-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1c
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 20JUN17
Shaft Center Check Performed:	Initials: DMS Date: 20JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530265, 5530266	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.0 °C
2	37.0 °C	37.0 °C
Sample number:	5530265, 5530266	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	36.9 °C
4	36.9 °C	36.8 °C
Sample number:	5530265, 5530266	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	36.9 °C
6	36.9 °C	36.9 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	DMS 20JUN17 °C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 015806

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 05/5°C Expiration Date: —

Dissolution performed by DMS on 20JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170116-1 **Test Sample ID** 5529901

Active Ingredient Weight: 1253.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	YES
Dissolution System	017141
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 MM NYLON
Sample Times (minutes)	60
Height Check Performed:	Initials: KLA Date: 16JAN17
Shaft Center Check Performed:	Initials: KLA Date: 16JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530267	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.0 °C
2	37.1 °C	37.1 °C
Sample number:	5530267	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.0 °C
4	37.0 °C	37.1 °C
Sample number:	5530267	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.0 °C
6	37.0 °C	37.0 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
KLA 16JAN17	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

After 60 minutes, the tablets were fully disintegrated.

Storage Location/Condition: Probe US/5C Expiration Date: _____

Dissolution performed by KLA on 16JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529902

Active Ingredient Weight: 233.3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011516 S
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	N/A
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JUN17
Shaft Center Check Performed:	Initials: DMS Date: 09JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530270	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	37.2 °C
2	37.4 °C	37.2 °C
Sample number:	5530270	
Vessel #	Start Temp.	End Temp.
3	37.4 °C	37.2 °C
4	37.2 °C	37.2 °C
Sample number:	5530270	
Vessel #	Start Temp.	End Temp.
5	37.4 °C	37.2 °C
6	37.3 °C	37.2 °C
~~Sample number:~~		
~~Vessel #~~ DMS 09JUN17	~~Start Temp.~~	~~End Temp.~~
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004020

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

Storage Location/Condition: Probe 05/5°C Expiration Date: ———

Dissolution performed by DMS on 09JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170123-1 **Test Sample ID** SS2 9902

Active Ingredient Weight: 233.3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31 DEC17
Dissolution Media (Lot/PN)	DISL-HCL-170119-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 23JUN17
Shaft Center Check Performed:	Initials: DMS Date: 23JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30271, SS30272	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.2 °C
2	37.1 °C	37.1 °C
Sample number:	SS30271, SS30272	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.1 °C
4	37.0 °C	37.0 °C
Sample number:	SS30271, SS30272	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.0 °C
6	37.0 °C	37.1 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets do not appear to be fully disintegrated.

Storage Location/Condition: Probe 6S/5°C Expiration Date: —

Dissolution performed by DMS on 23JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170116-1 **Test Sample ID** 5529902

Active Ingredient Weight: 233.3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	YES
Dissolution System	011505
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	DISL-CB-170112-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	WIRE HELIX
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 NYLON
Sample Times (minutes)	60
Height Check Performed:	Initials: KVA Date: 170CT0
Shaft Center Check Performed:	Initials: KVA Date: 16JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530273	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.2 °C
2	37.2 °C	37.2 °C
Sample number:	5530273	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.2 °C
4	37.1 °C	37.0 °C
Sample number:	5530273	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.0 °C
6	37.1 °C	37.1 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
KVA 16JAN17	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

After 60 minutes, the tablets were fully disintegrated

Storage Location/Condition: PROBE 05/5°C Expiration Date: _____

Dissolution performed by KVA on 16JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

① writing error. should be 16JAN17. KVA 16JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170109-1 **Test Sample ID** 5529903

Active Ingredient Weight: 1245.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	ESXX-S-170109-01①
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JAN17
Shaft Center Check Performed:	Initials: DMS Date: 09JAN17
Auto sampler used?	☐ Yes ☑ No
Withdraw Volume (mL)	10

Sample number:	S530275	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.3 °C
2	37.3 °C	37.3 °C
Sample number:	S530275	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.2 °C
4	37.2 °C	37.2 °C
Sample number:	S530275	
Vessel #	Start Temp.	End Temp.
5	37.2 °C	37.3 °C
6	37.2 °C	37.2 °C
~~Sample number:~~		
Vessel #	~~Start Temp.~~ DMS 09JAN17	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets are completely disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: _____

Dissolution performed by DMS on 09JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:	
Mobile Phase:	
Calibration Standard:	
Verification Standard:	
Column Used:	
Runtime:	
Volume injected:	
Sample Set Method:	
Analytical Method Performed By:	

① ESXX-S-170109-02 was also used. DMS 09JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170123-1 **Test Sample ID** SS29903

Active Ingredient Weight: 1245.9 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31 DEC17
Dissolution Media (Lot/PN)	DISL-HCL-170119-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 23JUN17
Shaft Center Check Performed:	Initials: DMS Date: 23JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30278, SS30277	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.0 °C
2	37.0 °C	37.0 °C
Sample number:	SS30277, SS30278	
Vessel #	Start Temp.	End Temp.
3	36.9 °C	37.0 °C
4	36.8 °C	36.9 °C
Sample number:	SS30277, SS30278	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.0 °C
6	36.9 °C	37.0 °C
~~Sample number:~~		
Vessel # ~~DMS~~	Start Temp. ~~23JUN17~~ °C	End Temp. °C
	°C	~~°C~~

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 014026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes, the tablets are disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 23JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170116-1 **Test Sample ID** 5529903

Active Ingredient Weight: 124.59 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	017141
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	DISL-CB-170112-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 µM NYLON
Sample Times (minutes)	60
Height Check Performed:	Initials: KLA Date: 10JAN17
Shaft Center Check Performed:	Initials: KLA Date: 10JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530279	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.0 °C
2	37.1 °C	37.2 °C
Sample number:	5530279	
Vessel #	Start Temp.	End Temp.
3	37.1 °C	37.1 °C
4	37.0 °C	37.0 °C
Sample number:	5530279	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.1 °C
6	37.0 °C	37.0 °C
Sample number:	KLA 10JAN17	
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

After 60 minutes, the tablets were fully disintegrated

Storage Location/Condition: PROD 05 / 5C Expiration Date: ____

Dissolution performed by KLA on 10JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

A

DISSOLUTION CHECKLIST

Batch ID DSL-MA-170109-1 **Test Sample ID** SS29904

Active Ingredient Weight: 1468.3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	Yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	ESXX-S-170109-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 09JUN17
Shaft Center Check Performed:	Initials: DMS Date: 09JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30281	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	37.3 °C
2	37.3 °C	37.3 °C
Sample number:	SS30281	
Vessel #	Start Temp.	End Temp.
3	37.3 °C	37.3 °C
4	37.1 °C	37.1 °C
Sample number:	SS30281	
Vessel #	Start Temp.	End Temp.
5	37.3 °C	37.3 °C
6	37.2 °C	37.2 °C
~~Sample number:~~		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

DMS 09JUN17

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets are completely disintegrated.

Storage Location/Condition: Probe 65/5°C Expiration Date: —

Dissolution performed by DMS on 09JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170124-1 **Test Sample ID** 5529904

Active Ingredient Weight: 1468.3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-HCL-170119-01 (1)
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45µm Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 29JUN17
Shaft Center Check Performed:	Initials: DMS Date: 29JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530283, 5530284	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.1 °C
2	36.8 °C	37.1 °C
Sample number:	5530283, 5530284	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.1 °C
4	36.8 °C	37.1 °C
Sample number:	5530283, 5530284	
Vessel #	Start Temp.	End Temp.
5	36.7 °C	37.0 °C
6	36.8 °C	37.0 °C
~~Sample number:~~		
Vessel #	Start Temp.	End Temp.
DMS	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes the tablet is disintegrated.

Storage Location/Condition: Probe 05/5°C Expiration Date: —

Dissolution performed by DMS on 29JUN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

(1) DISL-HCL-170119-02 was also used. DMS 29 JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170111-1 **Test Sample ID** 55299104

Active Ingredient Weight: 1408.3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	YES
Dissolution System	011565
Dissolution System Calibration Due:	31DEC17
Dissolution Media (Lot/PN)	DISL-CB-170112-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 NYLON
Sample Times (minutes)	60
Height Check Performed:	Initials: KVA Date: 11JAN17
Shaft Center Check Performed:	Initials: KVA Date: 11JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530285	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.3 °C
2	37.4 °C	37.4 °C
Sample number:	5530285	
Vessel #	Start Temp.	End Temp.
3	37.3 °C	37.4 °C
4	37.2 °C	37.2 °C
Sample number:	5530285	
Vessel #	Start Temp.	End Temp.
5	37.2 °C	37.2 °C
6	37.3 °C	37.3 °C
Sample number:	KVA 11JAN17	
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 004026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

After 60 minutes, the tablets were fully disintegrated.

Storage Location/Condition: PROBE 05 / 5°C Expiration Date: —

Dissolution performed by KVA on 11JAN17

ANALYTICAL METHOD

Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

☐ HPLC

System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By: