DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-2 **Test Sample ID** 352 9864

Active Ingredient Weight: 583.5 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)	ESXX-S-170105-05
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: 06Jan17
Shaft Center Check Performed:	Initials: DMS Date: 06Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530160	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.2 °C
2	37.2 °C	37.2 °C
Sample number:	5530160	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.2 °C
4	37.2 °C	37.1 °C
Sample number:	5530160	
Vessel #	Start Temp.	End Temp.
5	37.2 °C	37.1 °C
6	37.2 °C	37.1 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

DMS 06Jan17

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 0090260

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets appeared completely disintegrated.

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

Dissolution performed by DMS on 06Jan17

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-170117-1 **Test Sample ID** 5529864

Active Ingredient Weight: 1583.5 mg Stage: 1

Ribo / Dron

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-170105-01
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: 17Dec16
Shaft Center Check Performed:	Initials: DMS Date: 17Dec16
Auto sampler used?	☐ Yes ☑ No
Withdraw Volume (mL)	10

Sample number:	5530161, 5530162	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.1 °C
2	36.8 °C	37.1 °C
Sample number:	5530161, 5530162	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.1 °C
4	36.8 °C	37.1 °C
Sample number:	5530161, 5530162	
Vessel #	Start Temp.	End Temp.
5	36.7 °C	37.1 °C
6	36.8 °C	37.1 °C
Sample number:		
Vessel # DMS 17Jan17	Start Temp. °C	End Temp. °C
		°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 0158016

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 17Jan17

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** SS298604

Active Ingredient Weight: 1583.5 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-170123-01
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: 24JUN17
Shaft Center Check Performed:	Initials: DMS Date: 24JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS301163	
Vessel #	Start Temp.	End Temp.
1	36.8 °C	37.1 °C
2	36.7 °C	37.1 °C
Sample number:	SS301163	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.1 °C
4	36.7 °C	37.1 °C
Sample number:	SS301163	
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. 24JUN17 °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 24JUN17

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-17-0104-1 **Test Sample ID** 55299877

Active Ingredient Weight: 1740.2 mg Stage: 1

Vb A

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01714
Dissolution System Calibration Due:	31 Dec 16
Dissolution Media (Lot/PN)	ESXX-S-170104-01
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: 04Jan17
Shaft Center Check Performed:	Initials: DMS Date: 04Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530164	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	37.4 °C
2	37.4 °C	37.4 °C
Sample number:	5530164	
Vessel #	Start Temp.	End Temp.
3	37.3 °C	37.3 °C
4	37.3 °C	37.4 °C
Sample number:	5530164	
Vessel #	Start Temp.	End Temp.
5	37.4 °C	37.3 °C
6	37.3 °C	37.4 °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:

The tablets completely disintegrated, and the solution is a cloudy pink color.

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

Dissolution performed by DMS on 04Jun17

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-170117-1 **Test Sample ID** 552987

Active Ingredient Weight: 1740.2 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-170105-01
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: DMS Date: 17JUN17
Shaft Center Check Performed:	Initials: DMS Date: 17JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530165, 5530166	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3 °C
2	37.1 °C	37.3 °C
Sample number:	5530165, 5530166	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.2 °C
4	36.9 °C	37.2 °C
Sample number:	5530165, 5530166	
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. 17JUN17 °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 17JUN17

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-170111-1 **Test Sample ID** 5529877

Active Ingredient Weight: 1740.2 mg Stage: 1

Folic

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-170110-01
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: 11Jan17
Shaft Center Check Performed:	Initials: DMS Date: 11Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530167	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.4 °C
2	37.1 °C	37.4 °C
Sample number:	5530167	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.3 °C
4	36.9 °C	37.2 °C
Sample number:	5530167	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.3 °C
6	37.0 °C	37.2 °C
Sample number:		
Vessel # DMS	Start Temp. 11Jan17 °C	End Temp. °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 004024

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At ~~45~~ 60 minutes the tablets are completely disintegrated.

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

Dissolution performed by DMS 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:

(1) R.E. DMS 11Jan17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170104-1 **Test Sample ID** 5529878

Active Ingredient Weight: 1652.8 mg Stage: 1

A

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-170104-07
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)	45
Height Check Performed:	Initials: DMS Date: 04Jan16
Shaft Center Check Performed:	Initials: DMS Date: 04Jan16
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530168	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.3 °C
2	37.4 °C	37.3 °C
Sample number:	5530168	
Vessel #	Start Temp.	End Temp.
3	37.3 °C	37.3 °C
4	37.3 °C	37.3 °C
Sample number:	5530168	
Vessel #	Start Temp.	End Temp.
5	37.3 °C	37.3 °C
6	37.3 °C	37.3 °C
~~Sample number:~~		
Vessel # DMS 04Jan16	~~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 ① completely disintegrated.

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

Dissolution performed by DMS on ~~04Jan16~~ ① 04Jan17

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 04Jan17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170117-1 **Test Sample ID** ~~5530169~~ ① 5529878

Active Ingredient Weight: 1652.8 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-170105-01, DISL-HCL-170116
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	N/A
Filter (cannula tip)	NA
Filter (syringe filter)	0.45µM Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 17JUN17
Shaft Center Check Performed:	Initials: DMS Date: 17JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530169, 5530170	
Vessel #	Start Temp.	End Temp.
1	36.7 °C	37.0 °C
2	36.5 °C	36.9 °C
Sample number:	5530169, 5530170	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	36.9 °C
4	36.6 °C	36.9 °C
Sample number:	5530169, 5530170	
Vessel #	Start Temp.	End Temp.
5	36.5 °C	36.9 °C
6	36.8 °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 05/5°C Expiration Date: ~~17JUN17~~

Dissolution performed by DMS on 17JUN17

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 17JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170111-1 **Test Sample ID** 5529878

Active Ingredient Weight: 1652.8 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)	DISL-CB-170110-01
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: 11JAN17
Shaft Center Check Performed:	Initials: DMS Date: 11JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530171	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.2 °C
2	36.7 °C	37.2 °C
Sample number:	5530171	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.6 °C	37.2 °C
Sample number:	5530171	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.2 °C
6	36.5 °C	37.2 °C
Sample number:		
Vessel # DMS	Start Temp. 11JAN17	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 009026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 (60)(1) minutes, the tablets are completely disintegrated.

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

Dissolution performed by DMS 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:

(1) R.E. DMS 11Jan17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-2 **Test Sample ID** SS 29879 Vit A

Active Ingredient Weight: 1415.6 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-170105-05
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: 06JAN17
Shaft Center Check Performed:	Initials: DMS Date: 06JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS3017 2	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	37.4 °C
2	37.4 °C	37.4 °C
Sample number:	SS3017 2	
Vessel #	Start Temp.	End Temp.
3	37.3 °C	37.3 °C
4	37.3 °C	37.2 °C
Sample number:	SS3017 2	
Vessel #	Start Temp.	End Temp.
5	37.4 °C	37.4 °C
6	37.3 °C	37.3 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 0040276

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes the tablets appeared completely disintegrated.

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

Dissolution performed by DMS on 06JAN17

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-170117-1 **Test Sample ID** 55209879

Active Ingredient Weight: 1415.6 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-170116-04
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: 17Jan17
Shaft Center Check Performed:	Initials: DMS Date: 17Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530173, 5530174	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.4 °C
2	36.8 °C	37.3 °C
Sample number:	5530173, 5530174	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	37.2 °C
4	36.5 °C	37.2 °C
Sample number:	5530173, 5530174	
Vessel #	Start Temp.	End Temp.
5	36.7 °C	37.2 °C
6	36.6 °C	37.2 °C
~~Sample number:~~ DMS 17Jan17		
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 17Jan17

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-170111-1 **Test Sample ID** 5529879

Active Ingredient Weight: 145.6 mg Stage: 1

Folic

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	OILS65
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	DISL-CB-170110-01
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)	0.45µm Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 11JAN17
Shaft Center Check Performed:	Initials: DMS Date: 11JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530175	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.4 °C
2	36.8 °C	37.4 °C
Sample number:	5530175	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	37.2 °C
4	36.5 °C	37.2 °C
Sample number:	5530175	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.3 °C
6	36.7 °C	37.3 °C
Sample number:		
Vessel # DMS	Start Temp.	End Temp.
	11JAN17 °C	°C
	°C	°C

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

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At ~~45~~ 60 minutes the tablets are completely disintegrated. (1)

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

Dissolution performed by DMS 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:

(1) R.E. DMS 11JAN17

A

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-2 **Test Sample ID** 5529881

Active Ingredient Weight: 1277.8 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-170105-05, ①
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)	45
Height Check Performed:	Initials: DMS Date: 06JAN17
Shaft Center Check Performed:	Initials: DMS Date: 06JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530176	
Vessel #	Start Temp.	End Temp.
1	36.8 °C	37.3 °C
2	36.7 °C	37.3 °C
Sample number:	5530176	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.6 °C	37.2 °C
Sample number:	5530176	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.2 °C
6	36.5 °C	37.2 °C
Sample number:		
Vessel # DMS	Start Temp. 06JAN17 °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 completely disintegrated.

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

Dissolution performed by DMS on 06JAN17

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-170106-02 was also used. DMS 06JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170117-1 **Test Sample ID** 55298S1

Active Ingredient Weight: 1277.8 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-170116-04
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	N/A
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 µm Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 17JUN17
Shaft Center Check Performed:	Initials: DMS Date: 17JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530177, 5530178	
Vessel #	Start Temp.	End Temp.
1	36.8 °C	37.3 °C
2	36.7 °C	37.3 °C
Sample number:	5530177, 5530178	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	37.3 °C
4	36.6 °C	37.3 °C
Sample number:	5530177, 5530178	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.2 °C
6	36.6 °C	37.3 °C
Sample number:		
Vessel # DMS 17JUN17	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 05/5°C Expiration Date: ———

Dissolution performed by DMS on 17JUN17

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-170111-1 **Test Sample ID** 55 29881

Active Ingredient Weight: 1277.8 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-170110-01
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: 11JAN17
Shaft Center Check Performed:	Initials: DMS Date: 11JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	55 30179	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.2 °C
2	37.0 °C	37.2 °C
Sample number:	55 30179	
Vessel #	Start Temp.	End Temp.
3	36.9 °C	37.2 °C
4	37.0 °C	37.2 °C
Sample number:	55 30179	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.2 °C
6	36.9 °C	37.2 °C
Sample number:		
Vessel # DMS 11JAN17	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~~ 60 minutes the tablets are completely disintegrated.

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

Dissolution performed by DMS 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:

(1) R.E. DMS 11JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-2 **Test Sample ID** 55 29882

Active Ingredient Weight: 1653.4 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	011565
Dissolution System Calibration Due:	31Dec16
Dissolution Media (Lot/PN)	ESXX-S-170106-02
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 1 6
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 um Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 06JUN17
Shaft Center Check Performed:	Initials: DMS Date: 06JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530180	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.3 °C
2	37.0 °C	37.4 °C
Sample number:	5530180	
Vessel #	Start Temp.	End Temp.
3	36.9 °C	37.3 °C
4	36.8 °C	37.3 °C
Sample number:	5530180	
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.~~ 06JUN17 °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 completely disintegrated.

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

Dissolution performed by DMS on 06JUN17

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-170117-1 **Test Sample ID** 5529882

Active Ingredient Weight: 1653.4 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-170116-04
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: 17JAN17
Shaft Center Check Performed:	Initials: DMS Date: 17JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530181, 5530182	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.5 °C
2	37.1 °C	37.5 °C
Sample number:	5530181, 5530182	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.5 °C
4	36.8 °C	37.3 °C
Sample number:	5530181, 5530182	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.5 °C
6	37.0 °C	37.5 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
DMS 17JAN17	°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 17JAN17

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-170111-1 **Test Sample ID** 55298882 Follow

Active Ingredient Weight: 1653.4 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-170110-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 1b
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: 11 JUN17
Shaft Center Check Performed:	Initials: DMS Date: 11 JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530183	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.4 °C
2	36.7 °C	37.4 °C
Sample number:	5530183	
Vessel #	Start Temp.	End Temp.
3	36.5 °C	37.3 °C
4	36.5 °C	37.2 °C
Sample number:	5530183	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.4 °C
6	36.7 °C	37.3 °C
~~Sample number:~~		
Vessel # DMS	~~Start Temp.~~ 11JUN17 °C	°C
	°C	°C

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

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 ~~MINUTES~~ (1) minutes, the tablets are disintegrated.

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

Dissolution performed by DMS on 11JUN17

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) write over. DMS 11JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-02 **Test Sample ID** 5529883 A

Active Ingredient Weight: 1525.7 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-170106-02
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)	45
Height Check Performed:	Initials: DMS Date: 06JUN17
Shaft Center Check Performed:	Initials: DMS Date: 06JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530184	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.2 °C
2	37.1 °C	37.2 °C
Sample number:	5530184	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.2 °C
4	37.0 °C	37.2 °C
Sample number:	5530184	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.2 °C
6	37.0 °C	37.2 °C
Sample number:		
Vessel # DMS 06JUN17	Start Temp. °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 but not entirely dissolved in the media.

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

Dissolution performed by DMS on 06JUN17

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** 5529883

Active Ingredient Weight: 1525.7 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-170116-04~~ (1)
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / 6
Stirring Speed (rpm)	75
Sinkers (Type)	N/A
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:	5530185, 5530186	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.3 °C
2	36.8 °C	37.2 °C
Sample number:	5530185, 5530186	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.8 °C	37.2 °C
Sample number:	5530185, 5530186	
Vessel #	Start Temp.	End Temp.
5	36.7 °C	37.2 °C
6	36.8 °C	37.2 °C
Sample number:		
Vessel # DMS	Start Temp. 18JUN17 °C	End Temp. °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 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) R.E. Should be DISL-HCL-170116-03. DMS 18JUN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170111-1 **Test Sample ID** 5529883

Active Ingredient Weight: 1525.7 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-170110-01
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: 11JAN17
Shaft Center Check Performed:	Initials: DMS Date: 11JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530187	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.3 °C
2	37.0 °C	37.2 °C
Sample number:	5530187	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.2 °C
4	37.1 °C	37.2 °C
Sample number:	5530187	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.2 °C
6	36.9 °C	37.2 °C
~~Sample number:~~		
Vessel # DMS	~~Start Temp.~~ 11JAN17 °C	End Temp. °C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☑ Manually with Tracking # 0049026

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 60 minutes the tablets are disintegrated completely.

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

Dissolution performed by DMS 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:

A

DISSOLUTION CHECKLIST

Batch ID ~~DISL-MA-170106-01~~ DISL-MA-170105-2 **Test Sample ID** 5529884

Active Ingredient Weight: 1496.6 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)	ESXX-S-170106-02, ESXX-S-170106-03
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)	45
Height Check Performed:	Initials: DMS Date: 06JAN17
Shaft Center Check Performed:	Initials: DMS Date: 06JAN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530188	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	37.4 °C
2	37.4 °C	37.4 °C
Sample number:	5530188	
Vessel #	Start Temp.	End Temp.
3	37.2 °C	37.3 °C
4	37.1 °C	37.3 °C
Sample number:	5530188	
Vessel #	Start Temp.	End Temp.
5	37.3 °C	37.4 °C
6	36.7 °C	37.3 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	°C	°C
	°C	°C

DMS 06JAN17

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

Replacement Media Temperatures Taken With Tracking # NA

Procedure/Observations:

At 45 minutes, the tablets have completely disintegrated.

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

Dissolution performed by DMS on 06JAN17

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 06JAN17

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170118-1 **Test Sample ID** 55299884

Active Ingredient Weight: 1496.6 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)	DISL-HCL-170116-03
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: 18JUN17
Shaft Center Check Performed:	Initials: DMS Date: 18JUN17
Auto sampler used?	☐ Yes ☑ No
Withdraw Volume (mL)	10

Sample number:	5530180, 5530190	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.5 °C
2	37.1 °C	37.5 °C
Sample number:	5530189, 5530190	
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.4 °C
4	36.8 °C	37.3 °C
Sample number:	5530189, 5530190	
Vessel #	Start Temp.	End Temp.
5	37.0 °C	37.4 °C
6	36.9 °C	37.4 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
DMS 18JUN17	°C	°C
	°C	°C

Vessel Temperatures taken: ☐ Automatically ☒ Manually with Tracking # 01580 6

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 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-170111-1 **Test Sample ID** 5529884

Active Ingredient Weight: 1496.6 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)	DISL-CB-170110-01
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: 11Jan17
Shaft Center Check Performed:	Initials: DMS Date: 11Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530191	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.4 °C
2	36.9 °C	37.4 °C
Sample number:	5530191	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	37.3 °C
4	36.6 °C	37.2 °C
Sample number:	5530191	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.3 °C
6	36.8 °C	37.3 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	DMS 11Jan17 °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 completely disintegrated.

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

Dissolution performed by DMS 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:

A

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-2 **Test Sample ID** SS29885

Active Ingredient Weight: 1669.6 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature in a desiccator:	yes
Dissolution System	01741
Dissolution System Calibration Due:	31Dec16
Dissolution Media (Lot/PN)	ESXX-S-170106-03
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-µm Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 06Jan17
Shaft Center Check Performed:	Initials: DMS Date: 06Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30192	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.2°C
2	36.8 °C	37.2°C
Sample number:	SS30192	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.7 °C	37.2 °C
Sample number:	SS30192	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.2 °C
6	36.7°C	37.2°C
Sample number:		
Vessel # DMS 06Jan17	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, but not completely dissolved in the media.

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

Dissolution performed by DMS on 06Jan17

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** 5529885

Active Ingredient Weight: 1669.6 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-170116-03
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: 18JUN17
Shaft Center Check Performed:	Initials: DMS Date: 18JUN17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	5530193, 5530194	
Vessel #	Start Temp.	End Temp.
1	37.0 °C	37.5 °C
2	36.7 °C	37.5 °C
Sample number:	5530193, 5530194	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.5 °C
4	36.8 °C	37.5 °C
Sample number:	5530193, 5530194	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.4 °C
6	36.7 °C	37.4 °C
~~Sample number:~~		
Vessel # DMS	~~Start Temp.~~ 18JUN17	~~End Temp.~~ °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. Large chunks of undisolved tablet are floating around the media.

Storage Location/Condition: Prove us/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:

Folio

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** 55297885

Active Ingredient Weight: 1669.6mg 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-170110-01, 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:	5530195	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.3 °C
2	36.9 °C	37.2 °C
Sample number:	**5530195**	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.8 °C	37.2 °C
Sample number:	**5530195**	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.2 °C
6	36.6 °C	37.1 °C
Sample number:		
Vessel # DMS 12Jan17	Start Temp. °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 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:

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DISSOLUTION CHECKLIST

Batch ID DISL-MA-170105-2 **Test Sample ID** SS29887

Active Ingredient Weight: 145.0 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)	FSXX-5-170106-03
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)	45
Height Check Performed:	Initials: DMS Date: 06Jan17
Shaft Center Check Performed:	Initials: DMS Date: 06Jan17
Auto sampler used?	☐ Yes ☒ No
Withdraw Volume (mL)	10

Sample number:	SS30200	
Vessel #	Start Temp.	End Temp.
1	37.3 °C	37.4 °C
2	37.2 °C	37.4 °C
Sample number:	SS30200	
Vessel #	Start Temp.	End Temp.
3	37.1 °C	37.3 °C
4	37.0 °C	37.3 °C
Sample number:	SS30200	
Vessel #	Start Temp.	End Temp.
5	37.1 °C	37.4 °C
6	37.0 °C	37.3 °C
Sample number:		
Vessel # DMS 06Jan17	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 605/5°C Expiration Date: —

Dissolution performed by DMS on 06Jan17

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** SSZ9887

Active Ingredient Weight: 145.0 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-170116-03
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)	0.45-um Nylon
Sample Times (minutes)	60
Height Check Performed:	Initials: DMS Date: 18JAN17
Shaft Center Check Performed:	Initials: DMS Date: 18JAN17
Auto sampler used?	☐ Yes ☑ No
Withdraw Volume (mL)	10

Sample number:	5530197, 5530198	
Vessel #	Start Temp.	End Temp.
1	37.1 °C	37.5 °C
2	37.0 °C	37.5 °C
Sample number:	5530197, 5530198	
Vessel #	Start Temp.	End Temp.
3	36.8 °C	37.5 °C
4	36.7 °C	37.4 °C
Sample number:	5530197, 5530198	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.5 °C
6	36.8 °C	37.5 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
DMS 18JAN17	°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: Prone 65 / 5°C Expiration Date: ____

Dissolution performed by DMS on 18JAN17

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** 5529887

Active Ingredient Weight: 145.0 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)	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)	0.45um Nylon
Filter (syringe filter)	60
Sample Times (minutes)	Initials: DMS Date: 25Jun17
Height Check Performed:	Initials: DMS Date: 25Jun17
Shaft Center Check Performed:	☐ Yes ☒ No
Auto sampler used?	10
Withdraw Volume (mL)	

Sample number:	5530197	
Vessel #	Start Temp.	End Temp.
1	37.2 °C	37.1 °C
2	37.1 °C	37.1 °C
Sample number:	5530197	
Vessel #	Start Temp.	End Temp.
3	37.1 °C	37.1 °C
4	37.1 °C	36.9 °C
Sample number:	5530197	
Vessel #	Start Temp.	End Temp.
5	36.9 °C	37.1 °C
6	37.1 °C	37.0 °C
Sample number:		
Vessel #	Start Temp.	End Temp.
	DMS 25Jun17 °C	°C
	°C	°C

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

DISSOLUTION CHECKLIST

Batch ID DISL-MA-170112-1 **Test Sample ID** 5529887

Folic

Active Ingredient Weight: 145.0 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-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:	5530199	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.3 °C
2	36.8 °C	37.3 °C
Sample number:	5530199	
Vessel #	Start Temp.	End Temp.
3	36.6 °C	37.2 °C
4	36.6 °C	37.2 °C
Sample number:	5530199	
Vessel #	Start Temp.	End Temp.
5	36.8 °C	37.3 °C
6	36.7 °C	37.2 °C
~~Sample number:~~		
~~Vessel #~~ DMS 12 JAN 17	~~Start Temp.~~ °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 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-170123-1 **Test Sample ID** 5529887

Active Ingredient Weight: 145.0 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)	DISL-CB-170123-01
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:	SS 30199	
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.2 °C
2	36.7 °C	37.1 °C
Sample number:	SS30199	
Vessel #	Start Temp.	End Temp.
3	36.7 °C	37.1 °C
4	36.7 °C	37.1 °C
Sample number:	SS30199	
Vessel #	Start Temp.	End Temp.
5	36.6 °C	37.0 °C
6	36.7 °C	37.1 °C
~~Sample number:~~ DMS 23JUN17		
Vessel #	Start Temp.	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, but they are not fully dissolved into the solution.

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: