Batch ID DISL-MA	1-170 8-1 Test Sampl	le II	D <u>SSZ988</u>	8		
active Ingredient Weight: <u>1209. 4</u>	mg Stage: \					
DISSOLUTION OPERATING CO	NDITIONS					
ample brought to room temperature		Γ	Sample number:	5530201,	553020	7
Dissolution System	017141		Vessel #	Start Temp.	End Ter	
Dissolution System Calibration Due:		F	1	369 °C	373	°C
	DISL-HCL-170116-03, 0	r	2	36,7 °C	37.3	
Dissolution Media (Lot/PN)	NA NA	┢		SS 307.01,5		
Media Delivery Tracking #	NA NA		Vessel #	Start Temp.	End Ter	
Media Delivery Calibration Due:		\vdash	3	36.7 °C	37.3	
Media Vol. (mL) / Apparatus	900 / 6	H	4	36.7°C	31.3	
Stirring Speed (rpm)	NA	H	Sample number:	5530201,	553020	
Sinkers (Type)				Start Temp.	End Ter	
filter (cannula tip)	NA	ŀ	Vessel #	36.6 °C	37.2	
Filter (syringe filter)	0.45 um NyIVM	l ŀ	<u> </u>	36.7 °C	37-3	
Sample Times (minutes)	(0) C = C + 20 101 7	ŀ		Na. F	()-1-1)	
leight Check Performed:	Initials: OMS Date: 1870/13		Sample number:	Ctant Tomas	End Ter	mn
Shaft Center Check Performed:	Initials: YMS Date: 185W117	[Vessel #	Start Temp.	End 16	
Auto sampler used?	☐ Yes No	-	<i>P111</i>	18 Teure		<u>-₀€</u>
Withdraw Volume (mL)	10	L	Tracking #		<u> </u>	T
Replacement Media Temperatures Ta Procedure/Observations: † (10 MINUTES, TVU TO Storage Location/Condition: Probe Dissolution performed by	usters are distributed in the second	<i>F</i> e o	grafed. n Date:		-	
ANALYTICAL METHOD			lenele Dibredhen			
Sample Dilution: Dilu	ent:	S	sample Diluted by:			
□ HPLC						_
System Tracking #:						\dashv
Calibration Standard:						
Verification Standard:						
Column Used:						
- 1				···		
Volume injected:						

Sample Set Method:

Analytical Method Performed By:

ODISL-HCL-170116-02 also used. DMS 1870417

Ratch ID DISL-1	1A-170112-1 Test Samp	le I	D_55298	88
Active Ingredient Weight: 1209.4				
DISSOLUTION OPERATING CON	IDITIONS	_		(1)
Sample brought to room temperature in	n a desiccator: U-es		Sample number:	-5530230 5530203
Sample brought to room temperature in	017141		Vessel #	Start Temp. End Temp.
Dissolution System Calibration Due:	31Dec17			370 °C 37,2°C
Dissolution System Canonation Suc-	DISL-(B-170110-02		2	36.6 ℃ 37.2℃
	NA]	Sample number:	5 7 20 20
Media Delivery Tracking # Media Delivery Calibration Due:	NA]	Vessel #	Start Temp. End Temp.
Media Vol. (mL) / Apparatus	900/6]	3	
Stirring Speed (rpm)	75]	4	36.8 °C 37.2 °C
	NA	┇ '	Sample number:	\$\$30203
Sinkers (Type) Filter (cannula tip)	NA]	Vessel #	Start Temp. End Temp.
Filter (cannula up) Filter (syringe filter)	0.45 um Nylon	_		
Sample Times (minutes)	60]	6	36.6 °C 37.1 °C
Height Check Performed:	Initials: OMS Date: 12 JUNI	1	Sample number:	Start Temp. End Temp.
Shaft Center Check Performed:	Initials: OMS Date: 12 JUNI	1	Vessel # Dm	Start Temp. End Temp.
Auto sampler used?	☐ Yes No	_		°C °C
Withdraw Volume (mL)	, 0	_]		<u> </u>
			h Tracking#	407.60
V COSCI TOMPOSITION	-			
Replacement Media Temperatures Ta	aken With Tracking #		NA	
				. 1
Procedure/Observations: At 60 minutes the	and a second	_	lis in teard	ted.
as commingues the	e tablets our	\mathcal{C}	XIS IVI. I	
AT 60 MINIMICS				
Ondo	$\sim (. Exp$	nirat	tion Date:	
Storage Location/Condition: PMD4	20750			
Dissolution performed by	15 on12500111			
Dissolution performed 5				
ANALYTICAL METHOD				
Sample Dilution: Dil	want!		Sample Diluted b	y:
Sample Dilution:Dil	uent			
☐ HPLC				
System Tracking #:				
Carioration				
Verification Standard: Column Used:				
Runtime: Volume injected:				
G 1- Cat Mothod:				
Sample Set Method: Analytical Method Performed By:				
Analytical Method Performed Dy.				

OR.F. DMS 12Jan17

Height Check Performed: Initials: \(\text{Initials: \(\text{Imagents} \) \(\text{Date: \(\text{QJM17} \) \(\text{Sample number: } \) \(\text{Vessel # \(\text{DNO} \) \(\text{Start Temp. } \) \(\text{End Temp. } \) \(\text{Auto sampler used? } \(\text{Q Yes } \(\text{Q No} \) \(\text{Q No} \)					
Dissolution System Dissolution System Calibration Due: Dissolution System Calibration Due: Dissolution Media (Lot/PN) Disc - CB - 170110 - 07 Media Delivery Tracking # Media Delivery Calibration Due: NA Media Vol. (mL) / Apparatus Pilter (cannula tip) NA Sinkers (Type) NA Filter (syringe filter) Sample Times (minutes) Height Check Performed: Initials: 0/M 5 Date: 2 JUM 17 Auto sampler used? Withdraw Volume (mL) Vessel # Start Temp. End Temp. Sample number: Vessel # NA Wessel # Start Temp. End Temp. Sample number: Vessel # NA Manually with Tracking # Procedure/Observations:					
Dissolution System Dissolution System Calibration Due: Dissolution System Calibration Due: Dissolution Media (Lot/PN) Disc - CB - 170110 - 07 Media Delivery Tracking # Media Delivery Calibration Due: NA Media Vol. (mL) / Apparatus Pilter (cannula tip) NA Sinkers (Type) NA Filter (syringe filter) Sample Times (minutes) Height Check Performed: Initials: 0/M 5 Date: 2 JUM 17 Auto sampler used? Withdraw Volume (mL) Vessel # Start Temp. End Temp. Sample number: Vessel # NA Wessel # Start Temp. End Temp. Sample number: Vessel # NA Manually with Tracking # Procedure/Observations:					
Dissolution System Calibration Due: 3 Dec[7] Dissolution Media (Lot/PN) D 5C - CB - 170 10 - 07 Media Delivery Tracking # NA Media Delivery Calibration Due: NA Media Vol. (mL) / Apparatus					
Dissolution Media (Lot/PN) Dissolution Media (Lot/PN) Media Delivery Tracking # Media Delivery Calibration Due: NA Media Delivery Calibration Due: NA Media Vol. (mL) / Apparatus Stirring Speed (rpm) Sinkers (Type) Filter (cannula tip) Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Shaft Center Check Performed: Muto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Manually with Tracking # Procedure/Observations: And Procedure/Observations:					
Media Delivery Tracking # NA Media Delivery Calibration Due: NA Media Delivery Tracking # Sample number: \$\(\sigma \) \$\(
Media Delivery Calibration Due: Media Vol. (mL) / Apparatus Olu 0 / 6 Stirring Speed (rpm) Sinkers (Type) Filter (cannula tip) Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Initials: DW 5 Date: 2 JUN17 Auto sampler used? Wessel # Start Temp. End Temp. Sample number: Vessel # Start Temp. End Temp. Start Temp. End Temp. Sample number: Vessel # Start Temp. Start Temp. Sample number: Vessel # Start Temp. Start Temp. Sample number: Vessel # DNo Sample number: NA DNO Sample number: Vessel # DNO Sample number: NA DNO Sample number: NA DNO NA DN					
Media Vol. (mL) / Apparatus Stirring Speed (rpm) Sinkers (Type) Filter (cannula tip) Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Automatically Manually with Tracking # O0402 (Ø Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations:					
Stirring Speed (rpm) Sinkers (Type) Filter (cannula tip) Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Automatically Manually with Tracking # O0402 6 Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations:					
Sinkers (Type) Filter (cannula tip) Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel # Start Temp. End Temp. Sample number: Start Temp. Sample number: Vessel # DAIS Sample number: Vessel # DAIS Start Temp. Vessel # DAIS Start Temp. Start Temp. Start Temp. Vessel # DAIS Start Temp. Start Temp. Start Temp. Vessel # DAIS Start Temp. Start Temp. Start Temp. Vessel # DAIS NA Procedure/Observations:					
Sinkers (Type) Filter (cannula tip) Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel # Start Temp. End Temp. Sample number: Vessel # On 3 7.0 °C 37.3 °C Sample number: Vessel # Date: 2 JUN17 Sample number: Vessel # Date: 2 JUN17 Vessel # Date: 2 JUN17 Sample number: Vessel # Date: 2 JUN17 Vessel					
Filter (syringe filter) Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Automatically Manually with Tracking # O0402 6 Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations:					
Sample Times (minutes) Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Automatically Manually with Tracking # OO4026 Procedure/Observations:					
Height Check Performed: Shaft Center Check Performed: Auto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Replacement Media Temperatures Taken With Tracking #					
Shaft Center Check Performed: Initials: INITIAL Date: 12 TUNIT Vessel # DINS Start Temp. End Temp. Auto sampler used?					
Auto sampler used? Withdraw Volume (mL) Vessel Temperatures taken: Automatically Manually with Tracking # 00402 6 Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations:					
Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking #O402					
Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking #O402					
Replacement Media Temperatures Taken With Tracking #NA					
Procedure/Observations: At le0 minutes, the technets care disintegrated.					
Storage Location/Condition: Probe 65/5°C Expiration Date: NA					
Dissolution performed by DMS on 12 JUN 17					
ANALYTICAL METHOD					
Sample Dilution: Diluent: Sample Diluted by:					
□ HPLC					
System Tracking #:					
System Tracking #: Mobile Phase:					
Mobile Phase:					

Runtime:

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

Batch ID DISL - M	19.17018-1 Test Sample	m_552.98	89			
Active Ingredient Weight: 1688 4						
		Sample number:	5530707,	5530708		
Sample brought to room temperature		Vessel #	Start Temp.	End Temp.		
Dissolution System	011565	(37.0°C	31.5 °C		
Dissolution System Calibration Due:	31000	2	36.9 °C	31.5 °C		
Dissolution Media (Lot/PN)	DISL-HCL-17016-02	Sample number:	5530207,			
Media Delivery Tracking #	NA NA	Vessel #	Start Temp.	End Temp.		
Media Delivery Calibration Due:	NA 901) / G	vesser#	36. 7 °C	37.5 °C		
Media Vol. (mL) / Apparatus	900 / 0	4	36.5 ℃	31.4 °C		
Stirring Speed (rpm)		Sample number:	5550207			
Sinkers (Type)	NA	Vessel #	Start Temp.	End Temp.		
Filter (cannula tip)	NA N		36.8 °C	37.5 °C		
Filter (syringe filter)	0.4 Sum Nyun	5		37.5 °C		
Sample Times (minutes)	CO D 1502-1017	<i>(</i> /				
Height Check Performed:	Initials: ONE Date: STUMP	Sample-number:	CtastTomn	End Temp.		
Shaft Center Check Performed:	Initials: NWS Date: SIMI	Vessel # !)))	Start Temp.	Elia Temp.		
Auto sampler used?	☐ Yes No		°C	₹ °C °C		
Withdraw Volume (mL)	10		<u> </u>			
Vessel Temperatures taken:	Automatically 🂢 Manually wi	th Tracking#(DIS 806			
Replacement Media Temperatures T	aken With Tracking #	NA				
•						
Procedure/Observations:						
At 60 minutes, the tublets are disintegrated.						
Storage Location/Condition:	Expirat	ion Date:		_		
Dissolution performed byV	MS on 18TUMIT					
Dissolution performed by	on <u>(0)</u>					
ANALYTICAL METHOD						
Sample Dilution: Dilu	ient:	_Sample Diluted by:				
□ HPLC						
System Tracking #:						
Calibration Standard:						
Verification Standard:						
Column Used:						
_						
Volume injected:						
Sample Set Method:						
Analytical Method Performed By:						
i i i i i i i i i i i i i i i i i i i						

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

Patch ID DISL-MI	4 - 170109 - 1 Test Sample	Ш	332 100	
Batell ID4	72200			
Active Ingredient Weight: 1688.4	mg Stage:			5530206
Active Ingredient Weight: 1000 DISSOLUTION OPERATING CON	n a desiccator: yes		Sample frames	Start Temp. End Temp.
Sample brought to room temperature in	017141	L	Vessel #	343°C 37.2°C
Dissolution System	2.00017	L		37.2 ℃ 37.2 ℃
Dissolution System Calibration Duc.	ESXX-S-170109-01	L	2	5530206
Dissolution Media (Louity)	NA	1	Sample number:	Start Temp. End Temp.
Tracking #	NA	1	Vessel#	37.2 °C 37.2 °C
Delivery Calibration Duc.	900 16		3 4	37.1 °C 37.2 °C
Media Vol. (mL) / Apparatus	75	1	Sample number:	CC30206
Stirring Speed (rpm)	NA	1	Nample Humber.	Ctart Temp End Temp.
Sinkers (Type)	NA	1	Vessel#	37.1 °C 37.2 °C
Filter (cannula tip)	0.45um Nylon	- 1		37.1°C 37.2°C
Filter (syringe filter)	45	1	Sample number:	
Sample Times (minutes)	Date: 19 JUILT	1	Vessel # 09	Start Tellip. Little
Height Check Performed:	Initials: 1917 Date () 1944	4	V 03501	
Shaft Center Check Performed:	☐ Yes ☐ No	+		°C °C
Auto sampler used? Withdraw Volume (mL)		_		10262
	Manually	wit	h Tracking#O	04020
Vessel Temperatures taken:	6.57		NA	
Replacement Media Temperatures	Taken With Tracking #		INI	
Procedure/Observations:			Δ	Letit
ALAC MAILMILECS +	he tablets au	re	comple	recy
AT 45 MINUTES	1000000			5
100				
disintegra Ha.				
J				
Δ.	Ex. (C.15)	xpir	ation Date:	
Storage Location/Condition: Pro	108 65/30	1		
Storage 2	15 on091(4)11	1		
Dissolution performed by	15 on _09Jan1			
METHOD	Diluent:		_174	11
ANALYTICAL METHOD	-11		Sample Dilute	d by:
Sample Dilution:	Diluent:			
□ HPLC				
Mobile Phase:				
Calibration Standard:				
- Ct-mdord		_		
Column Used:				
Runtime:		_		
Volume injected:				
Sample Set Method:	By:			

Batch ID 5151-MA - 170109-1 Test Sample ID 55 2 9890

Batch ID bist-M	$\frac{14-170109-1}{100000000000000000000000000000000000$	m 33 Z 10 1	<u> </u>	
Active Ingredient Weight: 1586.5	mg Stage: /			
DISSOLUTION OPERATING CO	NDITIONS			
Sample brought to room temperature		Sample number:	5530210	
Dissolution System	011565	Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Due:		i	36.6 °C	37.3 °C
Dissolution Media (Lot/PN)	ESXX-S-170109-01	2	36.5 °C	37.3 ℃
	NA NA	Sample number:	5530210)
Media Delivery Tracking # Media Delivery Calibration Due:	NA NA	Vessel #	Start Temp.	End Temp.
	900 16		36.5 °C	37.3 ℃
Media Vol. (mL) / Apparatus	75	3	36.5 °C	37.2 °C
Stirring Speed (rpm)	NA	Sample number:	553021	
Sinkers (Type)	NA NA	Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	0.45um NyIUM	5	36.6 °C	37.2 °C
Filter (syringe filter)	44	6	36.6°C	37.Z °C
Sample Times (minutes)	Initials: DMS Date: 0970/17	Sample number:		
Height Check Performed:	Initials: DMS Date: 09TUN17		Start Temp.	End Temp.
Shaft Center Check Performed:	☐ Yes ☐ No	PHYS (Pan C	°C
Auto sampler used?	I ves Zi No		Start Temp.	°C
Withdraw Volume (mL)		ith Tracking # <u>004</u>	4 8 II	
At 4s minutes, disintegrated.	the tablets are	complet-	ely	
Storage Location/Condition: Profession performed by DMS		ation Date:	خـ	
ANALYTICAL METHOD Sample Dilution: Dilution	vent:	Sample Diluted by	:	
Sample Dilution:Direction	dent.			
☐ HPLC				
System Tracking #:				
Mobile Phase:				
Verification Standard:				
The second secon				
Runtime:				

Volume injected:

Sample Set Method:
Analytical Method Performed By:

DISSOLUTION CHECKLIST					
Batch ID DISL-N	MA-170118-1 Test Sample	em_55298	90		
Active Ingredient Weight: 1586.5 DISSOLUTION OPERATING CO					
		Sample number:	5530211,5530212		
Sample brought to room temperature Dissolution System	()1714)	Vessel #	Start Temp. End Temp.		
Dissolution System Calibration Due:)	36.9 °C 37.5 °C		
Dissolution Media (Lot/PN)	DISL-HCL-170116-02	2	36.7 °C 37.4 °C		
Media Delivery Tracking #	NA NA	Sample number:	5530211,5530212		
Media Delivery Tracking # Media Delivery Calibration Due:	NA	Vessel#	Start Temp. End Temp.		
Media Vol. (mL) / Apparatus	100 / 6	3	36.7 ℃ 37.5 ℃		
Stirring Speed (rpm)	75	4	36.7 °C 37.5 °C		
Sinkers (Type)	NA	Sample number:	5530211,5530212		
Filter (cannula tip)	NA	Vessel #	Start Temp. End Temp.		
Filter (syringe filter)	0.45 mm Millon	S	36.6 °C 37.5 °C		
Sample Times (minutes)	(00)	(0	36.6 °C 37.5 °C		
Height Check Performed:	Initials: DMS Date: 18 JUNIT	Sample number:			
Shaft Center Check Performed:	Initials: DWG Date: 18 TWIT	Vessel # Pr	Start Temp. End Temp.		
Auto sampler used?	☐ Yes ☑ No	1,77,	> 18 TCOLET °C		
Withdraw Volume (mL)	10		oc f oc		
Vessel Temperatures taken: Automatically Manually with Tracking # 015800 Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At ab minutes, The tables are disintegrated					

Storage Location/Condition: $\rho_{YO} he \omega S/S^*C$ Dissolution performed by $\rho_{YO} he \omega S/S^*C$	Expiration Date:
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:	

Active Ingredient Weight: 1586 DISSOLUTION OPERATING CO	5 mg Stage	: 1			
		yes	Sample number:	55302	13
Sample brought to room temperature	01714	1 90 -	Vessel#	Start Temp.	End Temp.
Dissolution System		17-	1	36.8°C	37-2 °C
Dissolution System Calibration Due: Dissolution Media (Lot/PN)	DISL - (B-1		2	36.6℃	37.1 °C
	NA	10110 0-	Sample number:	35302	
Media Delivery Tracking #	NA NA		Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	900	10	3	36.7 °C	37.2°C
Media Vol. (mL) / Apparatus	75	, 0	4	36.7°C	37.2 °C
Stirring Speed (rpm)	NA		Sample number:	5.5307	13
Sinkers (Type)	<u></u>		Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	NA CIAI	nnylon	S	36.6°C	37.1 °C
Filter (syringe filter)	0.4521	7 10 91 0	6	36,7 °C	37.1 °C
Sample Times (minutes)	(00	D 4 12-in #17	Sample number:	50.1	<u> </u>
Height Check Performed:		Date: 12 Jul 7	4 Yran 20 kg	Start Temp	End Temp.
Shaft Center Check Performed:		Date: 12 Tanif	VCSSCI # V	12100	°C
Auto sampler used?	☐ Yes 図 N	10		°C	₹ °C
Withdraw Volume (mL)	10				
, obser 1 timp	Automatically	,	th Tracking# OQ	4076	
Replacement Media Temperatures Ta	aken With Track	ing #	NA		
Procedure/Observations:				1	
Procedure/Observations:		; r	line a be a ro	red.	
Procedure/Observations: At ao minutes, t	he tabl	its are	disintegro	ited.	
Procedure/Observations: At 60 minutes, t	ne tabl	uts are	disintegro	red.	
Procedure/Observations: At (e0 minutes, t	ne tabl	uts are	disintegro	red.	
Procedure/Observations: At 60 minutes, t	ne tabl	cts are	disintegro	red.	
At 60 minutes, t					
At (20 minutes, to storage Location/Condition: Probe	· US/5°C	Expira	tion Date:		
At 60 minutes, t	· US/5°C	Expira	tion Date:		_
Storage Location/Condition: Probe Dissolution performed by	<u>vs/s°C</u> 15on_	Expira 12 TM 13	tion Date:		_
Storage Location/Condition: Probe Dissolution performed by	<u>vs/s°C</u> 15on_	Expira 12 TM 13	tion Date:		
At (e0 minutes, to Storage Location/Condition: Probe Dissolution performed by	<u>vs/s°C</u> 15on_	Expira 12 TM 13	tion Date:		
Storage Location/Condition: Probe Dissolution performed by	<u>> US/S^UC</u> 15on_ nent:	Expira	tion Date:		
Storage Location/Condition: Probe Dissolution performed by	<u>vs/s°C</u> nson_	Expira	tion Date:		
Storage Location/Condition: Probe Dissolution performed by	<u> </u>	Expira	tion Date: } _Sample Diluted by	;	
Storage Location/Condition: Probe Dissolution performed by	<u>> US/S ^OC</u> 15on_ nent:	Expira	tion Date:	;	
Storage Location/Condition: Probe Dissolution performed by	<u>vs/s</u> on_ nent:	Expira	tion Date:	;	

Volume injected: Sample Set Method:

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

2 7 10 0		2			
Active Ingredient Weight: 991.0 DISSOLUTION OPERATING CO	NDITIONS				
Sample brought to room temperature		Sample number:	553021	5	
Dissolution System	017141	Vessel #	Start Temp.	End Temp.	
Dissolution System Calibration Due:		1	37.1 °C	37.3 °C	
Dissolution Media (Lot/PN)	ESXX-S-170109-01	2	31.0 °C	37.2 °C	
Media Delivery Tracking #	NA	Sample number:	5530215		
Media Delivery Calibration Due:	NA NA	Vessel #	Start Temp.	End Temp.	
	900 / 6	3	36.9 °C	37-2 °C	
Media Vol. (mL) / Apparatus	75	4	36.9°C	37.2 °C	
Stirring Speed (rpm)	NA	Sample number:	553021		
Sinkers (Type)		Vessel #	Start Temp.	End Temp.	
Filter (cannula tip)	NA NA		57.0 °C	37.2 °C	
Filter (syringe filter)	0.45 um Nylon	5	The second secon	31-2 °C	
Sample Times (minutes)	4)	U	36.8 °C	77-6 C	
Height Check Performed:	Initials: DMS Date: 00 Jun 7	Sample number:	Ctart Tomp	End Temp.	
Shaft Center Check Performed:	Initials: DMS Date:09 Tan 17	Vessel #	Start Temp.		
Auto sampler used?	☐ Yes ☐ No		Tay °C	°C	
Withdraw Volume (mL)	10		, C	°C	
Vessel Temperatures taken: Automatically Manually with Tracking #					
Storage Location/Condition: Probe Dissolution performed by DMS		tion Date:	~	1 1	
ANALYTICAL METHOD					
Sample Dilution: Dilu	ent:	_Sample Diluted by:			
☐ HPLC					
System Tracking #:					
AND CORP. The Corp. The Corp.					
Verification Standard:					
G 1 11 1					
Runtime:					

Volume injected: Sample Set Method:

DISSOLUTION CHECKLIST					
Ratch ID DISL-N	14-170112-1 Test Sample	m 53298	91		
991.0	mg Stage:				
Active Ingredient Weight: 991. O DISSOLUTION OPERATING CO	mg Stage NDITIONS				
Sample brought to room temperature	in a desiccator: Yes	Sample number:	5550218		
Dissolution System	011565	Vessel #	Start Temp. End Temp.		
Dissolution System Calibration Due:	310ec17		37.1 °C 37. 3°C 37.3°C		
Dissolution Media (Lot/PN)	0151_CB-170110-02, 0151_CB-170110-015	2	37.0 °C 37.3°C \$530218		
Media Delivery Tracking #	NA '	Sample number:	Start Temp. End Temp.		
Media Delivery Calibration Due:	NA	Vessel#	36.8°C 37.2°C		
Media Vol. (mL) / Apparatus	900 10	3 4	36.5 ℃ 37.1 ℃		
Stirring Speed (rpm)	75	Sample number:	5530218		
Sinkers (Type)	NA	Vessel #	Start Temp. End Temp.		
Filter (cannula tip)	0.45 mm Nylon	S Vesser#	37.0 °C 37.3°C		
Filter (syringe filter)	0.45 MM 109100	(0	36.° °C 37.2 °C		
Sample Times (minutes)	Initials: DYMS Date: DIAMIF	Sample number:	553-0		
Height Check Performed:	Initials: 19175 Date: 1274177 Initials: PMS Date: 1274177	Versel #	Start Temp. End Temp.		
Shaft Center Check Performed:	☐ Yes ☒ No		4775 /2 °C °C		
Auto sampler used? Withdraw Volume (mL)	10		Mrs 12 Peg117 °C		
	Automatically Automatically w	rith Tracking #			
Vessel Temperatures taken: Automatically Wild Hadden Will Hadden W					
Storage Location/Condition: Probe US/SOC Expiration Date: Dissolution performed by DYNS on _IA JUNI 7 ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by:					
Sample Dilution: Di	luent:	Sample Diluted b	y:		
ET TIDE ()					
System Tracking #:					
Calibration Standard:					
Verification Standard.					
Runtime:					

Volume injected:

Sample Set Method:

Analytical Method Performed By:

() R.F. DM5 12 JUN 17

	DISSOLUTION CHECK	La T	D C < 7 980	1.1	
Batch ID_DISL-M	A-170118-1 Test Sampl	ie i	D_526_19		
Active Ingredient Weight: 991.0					
DISSOLUTION OPERATING CO	NDITIONS			6.60 11	5020217
Sample brought to room temperature	in a desiccator: 1965		Sample number:		55302/7
Sample brought to room temperature	011565		Vessel #	Start Temp.	End Temp. 3 7.5 °C
Dissolution System Dissolution System Calibration Due:	3112017			37.5 °C	23 3 2 C #
Dissolution System Cambration 2 us. Dissolution Media (Lot/PN)	DISL-HCL-170116-02		2	374 °C	<530247 5530218
Media Delivery Tracking #	NA		Outhpie		End Temp.
Media Delivery Calibration Due:	NA	֡֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓	Vessel #	Start Temp.	344°C
Media Vol. (mL) / Apparatus	90016		3	37.2 °C	37.4 °C
	75		4	37.1 °C	
Stirring Speed (rpm)	NA	_	Sample number:	5530216,5	
Sinkers (Type)	NA	1	Vessel #	Start Temp.	End Temp. 37.5 °C
Filter (cannula tip)	0.45 cm Mylor	1	5	37.3 °C	37.4 °C
Filter (syringe filter) Sample Times (minutes)	(a()	1	<u> </u>	37.2 °C	137.7 C
Height Check Performed:	Initials: MMS Date: 18 TUVII	1	Sample number:	G T.	End Temp.
Shaft Center Check Performed:	Initials: DMS Date: 18 JUN1	Ŧ	Vessel # DINS	Start Temp.	°C
Auto sampler used?	☐ Yes → No			18 DIN/ FOC	°C
Withdraw Volume (mL)	10				
	19.16	:4	h Tracking# 01	5806	
Vessel Temperatures taken:	Automatically Manually	WH	II Hacking# UI	<u>, , , , , , , , , , , , , , , , , , , </u>	
Replacement Media Temperatures T	aken With Tracking#		NA		
Procedure/Observations:			1	. 4	
At 60 minutes, t	no tablets are	2	disintegi	aleel.	
HT (60 MINOCLES)	va		J		
Storage Location/Condition: Pro	$\log (05/5^{\circ})$ Exp	oira	tion Date:		_
Storage Location/Condition. 110					
Dissolution performed by	O(N) on 10 $O(N)$	-	_ _		
ANALYTICAL METHOD					
Sample Dilution: Di	luent:		_Sample Diluted b	y:	
Sample Dilution: Di	idont.				
☐ HPLC					
System Tracking #:					
System Tracking #:					
Mobile Phase: Calibration Standard:					
Calibration Standard: Verification Standard:					
Verification Standard: Column Used:					
Column Used:					
Runtime: Volume injected:					
C 1- Cat Mathad					
Sample Set Method: Analytical Method Performed By					
Analytical Method Performed By					

OR. E. 18 Jan 17 DMS

	DISSOLUTION CHECKLI	.o // (*)	A7
> / . AA	A-1701/2-1 Test Sample	D <u>55298</u>	12
Batch ID DISL-101	H-110110		
" AWalaht: 1577.	mg Stage: 1		
		Sample number:	5530224
Sample brought to room temperature in	la desiocassical	Vessel #	Start Temp. End Temp.
Sample brought to room tomportuni	017141	1055	37.2 °C 37.2 °C
Dissolution System Dissolution System Calibration Due:	310ec17	2	37.1 °C 37.1 °C
Dissolution System Cards Dissolution Media (Lot/PN)	DKL-CB-17040-03	Sample number:	\$530224
Media Delivery Tracking #	NA	Vessel #	Start Temp. End Temp.
Media Delivery Calibration Due:	NA NA	3	3 3 4 00
Media Vol. (mL) / Apparatus	900 / 0	4)
Stirring Speed (rpm)		Sample number:	55 30124
Stirring Speed (1511)	NA	Vessel#	Start Temp. End Temp.
Sinkers (Type) Filter (cannula tip)	NA	5	1 2 T-1 - 0 - 2 - 1 - 0C
Filter (cannula up) Filter (syringe filter)	0.45um Nylon	6	37.1 °C 37.1 °C
Sample Times (minutes)	Initials: VMS Date: 12 JUN 17	Sample number:	Start Temp. End Temp.
Height Check Performed:	Initials: VMS Date: 12 JUN 7		Start Temp. End Temp.
Shaft Center Check Performed:	Initials: NMS Date: 2 MM7		S/2 Jeth/9c °C
Auto sampler used?	☐ Yes ☑ No		1790
Withdraw Volume (mL)	10	<u> </u>	- 2203 (-
	Manually V Manually	with Tracking #	00 102 0
Vessel Temperatures taken: \Box	Autometer	NA	
-	Faken With Tracking #		a
Replacement Media Temperatura	the telbuts ou		a weet ted?
Procedure/Observations:		a disint	egia.
TO main 11 1005	the telliers on	/4	
At 60 Million 3			
0.	when the state of Exp	piration Date:	
Storage Location/Condition: Pto	12 mile 17	,	
by Dh	nson_larun17	-	
Dissolution performed by			
TOTALOD			
ANALYTICAL METHOD		Sample Dilute	d by:
Gample Dilution:	Diluent:		
☐ HPLC			
T-ling#			
System Tracking #.			
Ter to then Standard'			
7.7			
Column Used:			
Runtime:			
Volume injected:			
Runtime: Volume injected: Sample Set Method: Analytical Method Performed			

	DISSOLUTION CHECKLI	ST
Ratch ID DISL - Mr	7-1-701(9-1 Test Sample	ID_ 552 01 8 9 2
1577 S	mg Stage: \	
Active Ingredient Weight: 1577.5 DISSOLUTION OPERATING CON	DITIONS	Sample number: \$530221, \$530222
Sample brought to room temperature in	la desicoutor.	Vessel # Start Temp. End 1
1 Curatam	<u> </u>	37-0 °C 37-2 C
Dissolution System Calibration Due.	31 Dell7 DISL-HCL-176116-02, DISL-HCL-17016	11 6/20227
Dissolution Media (LOVPN)	NA	Stort Temp. End Temp.
Modic Delivery Tracking #	NA	Vessel # Start 10th 37.2 °C
Media Delivery Calibration Duc.	900 16	36.600 37.600
Media Vol. (mL) / Apparatus	75	Sample number: 5530221,5530666
Stirring Speed (rpm)	NA	Yessel # Start Temp. End Temp.
Sinkers (Type)	NA NAVA	36.70
Filter (cannula tip) Filter (syringe filter)	0.45 um mylon	6 360.7°C 37.2°C
Sample Times (minutes)	Initials: 0MS Date: 19JUN17	Sample number: End Temp. End Temp.
TI-inht Check Performed:	1111010000	Vessel # Om Start Temp. End Temp. Vessel # Or Start Temp. © C
Shaft Center Check Performed:	Initials: pMS Date: 1950M1	°C °C
Auto sampler used?	10	
Withdraw Volume (mL)		with Tracking # 015800
Replacement Media Temperatures	Taken With Tracking #	NA
Replacement Media Temperatures		
Procedure/Observations:		ted.
	tablets are	disintegral
At 60 MINUTES, TU		disintegrated.
h. c		
		: Data
Storage Location/Condition: PY	obe 65/5°C Exp	piration Date:
Storage Location Condition 1	mas on 1950m17	
Dissolution performed by	0m5 on 1950m17	
ANALYTICAL METHOD		Sample Diluted by:
Sample Dilution:I	Oiluent:	Sample Diluted by:
☐ HPLC		
System Tracking #:		
- · · · Standard		
T		
Volume injected:		
Sample Set Method:	Ву:	
- I Deutomacc	- N	

016) -44 M-170119-1 Test Sample ID 600 0003

Active Ingredient Weight: 1554.2 mg Stage: 1 DISSOLUTION OPERATING CONDITIONS Sample brought to room temperature in a desiccator: 945 Sample number: 5530226, 553	
DISSOLUTION OF ENAMERS in a designator: 1405 Sample number: 5530226, SS2	2.60
	0628
Sample brought to room temperature in a call (1) Vessel # Start Temp. End	Temp.
	S °C
	- %c_
Dissolution Media (Lot/PN) DIST-HCC 1-01(W CT	02Z8
Media Delivery Tacking # Town End	Temp.
Modio Dolivery Calibration Due: NA Vessel # State Annual Calibration	S °C
Media Vol. (mL) / Apparatus	4 °C
Stiming Speed (rpm)	
	Temp.
Filter (cannula tip) NA Vesset in 36. 9 oc 37 Filter (syringe filter) O 45 MM NYON S 36. 9 oc 37	
	4 °C
Sample Times (minutes)	
	Temp.
Shaft Center Check Performed. Initials. 51/13 Date: 130211	°C
Auto sampler used:	°C
Withdraw Volume (mL) Vessel Temperatures taken: Automatically Manually with Tracking #	
Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At 60 minutes the tablets are disintegrated.	
Storage Location/Condition: Prove US/5°L Expiration Date:	
Dissolution performed by on	
Dissolution performed by on	
Dissolution performed by	
Dissolution performed by	
Dissolution performed byOmOnOn	
Dissolution performed by	
Dissolution performed byOmOnOn	
Dissolution performed by	
Dissolution performed by OMS on MTWITE ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime:	

Batch ID DISL-MA-17412-0 Test Sample ID 552 9893

Batch ID DESE	MA-17/1/2-0 Test Sample	ID 552 989	<u>5</u>
Active Ingredient Weight: 1556. DISSOLUTION OPERATING CO	2_mg Stage: │ NDITIONS		
DISSOLUTION OF ERATING CO	in a desiccator: Ue5	Sample number:	5530229
Sample brought to room temperature		Vessel#	Start Temp. End Temp.
Dissolution System		1	37.3 ℃ 37.3 ℃
Dissolution System Calibration Due:	31 DP (1)	2.	37,2 °C 37.3 °C
Dissolution Media (Lot/PN)	DISL-CB-170110-03	Sample number:	5530229
Media Delivery Tracking #	NA NA	Vessel #	Start Temp. End Temp.
Media Delivery Calibration Due:	NA China I fo	3	37.0 °C 37.2°C
Media Vol. (mL) / Apparatus	900 /6	4	36.9 °C 37.1 °C
Stirring Speed (rpm)	75	Sample number:	5530229
Sinkers (Type)	NA		Start Temp. End Temp.
Filter (cannula tip)	NA Lui	Vessel#	236.9° °C 37.3°C
Filter (syringe filter)	0.4 Sum Nylon	6 37.	37.1 °C 37.1 °C
Sample Times (minutes)	(0)		341 0 311 0
Height Check Performed:	Initials: OMS Date: 12 JUN 7	Sample number:	Start Temp. End Temp.
Shaft Center Check Performed:	Initials: DYMS Date: 12 DAMIT	Vessel # DM	Start Temp. End Temp.
Auto sampler used?	☐ Yes		°C °C
Withdraw Volume (mL)	10		
Procedure/Observations: At 60 minutes, to	ne tablets are dis	sintegrated.	
ANALVTICAL METHOD	e		
□ HPLC			
System Tracking #:			
Mobile Phase:			
Verification Standard:			

OR.F. OMS 12 TOUTH

Sample Set Method:
Analytical Method Performed By:

Column Used: Runtime:

Volume injected:

	DISSOLUTION CHECKL	IST	4
Batch ID DISL-N	1A-170119-1 Test Sample	ID 55298°	74
	h h		
Active Ingredient Weight: 160 1	NDITIONS	Sample number:	5530231,5530232
Sample brought to room temperature		Vessel #	Start Temp. End Temp.
Discolution System		1	36.8 °C 37.2 °C
Dissolution System Calibration Due:	31 pec17 DISL-HLL-170116-01	2	36.7 °C 37.1 °C
Dissolution Media (Lot/PN)	NA	Sample number:	1333000
Media Delivery Tracking #	NA	Vessel #	Diale voing
Media Delivery Calibration Due:	900/6	3	36.6 °C 37.0 °C 36.7 °C 37.1 °C
Media Vol. (mL) / Apparatus	75	\	1 (20122)
Stirring Speed (rpm) Sinkers (Type)	WA	Sample number: Vessel #	Start Temp. End Temp.
Filter (cannula tip)	NA NA	Vesser#	36.6 °C 37.0 °C
Filter (syringe filter)	0.45m Nylor)	6	36.6 °C 37.1 °C
Sample Times (minutes)	Initials: 1) MS Date: 19 JUN 7		2 17
Height Check Performed:	Initials: () (M) Date: () TWN		Start Temp. End Temp.
Shaft Center Check Performed:	☐ Yes ✓ No	, , , , , , , , , , , , , , , , , , ,	15 19 rung °C
Auto sampler used?	☐ Yes ✓ No		1
Withdraw Volume (mL)	77.3.6	with Tracking#0	1580Ce_
Vessel Temperatures taken:	1 2000		<u> </u>
Replacement Media Temperatures	Taken With Tracking #	NA	
Replacement Weday 1997			
Procedure/Observations:	21.00	alisinteered	tea.
A+ GO minutes. Th	e rables are	00(1)	
Procedure/Observations: At 60 minutes, The rabbets are disintegrated.			
		iration Date:	And the second s
Storage Location/Condition: P(
otoruge ====	on 1974/17		
Dissolution performed by			
ANALYTICAL METHOD			
ANALITICALIMETER	Piluent:	Sample Diluted	by:
☐ HPLC			
- 1 · //.			
3 5 1 1 Dl. 2001			
Calibration Standard:			
Verification Standard:			
Column Used:			
Runtime:			
Analytical Method Performed B	y:		
Anarytical intented 1 522	<u> </u>		

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

Batch ID 1/13 L W	W (10(1)		·
Active Ingredient Weight: 1601.1	mg Stage: 1		
DISSOLUTION OPERATING CON	DITIONS		
Sample brought to room temperature in	a desiccator: Ues	Sample number:	5530233
Dissolution System	017141	Vessel #	Start Temp. End Temp.
Dissolution System Calibration Due:	31Dec17		
Dissolution Media (Lot/PN)	DISL-(13-17011)-03, DISL-CB-170	12-01 2	36.9 °C 37.1 °C
Media Delivery Tracking #	NA	Sample number.	5530233
Media Delivery Calibration Due:	NA	Vessel #	Start Temp. End Temp.
Media Vol. (mL) / Apparatus	900 100	3	36.9 °C 37.1 °C
Stirring Speed (rpm)	75	4	36.9°C 37.1 °C
	NA	Sample number:	5530233
Sinkers (Type) Filter (cannula tip)	NA	Vessel #	Start Temp. End Temp.
Filter (canitula tip) Filter (syringe filter)	U. 45 UM MION	5	36.8°C 371 °C
Sample Times (minutes)	(e)	(v	36.8 ℃ 37.1 ℃
Height Check Performed:	Initials: OMS Date: 13 JUN1 7	Sample number:	D. L.T.
Shaft Center Check Performed:	Initials: MMS Date: 13 Jun 1	Vessel # On	Start Temp. End Temp.
Shart Contor Check I did	☐ Yes		
Withdraw Volume (mL)	10		°C 1 °C
			. 1 . 0 /
Vessel Temperatures taken: ☐ A	utomatically 🔲 Manually wi	th Tracking# <i>O</i> _0	7401 G
	kon With Tracking #	NA	
Replacement Media Temperatures Ta	iken with Hacking		
Procedure/Observations:		. 1	
	ne tablets are disiv	recivated.	
At 60 minutes. Th	re tablets are also	Healtour	
			_
Storage Location/Condition: _ \(\frac{\range \gamma_{\gamma\text{0}} \gamma_{\text{0}} \gamma_{\text{0}}}{\text{0}} \)	ρ_{e} ($\rho \leq / \leq \sigma \leq Expira$	tion Date:	
Storage Location/Condition F 10 F	1 711/17		
Dissolution performed by DM	$\frac{5}{\sqrt{15}}$ on $\frac{15}{\sqrt{15}}$		
ANALYTICAL METHOD			
Sample Dilution: Dilu	iont:	Sample Diluted by	y:
Sample Dilution: Dilu	ient.	- 1	
□ HPLC			
System Tracking #:			
Mobile Phase:			
Calibration Standard:			
Verification Standard:			
Column Used:			
Sample Set Method			
Analytical Method Performed By:			

ID DISL-114-17-113-1 Test Sample ID 5579895

Batch ID DISL-N	114-170113-1 Test Sample	в <u>Б</u>	_ 1 0 1	[
Active Ingredient Weight: 1572	mg Stage:				
DISSOLUTION OPERATING CO.	NDITIONS			772770	
Sample brought to room temperature	in a desiccator:	Sample nu	ımber:	5530 23	± End Temp.
Dissolution System	() 1/50/3	Vessel #		Start Temp.	37.2 °C
Dissolution System Calibration Due:	3) Dec17	<u> </u>		37.0°C	37.2°C
Dissolution Media (Lot/PN)	D15L-(B-17011 6-01	2		55302	
Media Delivery Tracking #	NA NA	Sample n	umber:	Start Temp.	End Temp.
Media Delivery Calibration Due:	NA NA	Vessel #		36. × °C	37.1 °C
Media Vol. (mL) / Apparatus	900/6	4		36, 7°C	37.0 °C
Stirring Speed (rpm)	75	Sample n	umber:	55302	
Sinkers (Type)	NA	Vessel #	umoer.	Start Temp.	End Temp.
Filter (cannula tip)	NA ONLO IO	V ESSEI #		37.0 ℃	37.2 °C
Filter (syringe filter)	0.4 Sun Ny10 M	6		37.0 °C	37.2°C
Sample Times (minutes)	(0)	Sample n			
Height Check Performed:	Initials: NMS Date: 137417			Start Temp.	End Temp.
Shaft Center Check Performed:	Initials: NYN Date: 3701	, vesser ii	DMS	13 Tanie	°C
Auto sampler used?	☐ Yes ☐ No			100	°C
Withdraw Volume (mL)		· •		- 1	
Vessel Temperatures taken: □ A Replacement Media Temperatures T	Automatically 📉 🕅 Manually was raken With Tracking #	NA NA	# <u>//</u>	<u>() </u>	
Procedure/Observations:					
Procedure/Observations.					
At 60 minutes,	the tablets ou	ve disi	nrc	jouted.	
	1000	.5 55 (
Storage Location/Condition: 19 m					
Dissolution performed by	on 13 Jan 17				
Dissolution performed by		_			
ANALYTICAL METHOD					
Sample Dilution: Dil	uent:	Sample D	iluted by	/:	
□ HPLC					
			_		
System Tracking #:					
Mobile Phase:					
Calibration Standard:					
Verification Standard:					
Runtime:					ļ

Volume injected:

Sample Set Method:
Analytical Method Performed By:

Batch ID_DISL-MA-170119-1 Test Sample ID_ 5529895 Active Ingredient Weight: 1572. 1 mg Stage: 1 DISSOLUTION OPERATING CONDITIONS 55 30235, 5530236 Sample brought to room temperature in a desiccator: Ues Sample number: End Temp. Start Temp. Vessel# 011565 37.3 ℃ 36.9 °C Dissolution System Dissolution System Calibration Due: 31Dec17 312 °C 36. 7°C DISL-HCL-170116-01 Dissolution Media (Lot/PN) 5530236 553023S, Sample number: NA Media Delivery Tracking # End Temp. Start Temp. Vessel# NA Media Delivery Calibration Due: 37.1 36.5 °C 900/4 3 Media Vol. (mL) / Apparatus °C 36.5 °C 37.1 7-5_ Stirring Speed (rpm) 530236 5530235,5 Sample number: NA Sinkers (Type) End Temp. Start Temp. Vessel# NA Filter (cannula tip) °C 37. 36.6°C 0.45 cm Nylon 5 Filter (syringe filter) 37.1 °C 36.5°C Ġ CO Sample Times (minutes) Initials: OMS Date: 19 JUNI Sample number: End Temp. Height Check Performed: Opp Start Temp. Vessel# Initials: MMS Date: 19 JUNIT Shaft Center Check Performed: 1910017 K No ☐ Yes Auto sampler used? °C W Withdraw Volume (mL) 015806 ☐ Automatically Vessel Temperatures taken: Replacement Media Temperatures Taken With Tracking # ______NA Procedure/Observations: At 60 minutes, the tablets are disintegrated. Storage Location/Condition: Prove 65/5°C Expiration Date: Dissolution performed by _____OMS ___ on ____19Tan17_ 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:

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01/1 0	A 13/11/9-1 Test Sample	le T	D 55298	96	
Batch ID DISL-N		10 1	<u> </u>		
Active Ingredient Weight: 1526	<u>Ø</u> mg Stage:				
DISSOLUTION OPERATING CO	NDITIONS	[Sample number:	55307,40	,5530241
Sample brought to room temperature	in a desiccator:		Vessel #	Start Temp.	End Temp.
Dissolution System	017141		1	36.6 °C	36.9 °C
Dissolution System Calibration Due:	31 Der 17 Dist = HCL +70116	1	2	36.5 °C	36.8 °C
Dissolution Media (Lot/PN)			Sample number:	5530240,	3530241
Media Delivery Tracking #	NA NA		Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	NA O(0) //a	1 !	3		36.8 °C
Media Vol. (mL) / Apparatus	75	1	1	36.5 °C	36.9 °C
Stirring Speed (rpm)		1	Sample number:	5530240,5	
Sinkers (Type)	NA	1	Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	NA NA	1	S S	3015 °C	36.8 °C
Filter (syringe filter)	0.45um mylon	1	6	3(1.5 °C	736.8°C
Sample Times (minutes)	100 Jatane	1	Sample number:	-/\(\bar{\bar{\bar{\bar{\bar{\bar{\bar{	
Height Check Performed:	Initials: OMS Date: 1970117	1/2		Start Temp.	End Temp.
Shaft Center Check Performed:	Initials: pm \ Date: 9 rdn	4′	V 63301 11 - 427	Start Temp.	°C
Auto sampler used?	☐ Yes ☐ No	1		°C	°C
Withdraw Volume (mL)		Ŀ	h Tracking #	(1)	806
Vessel Temperatures taken: Replacement Media Temperatures T Procedure/Observations: At 60 MINUTES, THE	tablets are disin	nt			
Storage Location/Condition: Pto	be 65/5°C Expi	irat	ion Date:		_
Dissolution performed by					
Dissolution performed by	<u> </u>		_		
ANALYTICAL METHOD			~ 1 D'1 1 11-		
Sample Dilution: Dil	uent:		_Sample Diluted by	/:	
☐ HPLC					
System Tracking #:					
Mobile Phase:					
Calibration Standard:					
Verification Standard:					
Column Used:					

Analytical Method Performed By:

(DR. E. Showld be DISL-HEL-17016-01. pm < 1970117

Runtime:

Volume injected: Sample Set Method:

Batch ID 0151-114 A-170113-1 Test Sample ID 552 9896

Batch ID ()130 - 1001 1 10	1 rest Sample ID 33 22 10 1.	-
Active Ingredient Weight: 1526 · 6 mg	Stage: 1	

Sample brought to room temperature	in a desiccator: Yes
Dissolution System	017141
Dissolution System Calibration Due:	31 Dec 17
Dissolution Media (Lot/PN)	DISL-CB-170112-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	90016
Stirring Speed (rpm)	75
Sinkers (Type)	l NA
Filter (cannula tip)	NA NA
Filter (syringe filter)	0.45 um NyiON
Sample Times (minutes)	<u>00</u>
Height Check Performed:	Initials: DMS Date: 330117
Shaft Center Check Performed:	Initials: OMS Date: 13 JUNIF
Auto sampler used?	☐ Yes
Withdraw Volume (mL)	10

Sample number:	553024	13
Vessel #	Start Temp.	End Temp.
+	36.9 °C	37.2 °C
2	36.7 ℃	37.1°C
Sample number:	55302	43
Vessel#	Start Temp.	End Temp.
3	30.7 °C	37.2 ℃
4	36,7°C	371 °C
Sample number:	55302	13
Vessel#	Start Temp.	End Temp.
3	34.5 °C	371 °C
6	36.6 °C	37.1 °C
Sample number:		
Vessel # nm	Start Temp.	End Temp.
	Brang	°C
		°C

Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking # _ <u>00402</u> ☐
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 0 MS on 13 Jan 7
ANALYTICAL METHOD
Sample Dilution: Diluent: Sample Diluted by:
□ HPLC
System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard: Column Used:
Runtime:
Volume injected:
Sample Set Method:
Analytical Method Performed By:

O marked paper with pen unintentionally. DMS 13 Jan 17

	DISSOLUTION CHECKLIST					
Batch ID DISL - MA - 170109 - 1 Test Sample ID 5529896						
Active Ingredient Weight: 1526	mg Stage		TE 2022 V			
DICCOLLITION OPERALING CO	IDITION	Sample number:	Start Temp. End Temp.			
Sample brought to room temperature	011565	Vessel #	37.0 °C 37.4 °C			
Dissolution System Calibration Due:	21 DO(17	2	36.9 ℃ 37.3 ℃			
Dissolution System Candidation Dissolution Media (Lot/PN)	ESXX-S-170109-01	Sample number:	5530238			
Media Delivery Tracking #	NA	Vessel #	Start Temp. End Temp.			
Media Delivery Calibration Due:	NA	3	36.8 °C 37.3 °C			
Media Vol. (mL) / Apparatus	900 16	4	36.7 °C 37.2 °C			
Stirring Speed (rpm)	75	Sample number:	5530238			
Sinkers (Type)	NA NA	Vessel#	Start Temp. End Temp.			
Filter (cannula tip)	0.45 um Ny ION	5	36.7 °C 37.3 °C			
Filter (syringe filter)	45 AS	6	O(V)			
Sample Times (minutes)	Initials: DMS Date: 097017	Sample number:				
Height Check Performed:	Initials: DMS Date: 977117	Vessel # Ons	ogranize °C			
Shaft Center Check Performed:	☐ Yes No		°C °C			
Auto sampler used? Withdraw Volume (mL)	10					
	Manually W	ith Tracking# <u> </u>	4026			
	1 Ittomisses					
Replacement Media Temperatures	Taken With Tracking #	NA .				
			_1			
Procedure/Observations:	e tablets are di	sintegrate	0.			
At 45 minutes Th	L Table 13 sold s	J				
7.1						
	Lecc Evni	ration Date:				
Storage Location/Condition: Pro		ration Date:				
Storage Location/Condition: Property Polymer Portion performed by						
Storage Location/Condition: Property Dissolution performed by	0be 65/5°C Expi MS on09Jan17					
Dissolution performed byPl	ns on 09Jan17					
Dissolution performed byPl	ns on 09Jan17					
Dissolution performed byPl	ns on 09Jan17					
ANALYTICAL METHOD Sample Dilution:I	on <u>097an17</u>	Sample Diluted				
Dissolution performed byPI ANALYTICAL METHOD Sample Dilution:I HPLC	on <u>097an17</u>	Sample Diluted				
Dissolution performed byPI ANALYTICAL METHOD Sample Dilution:I □ HPLC System Tracking #:	on <u>097an17</u> Diluent:	Sample Diluted				
Dissolution performed byPI ANALYTICAL METHOD Sample Dilution:I □ HPLC System Tracking #: Mobile Phase:	on <u>097an17</u> Diluent:	Sample Diluted				
Dissolution performed byPI ANALYTICAL METHOD Sample Dilution:I □ HPLC System Tracking #: Mobile Phase: Calibration Standard:	on <u>09Jan17</u> Diluent:	Sample Diluted				
ANALYTICAL METHOD Sample Dilution:I HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard:	on <u>09Jan17</u> Diluent:	Sample Diluted				
ANALYTICAL METHOD Sample Dilution:I HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used:	on <u>097an17</u> Diluent:	Sample Diluted				
ANALYTICAL METHOD Sample Dilution:I HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected:	on <u>09Jan17</u> Diluent:	Sample Diluted				
ANALYTICAL METHOD Sample Dilution:I HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used:	on <u>097an17</u> Diluent:	Sample Diluted				

DISSOLUTION CHECKLIST						
Batch ID DISL-MA-170119-1 Test Sample ID 552, 9897						
Active Ingredient Weight: 1133.0 mg Stage: 1						
DISSOLUTION OPERATING CO	ADITIONS	Sample number:	5530296	2,5530247		
Sample brought to room temperature	in a desiccator:	Vessel #	Start Temp.	End Temp.		
Dissolution System	011505	1 00801 11	36,7°C	36.9℃		
Dissolution System Calibration Due:	31 Del 17	2	36. 60°C	36.9°C		
Dissolution Media (Lot/PN)	DISL_H(L-170116-01	Sample number:	5530246/	5530247		
Media Delivery Tracking #	NA	Vessel #	Start Temp.	End Temp.		
Media Delivery Calibration Due:	NA		36,5 °C	36.8°C		
Media Vol. (mL) / Apparatus	900 / (0	<u>3</u>	34.5 °C	36-8°C		
Stirring Speed (rpm)	75		55302962			
Sinkers (Type)	NA	Sample number:	Start Temp.	End Temp.		
Filter (cannula tip)	NA NA	Vessel#	36.6 °C	36.8 °C		
Filter (syringe filter)	0.45um Wylon	5	36.5 °C	36.8 ℃		
Sample Times (minutes)	(00 '050017	<u> </u>	1 20. 2 C	JQ-2 U		
Height Check Performed:	Initials: DMS Date: 19 JUMIT	Sample number:	Start Temp.	End Temp.		
Shaft Center Check Performed:	Initials:) MS Date: 1971/19	Vessel #	Start Temp.	-Z °C		
Auto sampler used?	☐ Yes	,	THE VICES !	₹ °C		
Withdraw Volume (mL)	0		1			
Vessel Temperatures taken: Automatically Manually with Tracking # 05800 Replacement Media Temperatures Taken With Tracking # NA						
Procedure/Observations:			aled.			
At 60 minutes	, the tablets are	e disintegi	ano,			

Storage Location/Condition:	Probe GS/S°C_ on	Expiration Date:
ANALYTICAL METHOD		. = 4
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 0/51 - MA - 170/25-3 Test Sample ID 5529897

Batch ID VISC - K	17 - (1010) 3				$f^{\pm}g$	
Active Ingredient Weight: 1/33.0 mg Stage: / DISSOLUTION OPERATING CONDITIONS						
Sample brought to room temperature			Sample number:			
Dissolution System	011563		Vessel #	Start Temp.	End Temp.	
Dissolution System Calibration Due:	31 Dee 17		1	37.2°C	37,3 °C	
Dissolution Media (Lot/PN)	DISL-HCL-170119-02	ll	2	37.1 ℃	37.3 ℃	
	NA		Sample number:	5530244		
Media Delivery Tracking #	NA NA		Vessel #	Start Temp.	End Temp.	
Media Delivery Calibration Due:	900 / 6		3	37.1 °C	37,3 ℃	
Media Vol. (mL) / Apparatus	75	1	4	36.9 ℃	37.2℃	
Stirring Speed (rpm)	NA	1	Sample number:	5530246	>	
Sinkers (Type)		1	Vessel #	Start Temp.	End Temp.	
Filter (cannula tip)	NA And Colo	1	S	37.1 ℃	37.1 °C	
Filter (syringe filter)	0.45 em nylon	┨	6	37.0 °C	37.2 °C	
Sample Times (minutes)	60	1		31.0		
Height Check Performed:	Initials: OMS Date: 25TCLN/-		Sample number:	Stort Temp	End Temp.	
Shaft Center Check Performed:	Initials: MS Date: 25 JCLN/	\mathcal{T}	Vessel #	Start Temp.	°C	
Auto sampler used?	☐ Yes ☑ No	-		3,000	77 °C	
Withdraw Volume (mL)		_			605993	
Vessel Temperatures taken: Automatically Manually with Tracking # OGADEG OOS993 Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At Winnutes, the tablets are disintegrated. Storage Location/Condition: Probe (85/5°C Expiration Date:						
Storage Location/Condition: <u>frok</u> Dissolution performed by <u>DMS</u>					_	
ANALYTICAL METHOD			Sample Diluted by			
Sample Dilution: Dil	uent:		_Sample Diffued by			
☐ HPLC						
System Tracking #:						
Mobile Phase:						
Verification Standard:		-				
Column Used:						

OR.F. OMS as Jan 17

Analytical Method Performed By:

Runtime:

Volume injected:
Sample Set Method:

A-170113-1 Test Sample ID 55 Z 9897

|--|

Batch ID DISL-MA-170113-1 Test Sample ID 55 2 78 77						
Active Ingredient Weight: 1133.0 mg Stage:)						
DISSOLUTION OF ERATING CO.	n a desiccator: Ve)	Sample number:	Start Temp. End Temp.			
Sample brought to room temperature i	OUS 65	Vessel #				
Dissolution System	310e(17					
Dissolution System Calibration Due:	311) (11)	2				
Dissolution Media (Lot/PN)	DISL-CB-170112-01	Sample number:	5530249			
Media Delivery Tracking #	NA NA	Vessel #	Start Temp. End Temp.			
Media Delivery Calibration Due:	NA NA	3	36.7°C 37.2 °C			
Media Vol. (mL) / Apparatus	900/6	4	36.6 °C 37.0 °C			
Stirring Speed (rpm)	75	Sample number:	\$530249			
	NA		Start Temp. End Temp			
Sinkers (Type)	NA	Vessel #	36.9°C 37.0°C			
Filter (cannula tip)	0,45 mm Nylon		36.9 °C 37-2 °C			
Filter (syringe filter)	(00)	<u> </u>				
Sample Times (minutes)	Initials: OMI Date: 13 JUNIT	Sample number:	I CL. 4 Tames HRG CHUL			
Height Check Performed:	Initials: DMS Date:13 JUN17	Vessel # Dry				
Shaft Center Check Performed:	☐ Yes ☑ No		13 TUMPG 0C			
Auto sampler used?	10		170			
Withdraw Volume (mL)		with Tracking #(20117 6			
Vessel Temperatures taken: Automatically Manually with Tracking # NA Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At (10) Minutes, the tablets are disintegrated.						
Storage Location/Condition: Prove 65/50 C Expiration Date:						
Sample Dilution:D	iluent:					
☐ HPLC						
System Tracking #:						
Mobile Phase:						
Calibration Standard:		- ·				
Verification Standard:						
Column Used:						

Volume injected:
Sample Set Method:
Analytical Method Performed By: 10 0 E NML 12 TUNIT

Runtime:

		JIV CITE CIREDIO	
Batch ID	DISL-MA-170109-1	Test Sample ID	5529898

1	3
1	1
1	1
1	V
4	

Active Ingredient Weight: 1258.9 mg Stage: 1_DISSOLUTION OPERATING CONDITIONS

Sample brought to room temperature	in a desiccator: UES
Sample brought to room temperature	117141
Dissolution System	31 Dec 17
Dissolution System Calibration Due:	ESXX-S-170109-01
Dissolution Media (Lot/PN)	325.5407.4
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA CANAL CALL
Media Vol. (mL) / Apparatus	900 16
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA NA
Filter (syringe filter)	0.45um Aylon
Sample Times (minutes)	45
Height Check Performed:	Initials: OMS Date: 09 JUN 13
Shaft Center Check Performed:	Initials: DMS Date: 09JUM
Auto sampler used?	☐ Yes
Withdraw Volume (mL)	10

Sample number:	553025	
Vessel#	Start Temp.	End Temp.
1	37.1 °C	37-3 °C
2	37.0 °C	37.3 °C
Sample number:	55302	51
Vessel #	Start Temp.	End Temp.
2	37.0 °C	37.2 °C
4	36.9 °C	37.3 °C
Sample number:	55 3025	1
Vessel #	Start Temp.	End Temp.
S	37.0 °C	37.2 °C
1.	36.9 ℃	37.2 °C
Sample number:		
Vessel # One	Start Temp.	End Temp.
Vessel # Dm.	ograno C	°C
	167	°C

Withdraw Volume (mL)
Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking # <u>00402.6</u>
Replacement Media Temperatures Taken With Tracking #NA
Procedure/Observations:
At 4s minutes, the tablets are disintegrated.
At 45 minutes, The faburs are districtly
Storage Legation/Condition: PCO/OP (05/5°C Expiration Date:
Dissolution performed by DMS on OTTANI?
•
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:
Analytical Method 1 offermod 27.

Batch ID 015L - MA - 170119-1 Test Sample ID 5 5 2 9 8 9 8

redient Weight: 1258.9 mg Stage: /

	Active Ingredient Weight: 1000					
Г	DISSOLUTION OPERATING CO		1	Sample number:	55302.50	,5530253
ļ	Sample brought to room temperature	017141		Vessel #	Start Temp.	End Temp.
ŀ	Dissolution System			1	3/4,7 °C_	36.8 °C
ŀ	Dissolution System Calibration Due:	DISC= HCC-190119-01	1	2	36.6 °C	36.7 °C
l	Dissolution Media (Lot/PN)		1	Sample number:		5530233
ŀ	Media Delivery Tracking #	NA NA	1	Vessel #	Start Temp.	End Temp.
ŀ	Media Delivery Calibration Due:	900/6	1	3	36.6 °C	36.8 °C
١	Media Vol. (mL) / Apparatus	75	-	4	36.6 °C	36.8 °C
l	Stirring Speed (rpm)	NA	┨	Sample number:	5530252	
ļ	Sinkers (Type)		┨	Vessel #	Start Temp.	End Temp.
Ì	Filter (cannula tip)	NA SASAN AND HARONO	1	V CSSCI #	3(0.5 °C	36.7 °C
	Filter (syringe filter)	0.45mm Myron	┨	1-	3(0.5 °C	36.7 °C
	Sample Times (minutes)	(0) J	1	Cample number	1000	1 20 1 0
	Height Check Performed:	Initials: OMS Date: 19 JUNI	4	Sample number: Vessel #	Start Temp.	End Temp.
	Shaft Center Check Performed:	Initials: OMS Date: 197001	47	Vessei#	One oc	°C
	Auto sampler used?	☐ Yes No	+		ms 19 ruen	Z °C
	Withdraw Volume (mL)	10	┙		<u>Ur</u>	1/2
	Replacement Media Temperatures T Procedure/Observations: At W MiNUHCS White t			ed.		
	Storage Location/Condition: Prob	e US/S'C Expi	irati	on Date:		_
	Dissolution performed by	on 19 JUN 1	}_	-		
	ANALYTICAL METHOD					
	Sample Dilution: Dilu	ient:		Sample Diluted by	*	
	☐ HPLC					
	System Tracking #:					
	Mobile Phase:					
	Calibration Standard:					
	Verification Standard;					
	Column Used:					
	Runtime:					
	I Malanas amanatadi					

Sample Set Method:

Batch ID DISL-IMA-170113-1 Test Sample ID 5529898

Active Ingredient Weight:	1258.9 mg	Stage:	
DISSOLUTION OPERA	TING CONDITIO	NS	

DISSOLUTION OPERATING CO			553625
Sample brought to room temperature	in a desiccator: リピラ	Sample number:	<u> </u>
Dissolution System	011565	Vessel #	Start Temp.
Dissolution System Calibration Due:	21 her 16 31ne(17)	l	37.0 °C
Dissolution System Canoration Business Dissolution Media (Lot/PN)	DISL-CB-170112-01	2	36.7℃
	NA	Sample number:	55302
Media Delivery Tracking #		Vessel #	Start Temp.
Media Delivery Calibration Due:	NA 900 / 11	3	36.5 ℃
Media Vol. (mL) / Apparatus	900 / 0		36,5 °C
Stirring Speed (rpm)	7		55302
Sinkers (Type)	NA	Sample number:	
Filter (cannula tip)	NA	Vessel #	Start Temp.
Filter (syringe filter)	0.45em NYION	<u> </u>	36 8 °C
	(p()	6	36.70
Sample Times (minutes)	Initials: OMS Date: 13 TUNIF	Sample number:	
Height Check Performed:		77 111	Start Temp.
Shaft Center Check Performed:		Vessel # DIA	15 1377 C
Auto sampler used?	☐ Yes ☑ No		1-34/3/7
Withdraw Volume (mL)	10		
	- MAGanalkun	rith Tracking # <i>0.0</i>	14076
Vessel Temperatures taken:	Automatically 🔲 Manually w	THI Tracking #	1000
=			

Sample number:	553025	4
Vessel #	Start Temp.	End Temp.
(37.0 ℃	37.2 °C
2_	36.7℃	37.2℃
Sample number:	55302	54
Vessel#	Start Temp.	End Temp.
3	36,5 ℃	37.2 ℃
4	36.5 ℃	37.1 °C
Sample number:	55302	S4
Sample number: Vessel #		S 4 End Temp.
Sample number: Vessel #	55 302 Start Temp. 36 8 °C	· · · · · · · · · · · · · · · · · · ·
	Start Temp.	End Temp.
Vessel # 5' 6	Start Temp.	End Temp.
Vessel # 5 6 Sample number:	Start Temp. 36 8 °C 36.7 °C Start Temp.	End Temp.
Vessel # 5' 6	Start Temp. 36 8 °C 36.7 °C Start Temp.	End Temp. 37.2°C 37.1°C
Vessel # 5 6 Sample number:	Start Temp. 36.8 °C 36.7 °C	End Temp. 37.2°C 37.1°C

Replacement Media Temperature/Observations:	eratures Taken With Trac	cking #NA
At 60 minus disintegrat	res, the holds	ofs agree completely
Storage Location/Condition	on: Probe 65/5°C	Expiration Date:
Dissolution performed by	omso	n 13 JUN 17
ANALYTICAL METHO		
Sample Dilution:	Diluent:	Sample Diluted by:

()R.F. DMS 13Tan17

Analytical Method Performed By:

☐ HPLC

System Tracking #: Mobile Phase:

Column Used: Runtime:

Volume injected: Sample Set Method:

Calibration Standard: Verification Standard:

Batch ID DISL-MA-170116 Test Sample ID 552 9899 also I from Active Ingredient Weight: 1305. 8 mg Stage: | DISSOLUTION OPERATING CONDITIONS 5530257, 5530758 Sample brought to room temperature in a desiccator: US Sample number: End Temp. Start Temp. Vessel# 0115105 Dissolution System 36.9 °C =6. 8°C 1 31 Dee17 Dissolution System Calibration Due: 36.8 °C 36.6 °C DISL-HCL-170116-01 Dissolution Media (Lot/PN) 55302S 4530257 Sample number: NA Media Delivery Tracking # End Temp. Start Temp. Vessel# NA Media Delivery Calibration Due: 36. Sr °C 36.5 °C 900 / 6 Media Vol. (mL) / Apparatus *36.6* °C 36.7 °C Stirring Speed (rpm) 55302S <530257 NIA Sample number: Sinkers (Type) Start Temp. End Temp. Vessel# NA Filter (cannula tip) 36.8 °C 0.45 mm Nylori 36.6°C S Filter (syringe filter) 36.8 °C 36.5 °C 6 Sample Times (minutes) Initials: OMS Date: 193001 Sample number: Height Check Performed: Di Start Temp. E End Temp. Initials: DVMS Date: 1950M17 Vessel# Shaft Center Check Performed: √D No ☐ Yes Auto sampler used? Withdraw Volume (mL) Manually with Tracking # _ OIS80 6 ☐ Automatically Vessel Temperatures taken: Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At 60 minutes, the tablets are disintegrated. Storage Location/Condition: Prote 65/5°C Expiration Date:

Dissolution performed by on 197017 ANALYTICAL METHOD Sample Dilution: ______ Diluent: ______ Sample Diluted by: _____ ☐ HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Column Used: Runtime: Volume injected: Sample Set Method:

Analytical Method Performed By:

R. E. DMS 19 JW17

Bate

Batch ID DISL - MA - 170	113- Test Sample ID 5529899	ĹĈ
Active Ingredient Weight: 13 95.8 mg Sta	ge:\\	

	<i>-</i>		_
DISSOLUTION	OPERA'	TING CONE	ITIONS

DIDUCTION OF THE PROPERTY OF T	
Sample brought to room temperature	in a desiccator: US
Dissolution System	017141
Dissolution System Calibration Due:	
Dissolution Media (Lot/PN)	DISL-08-17012-01
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)	Ψ Ο γ
Height Check Performed:	Initials: DMS Date: 13 JUN17
Shaft Center Check Performed:	Initials: DMS Date: 3 JUNI 7
Auto sampler used?	□ Yes
Withdraw Volume (mL)	10
Shaft Center Check Performed: Auto sampler used?	Initials: DMS Date: 3 JUNI

Sample number:	S53025	9
Vessel #	Start Temp.	End Temp.
1	36.9 °C	37.1 ℃
2	36.7 °C	37.1°C
Sample number:	55 3025	59
Vessel #	Start Temp.	End Temp.
3	34.7 °C	37·1 °C
4	36.7°C	37.1 °C
Sample number:	55302.	59
Vessel #	Start Temp.	End Temp.
5	36.5 °C	371 °C
0	36.7 °C	370 °C
Sample number:		
	Start Temp.	End Temp.
177	137000	°C
	007	°C

Vessel Temperatures taken:	☐ Automatically	Manually	with Tracking	# <u>00402(0</u>
Replacement Media Temperature	s Taken With Tracking	#	<u>N</u> A	
Procedure/Observations:				đ
At 60 minutes,	, the fablet	is com	pretely	disintegrated.
Storage Location/Condition: P)	be 65/5°C	Expi	iration Date: _	
Dissolution performed by DN	1S on 13	3 JUN 17	<u>-</u>	
ANALYTICAL METHOD				
Sample Dilution: I	Oiluent:		Sample Di	luted by:
☐ HPLC				
System Tracking #:				
Verification Standard: Column Used:				
Runtime:				
Volume injected:		***		
Sample Set Method:				
Analytical Method Performed By	/:			

Batch ID DISL - MA - 170 | 09 - 1 Test Sample ID 5529900

	1
	11
1	1
1	%

°C °C

°C °C

Stage:_\ Active Ingredient Weight: 120(g.(g mg S)
DISSOLUTION OPERATING CONDITIONS

Column Used: Runtime: Volume injected: Sample Set Method:

Sample brought to room temperature	in a desiccator: Ves	ΙΓ	Sample number:	553026	0
Dissolution System	011565		Vessel #	Start Temp.	End Temp.
Dissolution System Calibration Due:) [1	37.4 °C	37.4 °C
Dissolution Media (Lot/PN)	ESXX-S-170109-01		2	37.3 ℃	37.4 °C
Media Delivery Tracking #	NA		Sample number:	553026	0
Media Delivery Calibration Due:	NA		Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900 16		3	37.2 °C	37.3 °C
Stirring Speed (rpm)	75	1 L	4	37.1 ℃	37.2 °C
Sinkers (Type)	NA		Sample number:	553026	0
Filter (cannula tip)	NA		Vessel #	Start Temp.	End Temp.
Filter (syringe filter)	0.45 um NylVN		5	37.3 °C	37.3 °C
Sample Times (minutes)	45	l L	6	37.2 °C	37.4 °C
Height Check Performed:	Initials: DMS Date: 097Uh1=	7	Sample number:		T
Shaft Center Check Performed:	Initials: OMS Date: 09JUN1=	1 L	Vessel # DMS	Start Temp.	End Temp.
Auto sampler used?	☐ Yes ☑ No		- 773	Start Temp.	°C
Withdraw Volume (mL)	10	JL		., 4€	eC
Procedure/Observations: At 45 Minutes, t	he tablets are	dis	sinlegrale	»d.	
Storage Location/Condition: Proba Dissolution performed by	S on 09Jan17		n Date:		,
Sample Dilution:Dilu	CIIL		ample Diffued by:		
□ HPLC					
Ct T1 #:					
System Tracking #:	and the second s				
Mobile Phase:					
Calibration Standard:					
Verification Standard:					

Batch ID DISL - MIA - 170120- | Test Sample ID 55 2 9 900

Active Ingredient Weight: 1206 (a) DISSOLUTION OPERATING COM					
Sample brought to room temperature is		Sample number	r: 6530761,5530262		
Dissolution System	017141	Vessel #	Start Temp. End Temp.		
Dissolution System Calibration Due:	31 Decl 7	1	37-1 ℃ 37-1 ℃		
Dissolution Media (Lot/PN)	DISI-HCL-170116-01, DISL	HU-110111-01 2	37.1°C 37.1 °C		
Media Delivery Tracking #	NA NA	Sample numbe			
Media Delivery Calibration Due:	NA	Vessel #	Start Temp. End Temp.		
Media Vol. (mL) / Apparatus	900 16	3	371 °C 371 °C		
Stirring Speed (rpm)	75	4	37.1 ℃ 37.1 ℃		
Sinkers (Type)	NA	Sample numbe			
Filter (cannula tip)	NA	Vessel #	Start Temp. End Temp.		
Filter (syringe filter)	0.45 UM NU		37.0 ℃ 37-1 ℃		
Sample Times (minutes)	60	6	37.0 °C 37.1 °C		
	initials: ()MS Date: 20				
	nitials: Date: Of	mmi Vessel # D			
	□ Yes	1	20 Trues °C		
Withdraw Volume (mL)	16		Start Temp. End Temp. OCC CC SC SC SC SC SC SC SC S		
Vessel Temperatures taken: Replacement Media Temperatures Tak	•	nually with Tracking # <u>&</u> NA	109 0 01580 004026		
Procedure/Observations:					
At 60 minutes, th	e tables	LIC MISTRIC			
Storage Location/Condition: Probe (os/ soc	Expiration Date:			
Dissolution performed by <u>OWYS</u>	on <u>20 TU</u>	117_			
ANALYTICAL METHOD					
Sample Dilution: Diluer	nt:	Sample Diluted b	oy:		
□ HPLC					
System Tracking #:					
Makila Dhasar					
Calibration Standard:			·		
Vanification Standard					
Column Used:					
Runtime:					
Volume injected:					
Sample Set Method:					
Analytical Method Performed By:					
10-20			· · · · · · · · · · · · · · · · · · ·		

OR.E. oms 20Tan17

Batch ID DISL-	MH-170113-1 Test Sample	ID 552990	00	
Active Ingredient Weight: 1206.0 DISSOLUTION OPERATING CO				
Sample brought to room temperature	in a desiccator: U25	Sample number:	553026	
Dissolution System	011565	Vessel#	Start Temp.	End Temp
Dissolution System Calibration Due:		1	37-1 °C	37.30
Dissolution Media (Lot/PN)	DISL-CB-170112-01	2	37.0°C	37.30
Media Delivery Tracking #	NA	Sample number:	553026	
Media Delivery Calibration Due:	NA	Vessel #	Start Temp.	End Temp
Media Vol. (mL) / Apparatus	900 / 0	3	36.7C	37.20
Stirring Speed (rpm)	75	4	36. 6°C	37.0 0
Sinkers (Type)	NA	Sample number:	55302	63
Filter (cannula tip)	NA	Vessel#	Start Temp.	End Temp
Filter (syringe filter)	0.45-um NyIVN	5	37.0°C	37.30
Sample Times (minutes)	(00)	W	36.9℃	37.10
Height Check Performed:	Initials: DMS Date: 13JUN17	Sample number:		T
			10000000 CONTACTOR C	T 1

Initials: DMS Date: 13 JUNI7

ĭ No

10

☐ Yes

Shaft Center Check Performed:

Auto sampler used?

Withdraw Volume (mL)

End Temp.

°C

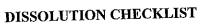
OC.

Start Temp.

13 TelnitoC

Vessel#

Vessel Temperatures taken: Automatically Manually with Tracking #
Replacement Media Temperatures Taken With Tracking #NA
Procedure/Observations:
At 60 minures, the tablets are disintegrated.
15 (10) Million of 1000 and 10
Storage Location/Condition: Probe 45/5°C Expiration Date:
Dissolution performed byOM S on137CUN 17
Dissolution performed by or or
ANALYTICAL METHOD
Sample Dilution: Diluent: Sample Diluted by:
System Tracking #:
Mobile Phase:
Calibration Standard:
Verification Standard:
Column Used:
Runtime: Volume injected:
Volume injected: Sample Set Method:
Analytical Method Performed By:





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

Active Ingredient Weight: 12 53, 9 mg Stage: 1	
DISSOLUTION OPERATING CONDITIONS	_
DISSOLUTION OF EXATING COLUMN	Cample

DISSOLUTION OPERATING COL Sample brought to room temperature	in a desiccator: Yes
Dissolution System	017141
Dissolution System Calibration Due:	31Dec17
Dissolution Media (Lot/PN)	FSXX_S-170109-01
Media Delivery Tracking #	NA NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900 /6
Stirring Speed (rpm)	75
Sinkers (Type)	N/ +
Filter (cannula tip)	NA NA
Filter (syringe filter)	0.45 Mm Nylon
Sample Times (minutes)	45
Height Check Performed:	Initials: DM5 Date: 09 Juni
Shaft Center Check Performed:	Initials: OMS Date: 09 rand
Auto sampler used?	☐ Yes
Withdraw Volume (mL)	

Volume injected:
Sample Set Method:

Sample number:	553026	4
Vessel #	Start Temp.	End Temp.
1	373 °C	37.3 ℃
2	37-3 °C	37.3 °C
Sample number:	553026	,4
Vessel#	Start Temp.	End Temp.
3	34.3 °C	31.3 °C
4	31.3 °C	373 °C
Sample number:	553026	4
Vessel #	Start Temp.	End Temp.
5	37.2 °C	37.2 °C
6	37.2 °C	37-3 ℃
Sample number:		
Vessel # Das	Start Temp.	End Temp.
	Jag/2C	°C
		°C
l.	1 "	- Commence

Vessel Temperatures taken:	☐ Automatically	Manually with			
Replacement Media Temperat	ures Taken With Trackin	ıg#1	NA	_	
Procedure/Observations:					
Storage Location/Condition: Dissolution performed by	Probe 65/5°C DMS on_	Expirati 09 Jan 17	ion Date:		
ANALYTICAL METHOD					
Sample Dilution:	Diluent:		_Sample Dilute	ed by:	
□ HPLC					
System Tracking #					
Mobile Phase					
Calibration Standard: Verification Standard:	<u></u>				
Verification Standard: Column Used:					
Runtime:					

Sample brought to room temperature in a desiccator: OLS Dissolution System Dissolution System Calibration Due: 3 Dec 7 Dissolution Media (Lot/PN) DISL_HCL-170 9-0 NA Sample number: Start Temp. End Temp. 1 37.0 °C 37.0 °C 37.0 °C 37.0 °C 37.0 °C 37.0 °C 37.0 °C 37.0 °C 37.0 °C 37.0 °C
Sample brought to room temperature in a desiccator: US Dissolution System Dissolution System Calibration Due: 3 Del 7 Dissolution Media (Lot/PN) DISL_HLL-1701 9-0 NA Sample number: \$53\(\text{2}\) \(\text{5}\) \(\te
Sample brought to room temperature in a desiccator: US Dissolution System Dissolution System Calibration Due: 3 Del 7 Dissolution Media (Lot/PN) DISL_HLL-1701 9-0 NA Sample number: \$53\(\text{2}\) \(\text{5}\) \(\te
Sample brought to room temperature in a desirection. Dissolution System Dissolution System Calibration Due: 3 De(7) Dissolution Media (Lot/PN) DISL_H(L-170) 9-0 NA Vessel # Start Temp. End Temp. / 37.0 °C
Dissolution System 011503 / 37.0 °C 37.0 °C Dissolution System Calibration Due: 31 De(17 2 37.0 °C 37.0 °C Dissolution Media (Lot/PN) DISL_HCL-170119-01 2 37.0 °C 37.0 °C Sample number: \$530265, \$530266 530266 530266
Dissolution Media (Lot/PN) DISL_HCL-1701 9-0 Sample number: \$530265
NA Sample number: S 3 Settle 5
NA Disput Tracking #
Media Delivery Tracking # Vessel # Start Temp. End Temp. NA Vessel # Start Temp.
Media Delivery Calibration Due: 37-0 °C 36. 9°C
Media Vol. (mL) / Apparatus 4 36.9 °C 36.8 °C
Stirring Speed (1911) Sample number: K < 20/6) 33 20 26 C
Sinkers (Type) Vessel # Start Temp. End Temp.
Filter (cannula tip) 36.9 °C 36.9 °C
Sample Times (minutes)
Height Check Performed: Initials: \(\rangle \) \(\rangle \) \(\rangle \) Date: \(\frac{20000}{2000} \) \(\rangle \) Vessel \(\frac{4}{2000} \) Start Temp. End Temp. \(\rangle \) Shaft Center Check Performed: Initials: \(\rangle \) \(\rangle \) \(\rangle \) Date: \(\frac{20000}{2000} \) \(\rangle \) \(\rangle \) Vessel \(\frac{4}{2000} \) \(\rangle \
Shaft Center Check Performed: Initials: 7) M 5 Date: 2 USDAT Vessel # Start Temp. Shaft Center Check Performed: Date: 2 USDAT Vessel # Start Temp. Shaft Center Check Performed: Date: 2 USDAT Vessel # Shaft Center
Height Check Performed: Initials: \(\rightarrow \mathbb{M} \rightarrow \) Date: \(\frac{20}{30} \mathbb{M} \rightarrow \) Tate: \(\frac{20}{30} \mathbb{M} \rightarrow \) Vessel \(\frac{8}{30} \mathbb{M} \rightarrow \) Start Temp. End Temp. Auto sampler used? \(\frac{1}{30} \mathbb{M} \rightarrow \) No \(\frac{1}{30} \mathbb{M} \rightarrow \) Withdraw Volume (mL)
1 0/(8/) (2
Vessel Temperatures taken: ☐ Automatically ☐ Manually with Tracking # _ Ø/580 ←
Replacement Media Temperatures Taken With Tracking #NA
Procedure/Observations:
Procedure/Observations.
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
At 60 minutes, the tablets are disintegrated'
Storage Location/Condition: Probe US/SOC Expiration Date: Dissolution performed by DMS on 2070M17
Storage Location/Condition: Probe 65/50C Expiration Date: Dissolution performed by 1MS on 207017
Storage Location/Condition: Probe US/SOC Expiration Date: Dissolution performed by DMS on 2070M17
Storage Location/Condition: Probe 65/50C Expiration Date: Dissolution performed by 1MS on 207017
Storage Location/Condition: Probe 65/5°C Expiration Date: Dissolution performed by DMS on 2070M17 ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by:
Storage Location/Condition: Probe 105/5°C Expiration Date: Dissolution performed by
Storage Location/Condition: Probe US/SOC Expiration Date: Dissolution performed by
Storage Location/Condition: Probe US/COC Expiration Date: Dissolution performed by
Storage Location/Condition: Probe 105/50 Expiration Date: Dissolution performed by
Storage Location/Condition: Probe US/COC Expiration Date: Dissolution performed by DMS on 2070M17 ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by: HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Verification Standard: Column Used:
Storage Location/Condition: Probe US/5°C Expiration Date: Dissolution performed by
Storage Location/Condition: Probe US/COC Expiration Date: Dissolution performed by DMS on 2070M17 ANALYTICAL METHOD Sample Dilution: Diluent: Sample Diluted by: HPLC System Tracking #: Mobile Phase: Calibration Standard: Verification Standard: Verification Standard: Column Used:

Batch ID DISL-MA	Test Sampl	e ID <u>5</u>	529901		
Active Ingredient Weight: 1253.					
DISSOLUTION OPERATING CO	NDITIONS			1 m E 2 n -31 -71	
Sample brought to room temperature	in a desiccator: Uts		<u>le number:</u>	5530247	End Temp.
Dissolution System	017141	Vesse	el #	Start Temp.	31.0 °C
Dissolution System Calibration Due:	31De(17		1	37.0 °C	
Dissolution Media (Lot/PN)	DISL-CB-170112-01	<u> </u>	2	37.1 °C	37.1 °C
Media Delivery Tracking #	NA		le number:	5530267	End Town
Media Delivery Calibration Due:	NA	Vesse	el#	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900 / 4		3	37.0 °C	<u> </u>
Stirring Speed (rpm)	75		4	37.0 °C	37. \ °C
Sinkers (Type)	NA		ole number:		T 17
Filter (cannula tip)	NA	Vess		Start Temp.	End Temp.
Filter (cannua up) Filter (syringe filter)	0.45 MM NYION		5	37.0 °C	37.0 °C
Sample Times (minutes)	(0)	L	<u>'Y</u>	37.0 °C	37.0 °C
Height Check Performed:	Initials: KUA Date: \UJUNIT		ole number:	1 2014	Harry Commen
Shaft Center Check Performed:	Initials: KUA Date: WINT	Vess	<u>el#</u>	Marila Temp-	End Temp.
Auto sampler used?	☐ Yes ☑ No		KIN	°C	°C
Withdraw Volume (mL)	10			°C	°C
Withdraw Volume (IIIL)	<u></u>			unala	
V 03301 1 0111 por una	Automatically Manually v		king # <u>U (</u>	19024	
Replacement Media Temperatures T	aken With Tracking #	NA_			
Procedure/Observations:			الم مرا		
	wildett interf fallil	dicint	ra vatta	ü	
After 40 minutes, the	TUNKIS WITH TORY	00131111	()		
711101					
and the	OLUS/50 Expi	ration Da	ite:	-	
Storage Location/Condition: PVV					
Dissolution performed by KUA	on Mall				
Dissolution performed by					
ANALYTICAL METHOD					
Sample Dilution: Di	luent:	Samp	ole Diluted b	y:	
-					
System Tracking #:					
Mobile Phase:					
Calibration Standard:				·	
Verification Standard:					
Column Used:					
Runtime:					
Sample Set Method:					
Analytical Method Performed By:					

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

Shanned Street	(*
S. Branch	

Active Ingredient Weight: 233-3 mg Stage: 1

DISSOLUTION OPERATING CONDITIONS

DISSOLUTION OF EXAMING CO	/I IDAXXOXID
Sample brought to room temperature	in a desiccator: UES
Dissolution System	011565
Dissolution System Calibration Due:	
Dissolution Media (Lot/PN)	ESXX-S-170109-01
Media Delivery Tracking #	NA
Media Delivery Calibration Due:	NA
Media Vol. (mL) / Apparatus	900/0
Stirring Speed (rpm)	75
Sinkers (Type)	NA
Filter (cannula tip)	NA
Filter (syringe filter)	0.45 um NyION
Sample Times (minutes)	45
Height Check Performed:	Initials: OMS Date: 19 July 17
Shaft Center Check Performed:	Initials: MS Date: 197017
Auto sampler used?	☐ Yes 🔼 No
Withdraw Volume (mL)	10

Sample number:	5530270	
Vessel#	Start Temp.	End Temp.
1	37.4 °C	37-2 ℃
2	37.4 ℃	34.2℃
Sample number:	5530270	
Vessel #	Start Temp.	End Temp.
3	37.4 ℃	37.2 °C
4	37.2 °C	37.2 ℃
Sample number:	SS3027)
Sample number: Vessel #	SS3()27(Start Temp.	End Temp.
	Start Temp. 37.4 °C	End Temp.
	Start Temp.	
	Start Temp. 37.4 °C	37.2 °C
Vessel #	Start Temp. 374 °C 37.3 °C	37.2 °C
Vessel # 5 1; Sample number:	Start Temp. 374 °C 37.3 °C	37.2 °C 37.2 °C
Vessel # S Sample number:	Start Temp. 374 °C 37.3 °C Start Temp.	37.2 °C 37.2 °C End Temp.

Auto sampler used?	☐ Yes		TOUNT C	°C
Withdraw Volume (mL)	10		Too.	°C
Vessel Temperatures taken:		nually with Tracking #	4026	
Replacement Media Temperatures T	aken With Tracking #	NA		
Procedure/Observations:				
	1 *			
Storage Location/Condition:	205/5°C	Expiration Date:		
Dissolution performed by DMS	on 09704	117		
Dissolution performed by	on on	//		
ANALYTICAL METHOD				
		g 1 7511 + 11		
Sample Dilution: Dilu	ient:	Sample Diluted by		
☐ HPLC				
G / T1:#.		<u> </u>		
System Tracking #: Mobile Phase:				
Calibration Standard:				
Verification Standard:				
Column Used:		1. N. 1707-1		
Runtime:				
Volume injected:				
Sample Set Method:	***			
Analytical Method Performed By				

Batch ID DISL-MA-170123-1 Test Sample ID 552 9902

Daten ID DIVE (V	1 (1018) 1 = 1 = 1 = 1				
Active Ingredient Weight: 233.3					
DISSOLUTION OPERATING CO		1	6 1 1	K = 7 4.	((2))74
Sample brought to room temperature			Sample number: Vessel #	5530 2 71 Start Temp.	End Temp.
Dissolution System	0)7141	-		37 C	372 °C
Dissolution System Calibration Due:	31 pec17	1	1		37.1 °C
Dissolution Media (Lot/PN)	DISL-HCL-170119-01	-	2 1	1/2	SS30272
Media Delivery Tracking #	NA NA	1	Sample number:		End Temp.
Media Delivery Calibration Due:	NA NA	1	Vessel #	Start Temp.	150
Media Vol. (mL) / Apparatus	900 / 6	┨	3	37.0 °C 37.0 °C	37.1 °C 37.0 °C
Stirring Speed (rpm)		1	4		
Sinkers (Type)	NA	-	Sample number:	5530271,	5530272
Filter (cannula tip)	NA NA	-	Vessel #	Start Temp.	End Temp. ろうの °C
Filter (syringe filter)	0.45 ym Nylon	-		36.9 °C	
Sample Times (minutes)	60	1	<i>\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\</i>	37-0 °C	37.1 °C
Height Check Performed:	Initials: DIMS Date: 23 JUNIA		Sample number:	Start Temp.	End Temp.
Shaft Center Check Performed:	Initials: DMS Date: 37411	†	Vessel # DL	ctart temp.	End Temp.
Auto sampler used?	☐ Yes XI No	-		700	°C °C °C
Withdraw Volume (mL)	16			<u>.</u>	30
Vessel Temperatures taken:	Automatically Manually	witl	n Tracking# <u>06</u>	9026	
Replacement Media Temperatures T	aken With Tracking #]	NA		
Procedure/Observations:			_		
Procedure/Observations: At 60 Minutes be fully disinted	the tablets o	do	, not app	iech re	>
THE SO PRINCE					
be fully disinted	gralect.				
	J				
Starra Landian/Condition: Purk	o lo C / C Evnis	rati	on Date:		
Storage Location/Condition: Prob	· · · · · · · · · · · · · · · · · · ·		on Bate		-
Dissolution performed byDMS	on 23 7ah 17				
•					
ANALYTICAL METHOD					
Sample Dilution: Dilu	ent:		Sample Diluted by:		
□ HPLC					
System Tracking #:					
Mobile Phase:					
C 17 / Ct d d.					
10 .1 O. 1 1					
Column Used:					
Runtime:					
I CHILLIII C.					

Volume injected: Sample Set Method:

Batch ID DISL-MA	-17 fills - Lest Samp	le I	D 5529902)_		
		10 .		<u> </u>		
Active Ingredient Weight: 233.3	mg Stage: i					
DISSOLUTION OPERATING CO	NDITIONS		Sample number:	5530273	**	
Sample brought to room temperature	in a desiccator: Uts		Vessel #	Start Temp.	End Ten	1p.
Dissolution System	<u> </u>		V 03301 11	37.2 °C		°C
Dissolution System Calibration Due:	3100017		2	37.2 °C	37.2	°C
Dissolution Media (Lot/PN)	DISL-(B-170112-02	1	Sample number:	553027		
Media Delivery Tracking #	NA NA	i	Vessel #	Start Temp.	End Ter	np.
Media Delivery Calibration Due:	900 / 6	1	3	37.2 °C	37.2	°C
Media Vol. (mL) / Apparatus	75	1	ŭ	37.1 °C	37.0	°C
Stirring Speed (rpm)	will beix	1	Sample number:	553077		
Sinkers (Type)	NA	1	Vessel #	Start Temp.	End Ter	
Filter (cannula tip)	0.45 NUION	1	5	37.0 °C	37.0	°C_
Filter (syringe filter)	(10)	1	V	37.∫ °C	37.1	°C
Sample Times (minutes)	Initials: KUA Date: 17060	1	Sample number:			
Height Check Performed: Shaft Center Check Performed:	Initials: KUA Date: MUNIT	1	Vessel#	Alalt Temp.	End Ter	
Auto sampler used?	☐ Yes 🏿 No]	KUTTE	Alalt Temp.	 	°C
Withdraw Volume (mL)	10	⅃		°C		°C
	Manually.	it	h Tracking#(_(\)	40210		
resser remperature	, ,					
Replacement Media Temperatures T	aken With Tracking #		NA			
Procedure/Observations:						
Procedure/Observations.	ادا دا شده ۱۰۰ میدود د.	di	un terivated			
After 40 minutes, the	tablets well tully	O()	III) II MIMILIA			
a i Gandisian Prola	e 145/56 Exp	irat	ion Date:			
Storage Location/Condition: PYOW						
Dissolution performed by KUA	on IUJUIII					
ANALYTICAL METHOD						
Sample Dilution: Dil	uent:		_Sample Diluted by	":		
□ HPLC						
System Tracking #:						
Mobile Phase:						
Verification Standard:						
Column Used:						
Runtime:				-		

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

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Batch ID DISL-N	14-170109-1 Test Sample	D <u>552990</u>	<u>) 5</u>	
Active Ingredient Weight: 1245 DISSOLUTION OPERATING COM	mg Stage: 1			
DISSOLUTION OPERATING COL	in a desiccator: VeS	Sample number:	5530275	
Sample brought to room temperature i	n a desiccator: 145	Vessel #	Start Temp.	End Temp.
Dissolution System	0171	1	313 °C	37.3 °C
Dissolution System Calibration Due:	31Dec17	2	31.3 °C	37.3 °C
Dissolution Media (Lot/PN)	ESXX-S-170109-010		553023	5
Media Delivery Tracking #	NA	Sample number:	Start Temp.	End Temp.
Media Delivery Calibration Due:	NA NA	Vessel #		37.2 °C
Media Vol. (mL) / Apparatus	900 / 6	3	6.0	37.2 °C
	75	4	37.2 °C	
Stirring Speed (rpm)	NA	Sample number:	553027	
Sinkers (Type)	NA	Vessel #	Start Temp.	End Temp.
Filter (cannula tip)	0.45mm NYION	5	37.2 °C	373 °C
Filter (syringe filter)		6	312°C	37.7 °C
Sample Times (minutes)	45 	The la number	<u> </u>	
Height Check Performed:	Initials: OMS Date: 09 Jun 7	Vessel #	Start Temp.	End Temp.
Shaft Center Check Performed:	Initials: OM) Date: 09 July -	V C33CI 11	Start Temp.	°C
Auto sampler used?	☐ Yes Yo		°C	°C
Withdraw Volume (mL)	10	ith Tracking # OC		<u> </u>
Procedure/Observations: A+ 45 minutes th	e tablets are c		,	
THE STATE OF THE S	on 09 Jan 17			
ANALYTICAL METHOD		Sample Diluted h	1 7 /*	
Sample Dilution:Di	luent:	sample Dirace -	·	
☐ HPLC				
System Tracking #:				
System Tracking #.				
Calibration Standard.				
Verification Standard:				
Column Used:				

Sample Set Method:
Analytical Method Performed By: (DESXX-5-170109-02 was also used DMS 09 Jan 17

Runtime:

Volume injected:

140173-1 Test Sample ID 5529903

Batch ID DISL-1	4A-170123-1 Test Sample	10_552990.	<u> </u>	
Active Ingredient Weight: 1245.	mg Stage: _			
DISSOLUTION OPERATING CO	in a desiccator: ULS	Sample number:	5530278,5	530277
Sample brought to room temperature	in a desiccator: UK >	Vessel #	Start Temp.	End Temp.
Dissolution System	011505	/ /	37.0 °C	37.0°C
Dissolution System Calibration Due:	31 bec17		37.0 °C	37.0 °C
Dissolution Media (Lot/PN)	DISL-H(L-170117-01	Sample number:	SS 30277, S	530278
Media Delivery Tracking #	NA NA	Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	NA		3 6.9 °C	37.0 °C
Media Vol. (mL) / Apparatus	900/6	3	36.8°C	36-9°C
Stirring Speed (rpm)	75	9	5530277	- 1
Sinkers (Type)	NA	Sample number:		End Temp.
Filter (cannula tip)	NA	Vessel #	Start Temp.	37.0 °C
Filter (syringe filter)	0.45 um MUV			37.0 °C
Sample Times (minutes)	ωO	6	36.9 ℃	1 340 C
Height Check Performed:	Initials: OMS Date: 237W17	Sample number:		E. J. Tomp
Shaft Center Check Performed:	Initials: 19MS Date: 23 JUN17	Vessel # PH1	Start Temp.	End Temp.
Auto sampler used?	☐ Yes		23Teng	°C
Withdraw Volume (mL)	10		<u>°°C</u>	°C
	e tablets are dis			
Storage Location/Condition: Proka	on $\frac{2370017}{}$	ation Date:		
ANALYTICAL METHOD		Sample Diluted b	v:	
Sample Dilution: Di	luent:	Sample Dilated of	<i>J</i> ·	
☐ HPLC				
Gartem Tracking #				
Mobile Phase:				
Calibration Standard:				
Column Used:				Ì

Runtime: Volume injected: Sample Set Method:

DISSOLUTION CHECKLIST						
Batch ID DISL-MA	-170114-1	_ Test Sample I	D <u>5529903</u>			
Active Ingredient Weight: 12459 DISSOLUTION OPERATING CO	mg Stage:_ <u>\</u> NDITIONS					
Sample brought to room temperature	in a desiccator:	Ats		5530279	End Ton	
Dissolution System	01 1191		Vessel #	Start Temp.	End Tem	
Dissolution System Calibration Due:	3108(17			30.9 °C		°C °C
Dissolution Media (Lot/PN)	DISL-CB-17011	2-02	2	37.1 °C	31.2	-
Media Delivery Tracking #	<u>N</u> A		Sample number:	S530279	End Ten	- l
Media Delivery Calibration Due:	NA		Vessel#	Start Temp. 37. \ °C	37.1	°C
Media Vol. (mL) / Apparatus	100	/ W	3	37.0 °C		-c
Stirring Speed (rpm)	15		<u> </u>	5530270		러
Sinkers (Type)	NA		Sample number:		End Ten	
Filter (cannula tip)	NA		Vessel #	Start Temp.	37.1	°C
Filter (syringe filter)	0.45 MM	MAION	5	37.0 °C	37.0	°C
Sample Times (minutes)	U	11.8101017	S l sand			
Height Check Performed:	Initials: KUA Da	ate: 100011	Sample number: Vessel #	Busit Femp.	End Ter	np.
Shaft Center Check Performed:	Initials: K Uf Da	ate: [[A]([A])	Vessel #	°C	<u> </u>	°C
Auto sampler used?	☐ Yes No			°C		°C
Withdraw Volume (mL)	10					
Vessel Temperatures taken:	Automatically	Manually wit	h Tracking#	4020		
Replacement Media Temperatures T	aken With Tracking	#	NA			
Procedure/Observations:						
		e Oil P a	aller dicha	Leava Lea		
Atter 40 minutes	the tubles	5 Were T	villy oush	(Coproof Cor		
Storage Location/Condition:	1 105 150	Expirat	ion Date:			
Storage Location/Condition. 1 10/2	1 00 700	=				
Dissolution performed by KLA	on	U(J(L) (II)	_			
ANALYTICAL METHOD						
Sample Dilution: Dil	ient:		_Sample Diluted by	:		
☐ HPLC						
System Tracking #:						\dashv
Mobile Phase:						\neg
Calibration Standard:					<u></u>	\neg
Verification Standard:						一
Column Used:						\neg
Runtime:						
7 0 200						\neg
Sample Set Method:						\neg
Analytical Method Performed By:						

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1	

Batch ID _ DISL - MA - 170109-1 Test Sample ID _ 55 29904

Active Ingredient Weight: 1468		Ш_ <u> </u>		
	3 _{mg} Stage: \			
DISSOLUTION OPERATING CO	NDITIONS			
		Sample number:	55302	81
Sample brought to room temperature	Olls 6	Vessel #	Start Temp.	End Temp.
Dissolution System		1	34.4 °C	31.3 °C
Dissolution System Calibration Due:	ESXX-S-170109-02	2	37.3 °C	31-3°C
Dissolution Media (Lot/PN)		Sample number:	553028	
Media Delivery Tracking #	NA NA	Vessel #	Start Temp.	End Temp.
Media Delivery Calibration Due:	$\frac{NA}{Q(t)}$	3	37.3 °C	373°C
Media Vol. (mL) / Apparatus		· · · ·	37.1 °C	34.1°C
Stirring Speed (rpm)	75	Gamala nymbori	\$\$302	
Sinkers (Type)	NA	Sample number:	Start Temp.	End Temp.
Filter (cannula tip)	NA NA	Vessel #		37.3 °C
Filter (syringe filter)	0.45um Nylon	5		37.2 °C
Sample Times (minutes)	45	6	37.Z °C	137.2 C
Height Check Performed:	Initials: DMS Date: 07JUN17	Sample number:	G. (T	End Tomp
Shaft Center Check Performed:	Initials: DINS Date: 09 JUN 7	Vessel #	Start Temp.	End Temp.
Auto sampler used?	☐ Yes		Start Temp.	°C
Withdraw Volume (mL)	10		1 -20/2	°C
Procedure/Observations: A+45 minutes th	e tables are con	morely d	isintegro	xted.
		A Part of	J	
Storage Location/Condition: Pyok Dissolution performed byOY ANALYTICAL METHOD	18 on 09 JUN17	ation Date:		_
Storage Location/Condition: Pyok Dissolution performed byOY ANALYTICAL METHOD	e 65/5°C Expira	ation Date:		_
Storage Location/Condition: Pyok Dissolution performed by	18 on 09 JUN17-	ation Date:		_
Storage Location/Condition: Pyok Dissolution performed byOY ANALYTICAL METHOD Sample Dilution: Dil	18 on 09 SUN 17-	ation Date: Sample Diluted by		_
Storage Location/Condition: OYO Dissolution performed byOY ANALYTICAL METHOD Sample Dilution: Dil HPLC System Tracking #:	18 on 09 JUNI 7-	ation Date:		_
Storage Location/Condition: OYO Dissolution performed byOY ANALYTICAL METHOD Sample Dilution: Dil HPLC System Tracking #:	18 on 09 SUN 17-	ation Date:		_
Storage Location/Condition: Pyolo Dissolution performed byOr ANALYTICAL METHOD Sample Dilution:Dil HPLC System Tracking #: Mobile Phase:	18 on 09 JUNI 7-	ation Date: Sample Diluted by		_
Storage Location/Condition: Pyolo Dissolution performed byOr ANALYTICAL METHOD Sample Dilution:Dil □ HPLC System Tracking #: Mobile Phase:	e 65/5°C Expira S on 09 SUN 17 uent:	ation Date: Sample Diluted by		_

Runtime: Volume injected: Sample Set Method:

Batch ID DISL-MA-170124-1 Test Sample ID 5579904 Active Ingredient Weight: 1468.3 mg Stage: 1 DISSOLUTION OPERATING CONDITIONS 5530284 5530283 Sample number: Sample brought to room temperature in a desiccator: End Temp. Start Temp. Vessel# 017141 Dissolution System 371 36.9 °C $^{\circ}C$ Dissolution System Calibration Due: 31Del17 DISL-HCL-170119-010 37.1 °C 36,8 ℃ 2 Dissolution Media (Lot/PN) Sample number: \$530283,5530284 NA Media Delivery Tracking # End Temp. Vessel# Start Temp. NA Media Delivery Calibration Due: 36:7 ℃ 37.1 90016 Media Vol. (mL) / Apparatus 36.8 °C 37.1 $^{\circ}C$ 7 S Stirring Speed (rpm) 5530284 5530183. Sample number: NA Sinkers (Type) End Temp. Start Temp. Vessel# NA Filter (cannula tip) 370 3 6<u>·7 °C</u> °C 0.45 MM NYIOM 5 Filter (syringe filter) 31-0 °C (oÙ Sample Times (minutes) Initials: DMS Date: 24 JUNI 7 Sample number: Height Check Performed: Start Temp. End Temp. Initials: NMS Date 29 JUM17 Vessel# Shaft Center Check Performed: °C °C Auto sampler used? °C Withdraw Volume (mL) Vessel Temperatures taken: Manually with Tracking # 004026 ☐ Automatically Replacement Media Temperatures Taken With Tracking # NA Procedure/Observations: At 60 minutes the tablet is disintegrated. Storage Location/Condition: Probe 65/5°C Expiration Date: Dissolution performed by 19195 on 24 run 17 ANALYTICAL METHOD Sample Dilution: _____ Diluent: _____ Sample Diluted by: _____

Mobile Phase:

Calibration Standard:

Verification Standard:

Column Used:

Runtime:

Volume injected:

Sample Set Method:

Analytical Method Performed By:

☐ HPLC

System Tracking #:

Batch ID DISL-MF	<u>-17011U-1</u>	Test Sample	10 <u>552991)4</u>		
A T	S ma Stages I				
Active Ingredient Weight: 1408.	mg Stage: _	4			
DISSOLUTION OPERATING CO		1 74	6 1 1	650 008G	
Sample brought to room temperature	in a desiccator: \	7.7	Sample number:	5530285	End Temp.
Dissolution System	011545		Vessel #	Start Temp.	
Dissolution System Calibration Due:	3 I Decl T		2	37. 3 °C	<u>37.3 °C</u>
Dissolution Media (Lot/PN)	DISL_(B-17011	2-02		37.4 °C	<u>37.4 °C</u>
Media Delivery Tracking #	<u>NA</u>		Sample number:	553 <u>0</u> 285	D 10
Media Delivery Calibration Due:	NA	1	Vessel #	Start Temp.	End Temp.
Media Vol. (mL) / Apparatus	900 /	V	3	37.3 °C	<u>37.4 °C</u>
Stirring Speed (rpm)	75		Ц.	37. 2 °C	37.2 °C
Sinkers (Type)	NA		Sample number:	5530285	
Filter (cannula tip)	NA		Vessel #	Start Temp.	End Temp.
Filter (syringe filter)	0.45 NUTOY		5	37. 2 °C	37.2 °C
Sample Times (minutes)	(00)		Č	37.3 °C	<i>3</i> 7.3 °C
Height Check Performed:	Initials: XUA Dat	=:110JUN1]	Sample number:	1017	- A CONTRACTOR OF THE PARTY OF
Shaft Center Check Performed:	Initials: KUA Dat	e:Hadani7	Vessel#	John Temp.	End Temp.
Auto sampler used?	☐ Yes ☑ No		KUA	°C	°C
Withdraw Volume (mL)	10			°C	°C
	<u> </u>	•			
Vessel Temperatures taken:	Automatically 🗘	Manually with	Tracking# _00 L	1036	
D. L M. dia Tamanantunaa T.	olson With Tracking #	7	٧A		
Replacement Media Temperatures Ta	iken wim Hacking #		<u>YFI</u>		
Procedure/Observations:					
Atter 60 minutes, th	u tablets u	iert full	y aisin kqu	rated.	
Storage Location/Condition: PYNY) Dissolution performed by KAA		-	on Date:		
ANALYTICAL METHOD					
Sample Dilution: Dilu	ent:		Sample Diluted by:		
□ HPLC					
System Tracking #:					
Mobile Phase:					
Calibration Standard:					
Verification Standard:					
C 1 YT 1					
				· · · · · · · · · · · · · · · · · · ·	
Volume injected:			··· ··································		

Sample Set Method:
Analytical Method Performed By: