A

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

Active Ingredient Weight: 1 583. DISSOLUTION OPERATING CO				4
Sample brought to room temperature			660 411	
Dissolution System	e in a desiccator: Yes	Sample number: Vessel #	5530160	
Dissolution System Calibration Due		Vessel #	Start Temp.	End Temp.
Dissolution Media (Lot/PN)	ESXX-S-170105-05	1	37.3 °C	31-2 °C
Media Delivery Tracking #		2	31.2 °C	37.Z °C
Media Delivery Tracking # Media Delivery Calibration Due:	NA NA	Sample number:	553016	
	NA (Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900 / 4	3	37.2 °C	37-2 °C
Stirring Speed (rpm)	75	4	37.2°C	3+1 °C
Sinkers (Type)	L NA	Sample number:	553016	20
Filter (cannula tip)	NA NA	Vessel #	Start Temp.	End Temp.
Filter (syringe filter)	U.45UM NYLOW	5	37-2 ℃	37-1 °C
Sample Times (minutes)	45	4	37.2 °C	371 °C
Height Check Performed:	Initials: DMS Date: 06JUN17	Sample number:		
Shaft Center Check Performed:	Initials: MMS Date: 06 Juni7	Vessel #	Start Temp.	End Temp.
Auto sampler used?	☐ Yes 🌣 No	en,	Ola DicoC	°C
Withdraw Volume (mL)	10		Start Temp.	°C
Vessel Temperatures taken: Replacement Media Temperatures T		vith Tracking #		
Procedure/Observations:	aken with Hacking #	INA		
At 45 minutes th	u tablets appeared	d completel	1 disinteq	rated.
Storage Location/Condition: Propo		tion Date:		
Dissolution performed by	on 00 TUN17	_		
ANALYTICAL METHOD				
Sample Dilution: Dilue	ent:	Sample Diluted by:		
□ HPLC				
System Tracking #:				
System Tracking #: Mobile Phase:				
0.111 .1 .0. 1 .1				
	17%			
Column Used:				
Runtime:				

Sample Set Method:

Batch ID DISL-MA-170117-1 Test Sample ID 55 29864 Pipo) gran Active Ingredient Weight: 15 83.5 mg Stage: 1 DISSOLUTION OPERATING CONDITIONS 5530161,5530162 Sample number: Sample brought to room temperature in a desiccator: US End Temp. Start Temp. Vessel# 1017191 Dissolution System 371 37.0 °C °C 3100017 Dissolution System Calibration Due: °C 36.<u>% °C</u> 31.1 DISL-HCL-170105-01 Dissolution Media (Lot/PN) 5530161,5530162 Sample number: NA Media Delivery Tracking # Start Temp. End Temp. Vessel# NA Media Delivery Calibration Due: 36.7 °C 37.1 $^{\circ}C$ 3 900 / 10 Media Vol. (mL) / Apparatus 311 °C 36.5 Stirring Speed (rpm) 5530162 S530161 Sample number: NA Sinkers (Type) End Temp. Start Temp. Vessel # NA Filter (cannula tip) 36.7 °C °C 37·1 0.45 MM NYION Filter (syringe filter) °C 37.L Sample Times (minutes) Initials: DYY) 5 Date: 1704 (10)
Initials: 01/1/5 Date: 1704 (10) Sample number: Height Check Performed: Start Temp. End Temp. Vessel# 17 min oc Shaft Center Check Performed: °C ☐ Yes ✓ No Auto sampler used? °C 1() Withdraw Volume (mL) Manually with Tracking # _015806 ☐ Automatically Vessel Temperatures taken: Replacement Media Temperatures Taken With Tracking # NA At 60 minutes, the tablets are disintegrated. Procedure/Observations: Storage Location/Condition: Probe 65/50C Expiration Date: Dissolution performed by 0MS 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:

Batch ID DISL-MA-170124-1 Test Sample ID 55201864

Active Ingredient Weight: 1583.5	mg Stage: 1			
DISSOLUTION OPERATING CO	NDITIONS	Sample number:	5530163	
Sample brought to room temperature i	n a desiccator: Yes	Vessel #	Start Temp.	End Temp.
Dissolution System	0(714)	7 03301 //	36.8 °C	371 °C
Dissolution System Calibration Due:	310ec17	7	36.7 °C	37.1 °C
Dissolution Media (Lot/PN)	DISL-(B-170123-01	Sample number:	5530163	3
Media Delivery Tracking #	NA NA	Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:		3	36.7 °C	371 °C
Media Vol. (mL) / Apparatus		4	36.7 °C	37-1 °C
Stirring Speed (rpm)	7 S NA	Sample number:	553016	3
Sinkers (Type)		Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	NA (1400 6) 11(1)()	V 03301 II	36.6°C	37.0 °C
Filter (syringe filter)	0.45 um aylon	[o	36.0 °C	37·1 °C
Sample Times (minutes)	Initials: OM S Date: 24 JUL 7	Sample number:		
Torgite Choose x or a constant	Initials: PMS Date ATUNG		Start Temp.	End Temp.
Shaft Center Check Performed:		Vessel # Dn75	24 Junize	°C
Auto sampler used?	Yes No		FC	-ee
Withdraw Volume (mL)				
,	•	h Tracking# _ <i>OC</i>	4026	
Replacement Media Temperatures Ta	ken With Tracking #	NA		
Procedure/Observations:				
	Value V	d		
At 60 minutes, the	tabuts are disint	egrateu.		
Storage Location/Condition:	$Oe(05/5^{\circ})$ Expirat	ion Date:		
Dissolution performed by	os on 24 Trep 13	7-		
Dissolution performed by	1) On On	L		
ANALYTICAL METHOD		Gl. Diluted by	7*	
Sample Dilution: Dilu	ent:	_Sample Diluted by	·	
□ HPLC				
System Tracking #:				
Verification Standard:				
Column Used:				
Runtime'				

Volume injected: Sample Set Method:

Batch ID DISL-MA-170104-1 Test Sample ID 5529877

Active Ingredient Weight: 1740. DISSOLUTION OPERATING CO	L_mg Stage: NDITIONS				
Sample brought to room temperature		Sample number:	5530164		
Dissolution System	017141	Vessel#	Start Temp.	End Temp.	
Dissolution System Calibration Due:		1	37.4 °C	37.4 °C	
Dissolution Media (Lot/PN)	ESXX-5-170104-01	2	37.4 °C	37.4 °C	
Media Delivery Tracking #	NA	Sample number:	5530169		
Media Delivery Calibration Due:	NA NA	Vessel #	Start Temp.	End Temp.	
	0.40	3	31.3 °C	31-3 °C	
Media Vol. (mL) / Apparatus	75	4	31.3℃	37.4 °C	
Stirring Speed (rpm)	700 / 6 75 NA	Sample number:	553016	1, <u>`</u>	
Sinkers (Type)	IND	Vessel #	Start Temp.	End Temp.	
Filter (cannula tip)	NA	S Vessel #	37.4 °C	37.3 °C	
Filter (syringe filter)	0.45um NYION		313℃	37.4 °C	
Sample Times (minutes)			3750	3111 °C	
Height Check Performed:	Initials: DMS Date: 04 Jan 14	Sample number: Vessel #	And and Tanan	End Temp.	
Shaft Center Check Performed:	Initials: DM5 Date: 04 yan 17	Vessel # VIII	Start Temp.	·	
Auto sampler used?	☐ Yes 🔯 No			°C	
Withdraw Volume (mL)	10		°C	<u> °C</u>	
Procedure/Observations: The tablets completely disintegrated, and the solution is a cloudy pink color.					
Storage Location/Condition: Problem Dissolution performed by DM 5	2 (65/5°C Expire	ation Date:		-	
Dissolution performed by VIVI	On 01 JUV 11 T				
ANALYTICAL METHOD Sample Dilution: Dilu HPLC					
System Tracking #:					
Calibration Standard:					
Verification Standard:					

Column Used: Runtime:

Volume injected:
Sample Set Method:

Batch ID DISL - MA - 170[17-1 Test Sample ID 552 9877							
Active Ingredient Weight: 1740 DISSOLUTION OPERATING CO	2 mg Stage: 1		V. (34)				
Sample brought to room temperature		Sample number:	5530165, 3	5530166			
Dissolution System	011565	Vessel #	Start Temp.	End Temp.			
Dissolution System Calibration Due:			37.1 ℃	37.3 °C			
Dissolution Media (Lot/PN)	DISL - HCL - 170105-01	2	37-1 °C	313 °C			
Media Delivery Tracking #	NA NA	Sample number:	<530165	5530166			
Media Delivery Tracking # Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	End Temp.			
Media Vol. (mL) / Apparatus	900 / 4	3	37.0 °C	31.2 °C			
	75	4	369 °C	37.7 °C			
Stirring Speed (rpm)	N'À	Sample number:	5530165.	5530166			
Sinkers (Type)	<u></u>	Vessel #	Start Temp.	End Temp.			
Filter (cannula tip)	NA NA NAME NAME NAME NAME NAME NAME NAME	V 655CI #	37.0 °C	37.2 °C			
Filter (syringe filter)	d.75 MM DYION	6	36.9 ℃	37.2 °C			
Sample Times (minutes)			1.50° 1 C	31.60			
Height Check Performed:	Initials: VMS Date: 17 ICM17	Sample number:	Start Temp.	End Temp.			
Shaft Center Check Performed:	Initials: OVY) S Date: 4 TOUNI 7	Vessel # pm					
Auto sampler used?	☐ Yes ☒ No		7 Jan G	-c C			
Withdraw Volume (mL)	10		<u> </u>	-6			
Vessel Temperatures taken: Automatically Manually with Tracking #							
Storage Location/Condition: Prope 65/5°C Expiration Date: Dissolution performed by on							
Sample Dilution: Dilution	uent:	_Sample Diluted by	•				
		-					
□ HPLC			<u></u>				
Mobile Phase:							
Calibration Standard:							
Verification Standard:							
Column Used:							
Runtime:							
Runtime.							

Volume injected:
Sample Set Method:

Batch ID DISL-MA - 170 1-1 Test Sample ID 552 9 87 7					
Active Ingredient Weight: 1740	mg Stage:		Ţ	edit	
DISSOLUTION OPERATING CO		0 11	613111 1		
Sample brought to room temperature		Sample number: Vessel #	\$530/67 Start Temp.	End Temp.	
Dissolution System	011565	Vessel #	37-Z °C	37-4 °C	
Dissolution System Calibration Due:		1			
Dissolution Media (Lot/PN)	DISL-CB-170/10-01	2	37-1 °C	37.4 °C	
Media Delivery Tracking #	NA	Sample number:	553016		
Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	End Temp.	
Media Vol. (mL) / Apparatus	900 16	3	37.0 °C	37.3 °C	
Stirring Speed (rpm)	75	4	36.9 °C	37.2 °C	
Sinkers (Type)	NA	Sample number:	5530167		
Filter (cannula tip)	NA	Vessel #	Start Temp.	End Temp.	
Filter (syringe filter)	a as um vyion	5	37.0°C	37.3 °C	
Sample Times (minutes)	60	4	37-0°C	37.2 °C	
Height Check Performed:	Initials: OMS Date: 11 Tan 17	Sample number:			
Shaft Center Check Performed:	Initials: DMS Date: // Tan/7	Vessel # Oh	Start Temp.	End Temp.	
Auto sampler used?	☐ Yes ☐ No		11 anito	°C	
Withdraw Volume (mL)	10		″ ⁶ C	°C	
Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At 45 Ominutes the tablets are completely disintegrated.					
Storage Location/Condition: Prove (05/500 Expiration Date:					
0 1 Dil di Dil.					
Sample Dilution: Dili	uent:	_Sample Diluted by:			
Sample Dilution:Dili	uent:	_Sample Diluted by:			
	uent:	_Sample Diluted by:			
□ HPLC	uent:	_Sample Diluted by:			
☐ HPLC System Tracking #:	uent:	_Sample Diluted by:			
☐ HPLC System Tracking #: Mobile Phase: Calibration Standard:	uent:	_Sample Diluted by:			
System Tracking #: Mobile Phase: Calibration Standard: Verification Standard:					
☐ HPLC System Tracking #: Mobile Phase: Calibration Standard:					

Analytical Method Performed By:

Sample Set Method:

Batch ID DISU-MA - 170104-1 Test Sample ID 5529878

Sample number Start Temp. End Temp.	Active Ingredient Weight: 1652.			 ***\
Dissolution System			0 1 1	100201100
Dissolution System Calibration Due: 310ec14				
Dissolution Media (LoVPN) ESXX-S-I+0104-07 Media Delivery Tracking # MA Media Delivery Calibration Due: NA Media Delivery Calibration Due: NA Media Delivery Calibration Due: NA Stirring Speed (rpm) NA Filter (cannula tip) NA Filter (cannula tip) NA Filter (cannula tip) NA Height Check Performed: Initials: DMN Date: 04 JANIU Auto sampler uscd? Withdraw Volume (mL) Vessel I Manually with Tracking # NA Procedure/Observations: At 45 Minutes I Automatically Storage Location/Condition: Proke 65/5°C Dissolution performed by DMNS on Addentific Sample Diluted by: Collina Used: Runtine: Wester Tracking #: Mobile Phase: Calibration Standard: Column Used: Runtine: Wolume injected:				
Media Delivery Tracking # NA Media Delivery Calibration Due: NA Media Vol. (mlt) / Apparatus 900		31Dec[+	-	
Media Delivery Calibration Due: NA Media Vol. (ml.) / Apparatus 900 / 6	Dissolution Media (Lot/PN)			
Media Vol. (mL) / Apparatus 900 / 60 Stirring Speed (rpm) 3 Stirring Speed (rpm) NA Filter (cannula tin) NA Filter (syringe filter) 0 Stirring Speed (rpm) NA Filter (syringe filter) 0 Stirring Speed (rpm) 3 Stirring Speed (rpm) 5 Stirring				
Stirring Speed (rpm)	Media Delivery Calibration Due:			
Sinkers (Type) NA Sinkers (Type) NA Filter (cannula tip) NA Sample filter) Sample filter (syringe filter) Sample filter (syr	Media Vol. (mL) / Apparatus			1
Filter (cannula tip) Filter (cannula tip) Filter (cyringe filter) ### Option	Stirring Speed (rpm)		····	
Filter (syringe filter) Sample Times (minutes) 45 Sample Times (minutes) 45 Strange Individed Performed: Initials: DMS Date: 04 Jan16 Strange number: Vessel # DMS Start Temp. End Temp. End Temp. Vessel Temperatures taken: Automatically Automatically Automatically NA Procedure/Observations: At 45 Minutes / The tablets and tablets are included by DMS Storage Location/Condition: Prope (65/5°C) Dissolution performed by DMS ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by: Storage Location Standard: Column Used: Runtime: Volume injected:	Sinkers (Type)	NA		
Sample Times (minutes) Sample Times (minutes)	Filter (cannula tip)		4.	
Height Check Performed: Initials: DMS Date: 04 JAM16 Shark Center Check Performed: Initials: DMS Date: 04 JAM16 DMS DMS DATE: 04 JAM16 DMS	Filter (syringe filter)	0.45 um Nylon		
Shaft Center Check Performed: Initials: DM 5 Date: 04.50.014 Auto sampler used?	Sample Times (minutes)	45	φ	37.3 °C 37.3 °C
Withdraw Volume (mL) Vessel Temperatures taken: Automatically Amanually with Tracking #	Height Check Performed:		Sample number:	
Withdraw Volume (mL) Vessel Temperatures taken: Automatically Amanually with Tracking #	Shaft Center Check Performed:	Initials: Dr 5 Date: 0450016	Vessel # 200	Start Temp. End Temp.
Vessel Temperatures taken: Automatically Manually with Tracking #	Auto sampler used?	☐ Yes		°C
Replacement Media Temperatures Taken With Tracking #	Withdraw Volume (mL)	10		°C °C
Storage Location/Condition: Probe 65/5°C Expiration Date:	Replacement Media Temperatures T	aken With Tracking #	NA	<u>-</u>
Dissolution performed by DMS on A45amt 045amt ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by: □ HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Verification Standard: Column Used: Runtime: Volume injected:				
ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by: HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected: Volume injected: Column Used: Volume injected:	Storage Location/Condition: Prov	e 65/5°C Expire		
Sample Dilution: Diluent: Sample Diluted by: HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected:	Dissolution performed by DMS	on 845an16 02	<u>J</u> an17	
System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected:				
System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected:	Sample Dilution: Dilu	ient:	_Sample Diluted by:	
Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected:	☐ HPLC			
Volume injected:	Mobile Phase: Calibration Standard: Verification Standard: Column Used:			

	DISSOLUTION CHECK	LIST			
Batch ID DISL - M	A . (70117 - Test Sampl	eD 553016 05529878			
Active Ingredient Weight: 1652.8 DISSOLUTION OPERATING CO	mg Stage: <u>_</u> NDITIONS				
Sample brought to room temperature Dissolution System	in a desiccator: Yes	Sample number: 5530169, 5530170 Vessel # Start Temp. End Temp 4 36.7 °C 31.0 °C			
Dissolution System Calibration Due: Dissolution Media (Lot/PN) Media Delivery Tracking #	31 pec 17 DISL-HCL-1701US-01, DISZ-HCL-1701 NA		()		
Media Delivery Placking # Media Delivery Calibration Due: Media Vol. (mL) / Apparatus	NA 966 / ω	Vessel # Start Temp. End Temp 3 36.6 °C 36.7 °C	C		
Stirring Speed (rpm) Sinkers (Type)	75 NA NA	4 36.6 °C 36.9 °C Sample number: \$\leq 3016 °C \$\leq 36.9 °C Vessel # Start Temp. End Temp	0		
Filter (cannula tip) Filter (syringe filter) Sample Times (minutes)	D. ASAM WYOUN	5 36.5 °C 36.9 °C 6 36.8 °	C		
Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL)	Initials: DMS Date: FIUNT Initials: DMS Date: FIUNT DA	8217/7-0). C C		
	automatically Manually w	vith Tracking# 015806			
Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At 60 Minutes, the tablets are disintly rated.					
Storage Location/Condition: Probable Dissolution performed by		ation Date:			
ANALYTICAL METHOD Sample Dilution: Dilu	ent:	Sample Diluted by:			
□ HPLC			7		
Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected:					
Sample Set Method: Analytical Method Performed By:			1		

OR. F. DMS 17 Jan 17

Batch ID_DISU-1	M H- 170111-1 Test Sample	m 5529878		n =
Active Ingredient Weight: 1652.	mg Stage: 1		70	Die
DISSOLUTION OPERATING CO.	NDITIONS	C1hom	5530171	
Sample brought to room temperature	in a desiccator: yes	Sample number:	Start Temp.	End Temp.
Dissolution System	01+14	Vessel #	3/1.9°C	37.2°C
Dissolution System Calibration Due:	31 Dec 17	1	36.7 °C	37.2 °C
Dissolution Media (Lot/PN)	DISL-CB-17010-01	_ 2		57.2 0
Media Delivery Tracking #	NA	Sample number:	5530191	E. J Tomp
Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	End Temp. 372 °C
Media Vol. (mL) / Apparatus	900 / 6	3	36.7 °C	
Stirring Speed (rpm)	75	4	36.0 °C	37.2 °C
Sinkers (Type)	NA	Sample number:	553017	
Filter (cannula tip)	NA	Vessel #	Start Temp.	End Temp.
	0 4 Sum Nylon	5	36.4 °C	37.2 °C
Filter (syringe filter)	(0()	(0	36.5 °C	37.2°C
Sample Times (minutes)	Initials: DMS Date: ITUNI7	Sample number:		
Height Check Performed:	Initials: DMS Date: ITAMI?	Vessel # Dm		End Temp.
Shaft Center Check Performed:	☐ Yes ☐ No		oc °C	°C
Auto sampler used?	1 les La Ro		°C	°C
Withdraw Volume (mL)	U		1 2 /	
, coper rem-		th Tracking #	79019	
Replacement Media Temperatures T	aken With Tracking #	NA		
Procedure/Observations:				
2			4	
A 1 450	ablets are complete	la disintec	wated.	
At 75 MINURS, THE T	would have compare	0(131011	,,,,,,	
Storage Location/Condition: P1015	e 105/5°C Expira	tion Date:		= <u>-</u> V
Storage Location/Condition. P1015	1,200			
Dissolution performed by	on IIJan17			
ANALYTICAL METHOD				
ANALY HEAL METHOD		Comple Diluted by	,•	
Sample Dilution: Dil	uent:	_Sample Diffuted by	•	
☐ HPLC				
System Tracking #:				
Mobile Phase:				
Calibration Standard				
Description				
Runtime:				
The state of the s				
Sample Set Method: Analytical Method Performed By:				
Analytical Method Performed By:				

UR.E. DMS 11Jan17

Sample brought to room temperature	in a desiccator: Yes
Dissolution System	011565
Dissolution System Calibration Due:	3IDECT7
Dissolution Media (Lot/PN)	ESXX-S-170105-05
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 16
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: 06 Jan 7
Shaft Center Check Performed:	Initials: DMS Date: 0(0) TUNI 7
Auto sampler used?	☐ Yes
Withdraw Volume (mL)	10

Sample number:	553 017	
Vessel #	Start Temp.	End Temp.
1	37.4 °C	374 °C
2	37.4 °C	37.4 °C
Sample number:	SS3017	
Vessel #	Start Temp.	End Temp.
3	37-3 °C	37-3 °C
4	37.3 °C	37.2 °C
Sample number:	553019	2
Vessel#	Start Temp.	End Temp.
5	37-4 °C	37.4 °C
6	37-3 ℃	37.3 °C
Sample number:		
Vessel # DIM	Start Temp.	End Temp.
	Start Temp.	°C
	°C	°C,

Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking #
Replacement Media Temperatures Taken With Tracking #NA
Flocedure Observations.
At 45 minutes the tabuis appeared compared
Procedure/Observations: At 45 minutes the tables appeared completely disintegrated.
Storage Location/Condition: Prope 65/56 Expiration Date:
Dissolution performed by NMS on OWNY
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:

Batch ID DISL-MA-170117-1 Test Sample ID 55 Z 9879						*Property
Active Ingredient Weight: 1415. (
DISSOLUTION OPERATING CO	NDITIONS		_			
Sample brought to room temperature		yo5		Sample number:	5530173,	
Dissolution System	0115105	J		Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Due:	SIDECT]	<u> </u>	36.9 °C	37.4 °C
Dissolution Media (Lot/PN)	DISL-HCL-1	701160-04		ν	36.8°C	37.3 °C
Media Delivery Tracking #	NA			Sample number:	5530173,	5530174
Media Delivery Calibration Due:	NA			Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	90	0/0		3	36.6 ℃	31.2 °C
Stirring Speed (rpm)	75 NA	·		4	36.5 ℃	37.2 °C
Sinkers (Type)	NA			Sample number:	5530173,5	T
Filter (cannula tip)	11/7			Vessel #	Start Temp.	End Temp.
Filter (syringe filter)	0.451AM	MAIDN		5	36. 7°C	37.2 °C
Sample Times (minutes)	60			<u> </u>	36.6°C	37.2 °C
Height Check Performed:	Initials: NMS	Date: 17JUN17		Sample number:	G T	End Tomp
Shaft Center Check Performed:	Initials: DMS	Date: 17 JUNI7		Vessel # One	Start Temp.	End Temp.
Auto sampler used?	□ Yes ☑ 1	No			Ficuntion C	°C
Withdraw Volume (mL)	10		Ì		/°C-	<u> </u>
<u> </u>	Automatically	Manually v	vit	h Tracking# <u>@1</u>	580G	
Replacement Media Temperatures T	aken With Tracl	king#		NA		
_						
Procedure/Observations:				,		
At 60 minutes, the	tablets	are distr	ĮΗ	egrafea.		
Storage Location/Condition: P(b)	<u>oe 65/5°C</u>			ion Date:		
ANALYTICAL METHOD				- 1 DU . II		
Sample Dilution: Dilu	uent:			Sample Diluted by	/:	
□ HPLC						
System Tracking #:						
Calibration Standard:						
Verification Standard:			_			
Column Used:						
Runtime:						
Volume injected:						
Sample Set Method:						
Analytical Method Performed By:	····					

Batch ID DISL- MA-170111-1 Test Sample ID 5529879				
Active Ingredient Weight: 1415. 4	mg Stage:		9	olet
DISSOLUTION OPERATING CO	n a desiccator: Ues	Sample number:	5530175	
Sample brought to room temperature i	,	Vessel #	Start Temp.	End Temp.
Dissolution System	011565	V CSSCI II	37,0°C	37.4 °C
Dissolution System Calibration Due:	31 Dec17		36.8 °C	37.4 °C
Dissolution Media (Lot/PN)	DISL-CB-170110-01	2		37.1
Media Delivery Tracking #	NA	Sample number:	12.10	P. J.Tamm
Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900 / 6	3	36.5 °C	37.2 °C
riedia voi. (mb) / ripparatus	75	4	36.5 °C	37. 2 °C
Stirring Speed (rpm)	NA	Sample number:	553017	5
Sinkers (Type)	NA	Vessel#	Start Temp.	End Temp.
Filter (cannula tip)		<	36.8 °C	37.3 °C
Filter (syringe filter)	0.4 Sum Nylon	(o	36.7 °C	37.3 ℃
Sample Times (minutes)	00	Sample number:		
Height Check Performed:	Initials: DMS Date: 1174117	The state of the s	Start Temp.	End Temp.
Shaft Center Check Performed:	Initials: DMS Date: NJUM 7	Vessel # DAYS	1/Juni 7°C	°C
Auto sampler used?	☐ Yes ☐ No		"San 7°C	°C
Withdraw Volume (mL)	T U		C	L.
	tablets are c			
Storage Location/Condition: Probable Dissolution performed by 1910		tion Date:		_
ANALYTICAL METHOD Sample Dilution: Dilution:	uent:	_Sample Diluted by	/:	
□ HPLC	M. (1998/1991)		-	
System Tracking #:				
Mobile Phase:				
Calibration Standard:				
Verification Standard:				
Column Used:				
Runtime:				
Sample Set Method:				
Analytical Method Performed By:				

1 R.E. PMS 11 Tan 17



Batch ID DISL - MA - 170 105-2 Test Sample ID 5529881

Active Ingredient Weight: 12778 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-5-170105-05, U
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: 06Jan 17
Shaft Center Check Performed:	Initials: DMS Date: Noruni
Auto sampler used?	☐ Yes
Withdraw Volume (mL)	10

Sample number:	5530170	
Vessel #	Start Temp.	End Temp.
1	36.8 °C	37-3 ℃
2_	36.7 °C	37.3 ℃
Sample number:	553017	6
Vessel #	Start Temp.	End Temp.
3	36.7 ℃	37-2 °C
4	36.6°C	37.2°C
Sample number:	553017	6
Vessel #	Start Temp.	End Temp.
5	36.8°C	37-2 °C
6	3(0-5 °C	37.2 ℃
Sample number:		
	Start Temp.	End Temp.
4775	Start Temp.	°C
	Z°C	°C

William Voia						19	
Vessel Tempera	atures taken:	☐ Automatica	ally 💆 Man	ually with T	racking #_	004026	
INCOMPANIES ALL DE		was Takan With	Tracking #	NA	Λ		
Replacement N	ledia Temperau	ures Taken With	Tracking "				
Procedure/Obse	ervations:						
At a	as minu	LHS The	tabuts	ave	com	surriy	

At 4s minutes The tablets are completely disintegrated.

Storage Location/Condition: Probe (05 5°C) Dissolution performed by DW/5 on	Expiration Date:
ANALYTICAL METHOD Sample Dilution: Diluent: HPLC	Sample Diluted by:
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-170 [17-] Test	Sample ID_SS	79881		
)ji) \	
Active Ingredient Weight: 1277.8 mg Stage: DISSOLUTION OPERATING CONDITIONS		7.	(
Sample brought to room temperature in a desiccator:			30177	SS 30178
Dissolution System	Vessel		Start Temp.	End Temp.
Dissolution System Calibration Due: 3106(17			36.8 °C 36.1 °C	31.3 °C 31.3 °C
Dissolution Media (Lot/PN) DISC_M(1-170116-	04 2		36. 1 ° C SS30197, S	
Media Delivery Tracking # NA	Sample		>> <i>5011.4₎ .</i> Start Temp.	End Temp.
Modia Delivery Calibration Due: NA	Vessel 3	"	36.6 °C	313 ℃
Media Vol. (mL) / Apparatus	 - 3		36.6° °C	37-3 °C
Stirring Speed (rpm)			530177,	5530178
Sinkers (Type)	Vessel		Start Temp.	End Temp.
Filter (cannula tip) NA Since Of the Control of t			36.6 °C	37.2 ℃
Filter (syringe filter) 0.45 eym Nylon			36.6 °C	31-3 °C
Sample Times (minutes) Height Check Performed: Initials: OMS Date: 171	rimia Sampl	e number:		
	TIME Vesse	The same of the sa	Start-Temp.	End Temp.
Shart Contor Chest	Jews-11-		17008Q	°C
Auto sampler useur			°C	-G
Withdraw Volume (mL)		# 016	206	
Vessel Temperatures taken: ☐ Automatically ☐ Mar	ually with Tracki	ng# <u>U</u>	30.0	
Replacement Media Temperatures Taken With Tracking #	<u>NA</u>			
Procedure/Observations:			n	
At 60 minutes, the tablets are	disinte	grate	· · · · · · · · · · · · · · · · · · ·	
Storage Location/Condition: Probe US/5°C Dissolution performed by PMS on 1777 ANALYTICAL METHOD				
Sample Dilution: Diluent:	Sample	e Diluted by.		
□ HPLC				7
System Tracking #:				
Mobile Phase:				
Calibration Standard:				
Verification Standard:				
Column Used:				
Runtime:				
Volume injected:				
Sample Set Method:				
Analytical Method Performed By:				

Batch ID DISL-M	A-170111-1 Test Sampl	e D <u>552988</u>	1
Active Ingredient Weight: 1277.			ANI CO
DISSOLUTION OPERATING CO			
Sample brought to room temperature	in a desiccator: UeS	Sample number:	5530179
Dissolution System	1 1171	Vessel#	Start Temp. End Temp.
Dissolution System Calibration Due:	31 Dec17		37.1 °C 37.2 °C
Dissolution Media (Lot/PN)	DISL-CB-17011U-01		37.0 °C 37.2 °C
Media Delivery Tracking #	NA	Sample number:	Start Temp. End Temp.
Media Delivery Calibration Due:	NA	Vessel #	
Media Vol. (mL) / Apparatus	900/0	$\frac{3}{7}$	36,9 °C 37.2 °C 37.0 °C 37.2 °C
Stirring Speed (rpm)	75	4	
Sinkers (Type)	NA	Sample number:	Start Temp. End Temp.
Filter (cannula tip)	NA NA	Vessel#	36.9 °C 37.2°C
Filter (syringe filter)	0.45um Ny10N	5	36.9 °C 371°C
Sample Times (minutes)	(00	<u> </u>	
Height Check Performed:	Initials: DMS Date: Jun 17	Sample number:	Start Temp. End Temp.
Shaft Center Check Performed:	Initials: DMS Date: Tan 17	Vessel # DMS	°C °C
Auto sampler used?	☐ Yes No		Janiz °C
Withdraw Volume (mL)	10		
Vessel Temperatures taken:	Automatically Manually v	with Tracking # <u>OC</u>	14026
Replacement Media Temperatures T	aken With Tracking #	NA	
Desardura/Observations			_
At 45 minutes the	l film	ala lalia	Enclosing Hed.
At Asminutes the	tablets are com	purely als	integral
		,	
	. (. C < 0 (ration Date:	-
Storage Location/Condition: Prob	e 05/00 Exp		
Dissolution performed byD	MS on <u>11JUN17</u>		
Dissolution personal sy			
ANALYTICAL METHOD			
Sample Dilution: Dil	uent:	Sample Diluted b	y:
LT TIDE C			
System Tracking #:			
Mobile Phase: Calibration Standard:			
Verification Standard:			
Column Used:			
Runtime: Volume injected:			
Sample Set Method: Analytical Method Performed By:			
Alialytical Method I chornica Dy.			

Batch ID DISL - MA - 170105 - Z Test Sample ID 55 2 9882

Active Ingredient Weig	nt: 1653.4	_ mg	Stage: 1	
THE PERSON OF THE	NAMED AND A STATE OF THE PARTY AND A STATE OF	\mathbf{DTTION}	JC	

Active ingredient weight.	*****
DISSOLUTION OPERATING CO	NDITIONS
Sample brought to room temperature	in a desiccator: Ves
Dissolution System	011865
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 16
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 MM NYION
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: 0 W JUNI
Shaft Center Check Performed:	Initials: DMS Date: De Jani
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	370°C	37.4°C
Sample number:	5530180)
Vessel #	Start Temp.	End Temp.
2	36.9 °C	37.3 °C
4	36.8 ℃	37.3 °C
Sample number:	5530180	0
Vessel #	Start Temp.	End Temp.
L VESSEL#		
vessei#	37.0 °C	37.2 °C
5 (2	37.0 °C 37.0 °C	37.2 °C 37.2 °C
5 6	0 0	
5 & Sample number:	37.0°C	
5 & Sample number:	37.0°C	34.2 ℃
5 & Sample number:	37.0 °C	37.2 °C End Temp.

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: Proble 65/5°C Expiration Date: Dissolution performed by DMS on OUTUN 17 ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by:
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- RA	A-170117-1 Test Sample	m 557 98	8 <u>L</u>	
	3			
Active Ingredient Weight: 1653 · 4				
DISSOLUTION OPERATING COM	n a desiccator: U25	Sample number:	55301815530182	
Sample brought to room temperature i	011565	Vessel #	Start Temp. End Temp.	
Dissolution System Dissolution System Calibration Due:	310017		37.2 °C 37.5 °C	
Dissolution System Cambration Duc.	DISL-HCL-170116-04	2	37.1 °C 37.5 °C	
Dissolution Media (Lot/PN) Media Delivery Tracking #	NA	Sample number:	3 2 7/2	
Media Delivery Calibration Due:	NA	Vessel#	0.200	
Media Vol. (mL) / Apparatus	900 / 6	3		
Stirring Speed (rpm)	75	4	36.8 °C 37.3 °C 5530187	
Sinkers (Type)	NA	Sample number:	Start Temp. End Temp.	
Filter (cannula tip)	NA	Vessel#	37.0°C 37.5°C	
Filter (syringe filter)	0.45 mm N/10M	5	37.0 ℃ 37.5 ℃	
Sample Times (minutes)	<u>(0)</u>			
Height Check Performed:	Initials: OMS Date: 17 JUN17	Sample number: Vessel # Dy	Start Temp. End Temp.	
Shaft Center Check Performed:	Initials: 0MS Date: 17 JUNI7	Vessel #	5/7/C/C ~ °C	
Auto sampler used?	☐ Yes ☑ No		&C - °C	
Withdraw Volume (mL)				
Vessel Temperatures taken:	Automatically Manually w	rith Tracking #	580Q_	
Replacement Media Temperatures T	aken With Tracking #	_NA		
=				
Procedure/Observations:				
At 60 minutes	s, the tabless a	ve alisinte	grafed.	
Storage Location/Condition: Prop Dissolution performed byDr	76. 9. 9. 1	ration Date:		
ANALYTICAL METHOD Sample Dilution: Di	bront!	Sample Diluted b	oy:	
	nient.	·		
☐ 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-	ЛА-170111-1 Т	est Sample l	D <u>55298</u> 9	<u> </u>	132
Active Ingredient Weight: 1653 DISSOLUTION OPERATING CO	4 mg Stage: 1				
Sample brought to room temperature		S	Sample number:	5530183	<u> </u>
Dissolution System	011565		Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Due			l .	36 · 9 °C	37.4 °C
Dissolution Media (Lot/PN)	DISL-(B-1701	10-01	2	36,7℃	37.4 °C
Media Delivery Tracking #	NA		Sample number:	553018	
Media Delivery Calibration Due:	NA		Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900 /6		3	36.5 ℃	37.3 °C
Stirring Speed (rpm)	75		4	36,5 °C	37.2 °C
Sinkers (Type)	NIA		Sample number:	553018	
Filter (cannula tip)	NA		Vessel#	Start Temp.	End Temp.
Filter (syringe filter)	0.45 MM NYIC) V 1	5	36.8 °C	374 °C
Sample Times (minutes)	(00)		(y	36.7 °C	37.3 ℃
Height Check Performed:	Initials: 10MS Date:	11 JUNI7	Sample number:		
Shaft Center Check Performed:	Initials: DMC Date:	1170017	Vessel # D M	Start Temp.	End Temp.
Auto sampler used?	☐ Yes ☐ No			11sunige	°C
Withdraw Volume (mL)	10			<u>°C</u> _	∞€
	Automatically □ N Faken With Tracking # _		h Tracking#0 NA		(ted.

Storage Location/Condition: Probe 65/5	Expiration Date:
Dissolution performed by	_ on
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:	

Batch ID_	DISL-MA-17	0\05- 2 Test Sar	mple ID 5529883	- A	1
	1525.7 mg	Stage:		1 1	

Active Ingredient Weight: 1525. DISSOLUTION OPERATING COL	<u>}</u> mg Stage: NDITIONS		1	
DISSOLUTION OF ENGLISH CO.	in a desiccator: Yes	Sample number:	5530184	•
Sample brought to room temperature	01714 l	Vessel #	Start Temp.	End Temp.
Dissolution System		1	372 °C	37.2 °C
Dissolution System Calibration Due:	ESXX-5-170106-02	2	37.1 °C	37.2 °C
Dissolution Media (Lot/PN)		Sample number:	553018	4
Media Delivery Tracking #	NA NA	Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	NA	3	37.0 °C	37.2 °C
Media Vol. (mL) / Apparatus	900 16	4	37.0 ℃	37.2°C
Stirring Speed (rpm)	T S	Sample number:	553018	
Sinkers (Type)	NA		Start Temp.	End Temp.
Filter (cannula tip)	NA	Vessel #	34.0 °C	37.2 °C
Filter (syringe filter)	0.45 ym Nylon	5	37.0 ℃	37.2 °C
Sample Times (minutes)	45	- G	37.0 -C	1.00
Height Check Performed:	Initials: DMS Date: 06 Jun 7	Sample number:	C T	End Tomp
Shaft Center Check Performed:	Initials: DMS Date: 0(0701)7	Vessel # Oms	Start Temp.	End Temp.
Auto sampler used?	☐ Yes No	. 73	0674717°C	°C
Withdraw Volume (mL)	10)		· · / °C	°C
Procedure/Observations: At 45 minutes but not entirely	the tablets as dissolved in the	e disinte media.	grated	
Storage Location/Condition: Proposition performed by DMS ANALYTICAL METHOD Sample Dilution:	on 06Jan17			
□ HPLC				
Calibration Standard				
Verification Standard:				

Column Used: Runtime:

Volume injected:

Sample Set Method:
Analytical Method Performed By:

Batch ID_	015L-MA-170118-1	Test Sample ID <u>5529883</u>

Active Ingredient Weight:	152 <u>5.7</u> mg	Stage: \(\frac{1}{2}\)
PERSON THE AND ADDED A	TIME COMBITIO	NC

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-HC6-170116-04	
Media Delivery Tracking #	NA	
Media Delivery Calibration Due:	NA	
Media Vol. (mL) / Apparatus	900/6	
Stirring Speed (rpm)	15	
Sinkers (Type)	NIT	
Filter (cannula tip)	NA	
Filter (syringe filter)	0.45 Um Nylovi	
Sample Times (minutes)	00	
Height Check Performed:	Initials: OMS Date: 1850417	
Shaft Center Check Performed:	Initials: MMS Date: 1854117	
Auto sampler used?	☐ Yes	
Withdraw Volume (mL)	10	

		<u> </u>
Sample number:	S\$30185,	5530186
Vessel #	Start Temp.	End Temp.
1	37.0 °C	313 °C
2	36-8 °C	37.2°C
Sample number:	553018S,	5530186
Vessel#	Start Temp.	End Temp.
3	36.7 °C	37.2 °C
4	36.8 °C	737.2 °C
•		1
Sample number:	5530185,	5530186
Sample number:	5530185,	
Sample number: Vessel #	Start Temp.	\$530186
	5530185, Start Temp. 36.7 °C	\$530/86 End Temp.
Vessel #	5530185, Start Temp. 36,7 °C	\$530/86 End Temp. 37.2 °C
Vessel # 5 () Sample number:	Start Temp. 36.7 °C 36.8 °C Start Temp.	\$530/86 End Temp. 37.2 °C
Vessel #	Start Temp. 36.7 °C 36.8 °C Start Temp.	\$530/86 End Temp. 37.2 °C 37.2 °C
Vessel # 5 () Sample number:	5530185, Start Temp. 36,7 °C 36,8 °C	5530/86 End Temp. 37.2 °C 37.2 °C

TYTERATORY TOTALLE			
Vessel Temperatures taken: Replacement Media Temperatur	☐ Automatically es Taken With Trackin	Manually with Tracking #NA	015806
*			
Procedure/Observations:			
At 60 minutes, th	e tablets ar	e disintegrated.	

Storage Location/Condition: Probe US Soc Omsolution performed by OMS on	Expiration Date:
ANALYTICAL METHOD Sample Dilution: Diluent: HPLC	Sample Diluted by:
System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime:	
Volume injected: Sample Set Method: Analytical Method Performed By:	12

Ratch ID	DISL-MA-170111-1	Test Sample ID_	5529883
Datelle	DIJI. 19111 1 1 2 111 1		

d	tic
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Active Ingredient Weight: 1525, 7 mg Stage: 1

DISSOLUTION OPERATING CO	NDITIONS				
Sample brought to room temperature in a desiccator: 19					
Dissolution System	017141 '				
Dissolution System Calibration Due:	31 De(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)	15				
Sinkers (Type)	NA				
Filter (cannula tip)	NA NA				
Filter (syringe filter)	0.4 Sum Nylon				
Sample Times (minutes)	(00				
Height Check Performed:	Initials: DMS Date: 1174/17				
Shaft Center Check Performed:	Initials: MMS Date: 1170017				
Auto sampler used?	☐ Yes No				
Withdraw Volume (mL)	į U				

Sample number:	553018	7
Vessel #	Start Temp.	End Temp.
(37.2 °C	31.3 °C
2	37.0 °C	37.2 ℃
Sample number:	553018	7
Vessel #	Start Temp.	End Temp.
3	37.0 °C	37.2 °C
4	37.1°C	37.2°C
Sample number:	553018	7
Vessel#	Start Temp.	End Temp.
5	36.9 °C	372 °C
Ce .	36.9 °C	37.2 °C
Sample number:		
Vessel # Dms	Start Temp.	End Temp.
	11Janize	°C
	00	071

Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking #OOGO 2 (a
Replacement Media Temperatures Taken With Tracking # NA NA
Procedure/Observations:
At 60 minutes the tablets are disintegrated complet
Storage Location/Condition: Probe 65/5°C Expiration Date: Dissolution performed by on
ANALYTICAL METHOD Sample Dilution: Sample Diluted by:
□ HPLC
System Tracking #: Mobile Phase:
Calibration Standard: Verification Standard:
Column Used:
Runtime: Volume injected:
Sample Set Method: Analytical Method Performed By:

70-111	DISSOLUTION	CHECKLIST
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Batch ID DISL-IM	1-170105-2 11-170101-2 Test Sampl	e I	D 552988	54	
Active Ingredient Weight: 1496.	mg Stage: L				
DISSOLUTION OPERATING CO	NUTTIONS	Ī	Sample number:	553018	8
Sample brought to room temperature	in a desiccator:	ŀ	Vessel #	Start Temp.	End Temp.
Dissolution System	011503	ł	V 63361 II	37.4 °C	37.4 °C
Dissolution System Calibration Due:	ESXX-S-170106-02, ESXX-S-176	wo (a	-03 2	37.4°C	37.4 °C
Dissolution Media (Lot/PN)		100	Sample number:	553018	8
Media Delivery Tracking #	NA NA		Vessel#	Start Temp.	End Temp.
Media Delivery Calibration Due:	900 16		3	37.2 °C	37.3 °C
Media Vol. (mL) / Apparatus	75		4	37.1 ℃	37.3 °C
Stirring Speed (rpm)	NA	"	Sample number:	553018	
Sinkers (Type)	NA	1	Vessel#	Start Temp.	End Temp.
Filter (cannula tip)	0.45 um Mylon	1	5	37.3 °C	37.4 °C
Filter (syringe filter) Sample Times (minutes)	45		6	36-7 °C	37.3 ℃
Height Check Performed:	Initials: Dins Date: 06 Jun 7		Sample number:		E 1 Tames
Shaft Center Check Performed:	Initials: DM 5 Date: 0(0 Jan 17		Vessel #	Start Temp.	End Temp.
Auto sampler used?	☐ Yes No	1		Dog C	°C °C
Withdraw Volume (mL)	10			62	
Vessel Temperatures taken:			h Tracking #	4026	
Replacement Media Temperatures T	Caken With Tracking #		NA		
Procedure/Observations:					
Procedure/Observations.					
At 45 minutes,	the tablets i	h	ave con	nputery	
disintegrated.				J	
Storage Location/Condition: Proj	OP. (05/5°C Expi	irat	ion Date:		<u> </u>
Storage Location/Condition					
Dissolution performed by	on Owself I		=		
ANALYTICAL METHOD					
Sample Dilution:Di	luent:		_Sample Diluted by	/:	
☐ HPLC					
System Tracking #:					
Mobile Phase:					
Calibration Standard:					
Verification Standard:					
Column Used:					
Runtime:					

Volume injected:
Sample Set Method:
Analytical Method Performed By:

(i) R.E. PMS 06 Jan 17

Batch ID 0/51-W	1A-170118-1 Test Sampl	le I	D 55298	84	
Active Ingredient Weight: 1496. CODISSOLUTION OPERATING CO	mg Stage: 1			Rilyo	
Sample brought to room temperature		[Sample number:	553018Q, S	
Dissolution System	011565	Ī	Vessel#	Start Temp.	End Temp.
Dissolution System Calibration Due:		I	1	37.1 °C	37.5 °C
Dissolution Media (Lot/PN)	DISL-HCL-170116-03		2	37.1 °C	37.5°C
Media Delivery Tracking #	NA		Sample number:	55301894	5530190
Media Delivery Calibration Due:	NA NA		Vessel#	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900/6		3	37.0 °C	37.4 °C
	75		4	36.8 °C	37.3 °C
Stirring Speed (rpm)	NÁ		Sample number:	5530189	,55 <u>30190</u>
Sinkers (Type)	NA		Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	0.45 UM NYION	1	- 5	37.0 °C	3 7-4°C
Filter (syringe filter)	60	1	φ	36.9 °C	37.4 °C
Sample Times (minutes)	Initials: OMS Date: 18JUN17		Sample number:		
Height Check Performed:	Initials: OMS Date: 18 TUNI	ħ.		Start Temp.	End Temp.
Shaft Center Check Performed:	Yes ⊠ No	ſ		& TCC °C	°C
Auto sampler used? Withdraw Volume (mL)	1()	1		18 TCHITT OC	°C
	Automatically 💢 Manually v	witl	h Tracking# <u>OI</u>	580 6	
1 6 5 5 5 1 × F					
Replacement Media Temperatures T	aken With Tracking #		NA		
Procedure/Observations:					
At 600 minuales Luc		,)	
mos minor of the	tablets are di	15	integrated	•	
			J		
O	(-/-0/ Fami	not:	ion Date:		
Storage Location/Condition: Proh	<u>e 65/5 C</u> Expi		ion Date:		_
Dissolution performed by	ms on 187417		=		
Dissolution performed by					
ANALYTICAL METHOD					
Sample Dilution: Dil	nent:		Sample Diluted by	/:	
Sample Dilution:Dir	uent.		_ 1		
□ HPLC					
System Tracking #:					
Mobile Phase:					
Calibration Standard:					
Verification Standard:					
Column Used:					

Sample Set Method:
Analytical Method Performed By:

Batch ID | DISL - MA - 170111 - | Test Sample ID | 55 2 9 8 8 4

Batch ID PISL-	MA-1401(1-1 Test Sample	em <u> 33 2 18 8</u>		1
Active Ingredient Weight: 1496	lo mg Stage: 1			1
DISSOLUTION OPERATING CO	<u> </u>			
Sample brought to room temperature	in a desiccator: UES	Sample number:	553019	D 175
Dissolution System	011565	Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Due:	31Dec17	1	37.0℃	37.4 °C 37.4 °C
Dissolution Media (Lot/PN)	DISL-CB-170110-01	2	36.9 °C	
Media Delivery Tracking #	NA	Sample number:	SS3019	End Temp.
Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	37.3°C
Media Vol. (mL) / Apparatus	900 / 6	3		37.2°C
Stirring Speed (rpm)	75	4	36.6 °C	
Sinkers (Type)	NA	Sample number:	< 53010	End Temp.
Filter (cannula tip)	NA	Vessel #	Start Temp.	37.3 °C
Filter (syringe filter)	0.4sum Nylon	5		37.3 °C
Sample Times (minutes)	(00)	0	36.8 °C	31.5
Height Check Performed:	Initials: MMS Date: 113017	Sample number:	Stort Temp	End Temp.
Shaft Center Check Performed:	Initials: Date: 11 JUNI 7	Vessel#	Start Temp.	°C °C
Auto sampler used?	☐ Yes ☐ No		Start Temp.	e _C
Withdraw Volume (mL)	10		<u></u>	
Replacement Media Temperatures 7 Procedure/Observations:			disinteg	vated.
Storage Location/Condition: Production Production performed by	ns on 1174117			
Sample Dilution: Di	luent.	Sample Diluted by	y:	
Sample Dilution:Di	iuonti			
☐ HPLC				
System Tracking #:				
Mobile Phase:				
Colibration Standard				
Verification Standard:				
Y OI II IOUGOII O CUITAUX GI				

Runtime:

Volume injected:

Sample Set Method:
Analytical Method Performed By:

	DISSOLUTION CHEC	
Batch ID	DISL-MA-170105-2 Test San	nple ID 5 5 2 7883

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1	1
Jack .	1
V	- (

Active Ingredient Weight: _	1669.6 mg	Stage:
Titliff ingress on one of	INC COMPITIO	NC

Sample brought to room temperature	in a desiccator: 1 463
Dissolution System	017191
Dissolution System Calibration Due:	310ec10
Dissolution Media (Lot/PN)	ESXX-S-170106-03
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 / (0
Stirring Speed (rpm)	78
Sinkers (Type)	NA
Filter (cannula tip)	NA NA
Filter (syringe filter)	0.45 ym aylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DMS Date: OUTUN
Shaft Center Check Performed:	Initials: 1) M S Date: () (0 TUM
Auto sampler used?	☐ Yes ✓ ✓ No
Withdraw Volume (mL)	10

Sample number:	553019	12
Vessel#	Start Temp.	End Temp.
1	37.0 °C	37.2°C
2	36.8 °C	37.2°C
Sample number:	553010	12
Vessel#	Start Temp.	End Temp.
3	36.7 ℃	37.2°C
4	34.7°C	31.2°C
Sample number:	55301	92
Vessel#	Start Temp.	End Temp.
5	36.8 ℃	37.2 °C
6	36.7℃	37.2°C
Sample number:		_
Vessel # PM	Start Temp.	End Temp.
	a taige:	°C
	°C	°C

Withdraw Volume (mL)	oC.	
William Volume (IIII)	1:01	
Vessel Temperatures taken: Automatically Manually with Tracking #	74026	
Replacement Media Temperatures Taken With Tracking #NA	1	Ject.
Procedure/Observations: At 45 minutes the tablets are completely of but not completely dissolved in the medic	disintegr	arcuj
At 45 minutes The Tursel in the modice	1.	
but not computely dissolved " " " " " "	λ ,	
, J		
Storage Location/Condition: Probe 65/56 Expiration Date:	ON THE PARTY NAMED IN COLUMN TO THE PARTY NAM	- 9
A CATULA 17		
Dissolution performed by DMS on 000017		
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:		

			ンぐ	
Batch ID DISL -IM	A-170118- Test Sample	ED 552988	<u> </u>	
Active Ingredient Weight: 1661.1				
DISSOLUTION OPERATING CO	NDITIONS		553004	
Sample brought to room temperature	in a desiccator: Цеб	Sample number:	5530193 5530194	
Dissolution System	0(7/4)	Vessel #		
Dissolution System Calibration Due:	31 Dec17	2.		
Dissolution Media (Lot/PN)	DISU-HCL-170116-03		36.7 °C 37.3 °C 5530194	
Media Delivery Tracking #	NA	Sample number:	Start Temp. End Temp.	
Media Delivery Calibration Due:	NA NA	Vessel #	36,7 °C 37.5 °C	
Media Vol. (mL) / Apparatus	900/0	3	36.8 °C 37.5 °C	
Stirring Speed (rpm)	75		5530193,5530194	
Sinkers (Type)	NA	Sample number:	Start Temp. End Temp.	
Filter (cannula tip)	NA NA	Vessel #	36.8 °C 37.4 °C	
Filter (syringe filter)	0.45 run Nylon	<u> </u>	36.7 °C 37.4 °C	
Sample Times (minutes)	(0)	Sample_number:		
Height Check Performed:	Initials: DMS Date: 18 TOM 7	Vessel # Dh	Start Temp. End Temp.	
Shaft Center Check Performed:	Initials: NY Date: \ TUNI	1 00001 11 (5)	18 18 TOURG °C	
Auto sampler used?	☐ Yes ☐ No		°C °C	
Withdraw Volume (mL)		rith Tracking #()	-12/	
Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At up minutes, the tablets are disintegrated. Large chunks of undisolved tablet are floating around the media.				
Storage Location/Conditions Cow Dissolution performed by)MS on 18 JUN 17			
Sample Dilution:Dil				
□ HPLC				
System Tracking #:				
Mobile Phase:				
Calibration Standard:				
Verification Standard:				
Column Used:				

Runtime:

Volume injected:
Sample Set Method:
Analytical Method Performed By:

7. lic

120112-1 Test Sample ID 552985

Ratch ID DISL-A	14-170112-1 Test Sample	ID 5529)	182
1669	lomg Stage: 1		
Active Ingredient Weight: 1669. DISSOLUTION OPERATING CON	DITIONS	1mher	5530195
Sample brought to room temperature in	n a desiccator.	Sample number: Vessel #	Start Temp. End Temp.
1 Discolution System		Vessel #	37-1 °C 37.3 °C
Dissolution System Calibration Due:	31 Dec 17	10-02 2	36.9 °C 37.2 °C
Dissolution System Dissolution Media (Lot/PN)	DISL-CB-170110-01, DISL-CB-1701	Sample number:	5530195
Modia Delivery Tracking #	NA	Vessel #	Start Temp. End Temp.
Media Delivery Calibration Due:	NA 900 / G	3	36.7 °C 37.2 °C
Media Vol. (mL) / Apparatus	900 10	4	1 7 C C
Stirring Speed (rpm)	NA	Sample number:	0001
Sinkers (Type)	NA	Vessel#	1 Diant 1 Diane
Filter (cannula tip)	0.45 um Nylon	5	36.8 °C 31.6 °C 36.6 °C
Filter (syringe filter)	(o ()	<u> </u>	J0:0 C 1311
Sample Times (minutes)	Initials: NMS Date: 12 Jun 7	Sample number:	Start Lemb. Ellu Lomp.
Height Check Performed:	Initials: 1919 5 Date: 12 Mil T	Vessel # Dins	12 True C °C
Shaft Center Check Performed:	□ Yes ☑ No		July/2°C °C
Auto sampler used? Withdraw Volume (mL)	10		
	Manually V	vith Tracking# <u>0</u>	04026
Vessel Temperatures taken:	11440	NA	
Replacement Media Temperatures T	Taken With Tracking #		1
	the tablets	- A . C	arated,
Procedure/Observations:	to think	ave chiz	when I.
At 60 minutes	100 TOTO 01.		
At GO			
· Wardition Ore	1 // PE	iration Date:	
Storage Location/Condition: Pro	12 table		
Dissolution performed by	on 127an17		
ANALYTICAL METHOD	Diluent:	Sample Diluted	l hv:
gle Dilution: D	Diluent:	Sample Direct	103.
☐ HPLC			
System Tracking #:			
Verification Standard:			
Column Used:			

Volume injected:
Sample Set Method:
Analytical Method Performed By:

Runtime:



Batch ID DISL-MA-170105-2 Test Sample ID 55 2 9 88 7

Batch ID DISL-M	4-170105-2 Test Sample	e п	0 33 6 3 80		
	mg Stage:				
Active Ingredient Weight: 145.0 DISSOLUTION OPERATING COL					
DISSOLUTION OF ERATING COL	in a desiccator: Ues		Sample number:	SS 3029	20
Sample brought to room temperature	OILS 65		Vessel #	Start Temp.	End Temp.
Dissolution System	31 De(17	ſ	(37.3 °C	37.4 °C
Dissolution System Calibration Due:	ESXX-S-170106-03		2	37-2 °C	37.4 °C
Dissolution Media (Lot/PN)	NA	Ţ	Sample number:	553020	
Media Delivery Tracking #	NA NA	[Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	900/6		3	37.1 °C	37.3 °C
Media Vol. (mL) / Apparatus	75		4	37.0 °C	37.3 °C
Stirring Speed (rpm)	NA	i	Sample number:	SS3020	
Sinkers (Type)	NA NA		Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	0.45 um Nylon		5	37.1 °C	31.4 °C
Filter (syringe filter)	45		C	37-0°C	37.3 °C
Sample Times (minutes)	Initials: OMS Date: OUTUNI?	-	Sample number:		
Height Check Performed:	Initials: DM S Date: DIO TUN	17	Vessel # Dhy	Start Temp.	End Temp.
Shaft Center Check Performed:	☐ Yes ☑ No		.73	OGHIN/9C	°C
Auto sampler used?	10	1		11/9C	°C_
Withdraw Volume (mL)			(1/1)	107/1	
Vessel Temperatures taken:	Automatically 💢 Manually v	with	n Tracking#	TUZU	
V CSSCI Temperature			NA		
Replacement Media Temperatures T	aken with Tracking #				
Procedure/Observations:				- · ·	
minutes +	s are completely		disintegrat	ecx.	
At 45 1 me table	3 Wil Court o	,	, ,		
				e e	
_	1				
Storage Location/Condition: Pro	60 60 Expi	irat	ion Date:		
Storage Location Condition	0670117	ļ			
Storage Location/Condition: Property Dissolution performed by	on <u>0 (0 0 0 11 1</u>		<u> </u>		
ANALYTICAL METHOD					
Sample Dilution: Dil	uent:		_Sample Diluted by	/:	
Sample Dilution:Dir	don.				
☐ HPLC					
		_			
System Tracking #:					
Mobile Phase:					
Calibration Standard:					
Verification Standard:		_			
Column Used:					
Runtime:		_			

Volume injected: Sample Set Method:

Batch ID DISL-MA-170118-1 Test Sample ID SSZ 9887				
Batch ID DISL-MA	1-170118-1 Test Sampl	e ID 3 > 2 4 8 8	Anger.	
Active Ingredient Weight: 145, 0	mg Stage:			
DISSOLUTION OPERATING CO	NDITIONS	Sample number:	5530197,5530198	
Sample brought to room temperature	in a desiccator: ye =	Vessel #	Start Temp. End Temp.	
Dissolution System	011203	V CSSCI #	37.1 °C 37.5 °C	
Dissolution System Calibration Due:	31 Dec 17	2	37.0 °C 37.5 °C	
Dissolution Media (Lot/PN)	DISC-FICE TIONS	Sample number:	5530197,5530198	
Media Delivery Tracking #	NA NA	Vessel #	Start Temp. End Temp.	
Media Delivery Calibration Due:	NA Cina / fa	3	36.8°C 31.5°C	
Media Vol. (mL) / Apparatus	900 / 6	4	36,7°C 37.4°C	
Stirring Speed (rpm)	7S N/T	Sample number:	(34)0.0	
Sinkers (Type)		Vessel #	Start Temp. End Temp.	
Filter (cannula tip)	NA N	V essei #	36° 7 °C 37.5 °C	
Filter (syringe filter)	0.45-M NYIOM	6	36.8 °C 37-5 °C	
Sample Times (minutes)	(0)	à la symbor		
Height Check Performed:	Initials: py Date: 18 JUNI 7	Vessel # DE	Start Temp. End Temp.	
Shaft Center Check Performed:	Initials: pms Date: 18JUN17	V C3301 II - 1) μ	75 18 JULEOT 9 °C	
Auto sampler used?	☐ Yes DNo		°C °C	
Withdraw Volume (mL)				
Vessel Temperatures taken:	Automatically \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	with Tracking #O	1780A	
Replacement Media Temperatures T	Taken With Tracking #	NA		
			i de la companya de	
Procedure/Observations:	s The total is a	. 1	ated.	
as in minute	5 The totallis al	re disintell	/4/	
AT GO VICTOR		U		
Storage Location/Condition: <u> </u>	e 65/5°C Exp	iration Date:		
Dissolution performed by DMS	THUTE! On ISTUNIT			
Dissolution performed by <u>DIMS</u>	On			
AND THE PROPERTY OF THE PROPER				
ANALYTICAL METHOD Sample Dilution: Di	1	Sample Diluted b	ру:	
	nuent:		•	
☐ HPLC				
System Tracking #:				
Mobile Phase:				
Calibration Standard:				
Verification Standard:				
Column Used:				
Runtime:				
Volume injected:				
Sample Set Method:				
Analytical Method Performed By:				

Batch ID DISL-MA-170125-3 Test Sample ID 5529887

	J		
Active Ingredient Weight: 145.0	_mg Stage: /		
DISSOLUTION OPERATING COM	(DITIONS	Gla numbor:	5530197
Sample brought to room temperature i	n a desiccator: Yes	Sample number: Vessel #	Start Temp. End Temp.
Dissolution System	<i>(1) 7(4)</i>	Vessel #	37.2 °C 37.1 °C
Dissolution System Calibration Due:	31Dec17	2	37.1 °C 37.1 °C
Dissolution Media (Lot/PN)	DISL-HCL-170119-02	Sample number:	5530197
Media Delivery Tracking #	NA	Vessel #	Start Temp. End Temp.
Media Delivery Calibration Due:	NA		37.1 °C 37.1 °C
Media Vol. (mL) / Apparatus	900/6	3, 4	37.1 °C 369 °C
Stirring Speed (rpm)	75		5530197
Sinkers (Type)	NA	Sample number:	Start Temp. End Temp.
Filter (cannula tip)	NA NA	Vessel #	36-9 °C 37-1 °C
Filter (syringe filter)	0.45um Nylon	.5	371 °C 37.0 °C
Sample Times (minutes)	60	G townshow	711 0 151
Height Check Performed:	Initials: DMS Date: 25 JUNI 7	Sample number: Vessel #	Start Temp. End Temp.
Shaft Center Check Performed:	Initials: OMS Date: 2S. KIN17	vessei#t	MS 2506 °C
Auto sampler used?	☐ Yes		Start Temp. End Temp. 75 25 6 °C 67 7 °C
Withdraw Volume (mL)	10	th Tracking # OC	
Replacement Media Temperatures Ta Procedure/Observations: At 60 MINUTES THE		sintegrat	ed.
Storage Location/Condition: Prob		ation Date:	
Dissolution performed by	on <u>25 JW11 +</u>	· ———	
ANALYTICAL METHOD		a 1 D9 / 15	
Sample Dilution: Dilu	uent:	_Sample Diluted b	y:
EL TIDI C			
System Tracking #:			
System Tracking #.			
Mobile Phase: Calibration Standard:			
Verification Standard:			
Column Used:			
Volume injected:			

Sample Set Method:

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

Active Ingredient Weight: 145.0 mg Stage: 1 DISSOLUTION OPERATING CONDITIONS					
			Sample number:	553019	9
Sample brought to room temperature	Olls(o)		Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Duo:	31 Dec 17		1	36.9°C	37.3 °C
Dissolution System Calibration Due:	DISL-CB-170110-02		2	36.8℃	37.3 °C
Dissolution Media (Lot/PN)	NA		Sample number:	553019	
Media Delivery Tracking #	NA NA		Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	900 16		3	36 · 6 ° C	37.Z °C
Media Vol. (mL) / Apparatus	75		4	34.6°C	37.2 °C
Stirring Speed (rpm)	NA		Sample number:	553019	9
Sinkers (Type)	<u></u>				End Temp.
Filter (cannula tip)	NA		Vessel #	Start Temp. 36.8 °C	37-3°C
Filter (syringe filter)	0.45 um wylon		<u> </u>		37.2°C
Sample Times (minutes)	(0) TTIME		6	36.7 °C	71.2.0
Height Check Performed:	Initials: MMS Date: 12 JUNI	<u></u>	Sample number:	C4 4 T	End Town
Shaft Center Check Performed:	Initials: DMS Date: 12 JUNI	7	Vessel #	Start 1 emp.	End Temp.
Auto sampler used?	☐ Yes 🏋 No	l	Vessel # Oms /2	Jun 17	°C
Withdraw Volume (mL)	(0)				°C
Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At (11) minutes the temperature distintegrated.					
Storage Location/Condition: Probe	$\frac{(\zeta)/\zeta^{c}(\zeta)}{(\zeta)^{c}}$ Expir	atio	on Date:		-
Dissolution performed by on 12 tan 17					
ANALYTICAL METHOD					
Sample Dilution: Dilu	ent:		Sample Diluted by:		
□ HPLC					
System Tracking #:	A CONTRACTOR OF THE CONTRACTOR				
Mobile Phase:					
		_			
Verification Standard:		_			
Column Used:					
Runtime:					
Volume injected:					

Sample Set Method:

Batch ID DISL-N	117-170 23-1 Test Sample	n <u>552988</u>	7	A A A A A
Active Ingredient Weight: 145.0	mg Stage: L		į	
DISSOLUTION OPERATING CO		G 1 1	CC 2 10C	
Sample brought to room temperature		Sample number:	SS 30190	
Dissolution System	017141 0	Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Due:		ì	36-9 °C	37-2 °C
Dissolution Media (Lot/PN)	DISL-CB-170123-01	2	36,7 ℃	37.1 ℃
Media Delivery Tracking #	NA NA	Sample number:	5530199	T
Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900/0	3	36.7 ℃	37-1 °C
Stirring Speed (rpm)	75	4	<u>36.7 °C</u>	37-1 °C
Sinkers (Type)	NA	Sample number:	553019	7
Filter (cannula tip)	NA	Vessel #	Start Temp.	End Temp.
Filter (syringe filter)	0.45m Nylon	5	36.6 ℃	37.0 °C
Sample Times (minutes)	(01)	6	367 ℃	37.1 °C
Height Check Performed:	Initials: OMS Date: 23 RIMI 7	Sample number:	1 2 1	
Shaft Center Check Performed:	Initials: DMS Date: 3350MIH		Start Temp.	End Temp.
Auto sampler used?	☐ Yes ☐ No	DW)	200°C	°C
Withdraw Volume (mL)	1()		Start Temp. Start Temp. Compared to the comp	°C
windraw volume (Inc.)	10		1 -1/27	
Vessel Temperatures taken: □ A Replacement Media Temperatures T Procedure/Observations:	aken With Tracking #	th Tracking #()() NA		Λ
At GO MINUTES	, the tablets o	ure disint	regrate	cl, but
they are not f	, the tablets of	e the solu	Hon.	
Storage Location/Condition: Prok Dissolution performed byOMS_	oe 65/5°C Expirat on 235W17	ion Date:		
ANALYTICAL METHOD				
Sample Dilution: Dilu	ent:	Sample Diluted by:		
□ HPLC				
System Tracking #:				
Mobile Phase:	and the land the same			
	and the state of t			
Calibration Standard:				
Verification Standard:				
-0				
Runtime:				
Volume injected:				1

Sample Set Method: