

QUALITY ASSURANCE

Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 1 of 73

PROCESS VALIDATION DRAFT TEMPLATES REPORT FOR UN-COATED TABLETS

PRODUCT NAME		
BATCH NO.		
DATE		
REPORT SUPERSEDES NO.	NIL	

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PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

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1.0 REPORT PRE-APPROVAL:

	Department	Name	Signature	Date
Prepared By	Quality Assurance			
Reviewed By	Production Quality Control			
	Engineering	TOCCO		
Approved By	Head-QA			



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN-COATED TABLET		
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00	
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2.0 INTRODUCTION:

Product shall be manufactured using the Wet Granulation Technology. The batches manufactured during the validation shall be setup for the stability study and other parameters monitored periodically and shall be reviewed by the validation Team.

3.0 OBJECTIVE:

The objective of this exercise is to develop a **PROCESS VALIDATION REPORT** to validate the process and have documented evidence to ensure that critical process variables are checked during validation. Also to demonstrate the process capability of the product meets its predetermined specifications and quality attributes.

4.0 SCOPE:

This protocol for the Process validation of *product name* formulation defines the procedural aspects to be followed while carrying out Process validation activity that includes prerequisites before commencing the actual work like, Master formula and process, approved vendors and characteristics of raw materials. Also it defines the acceptance criteria, re-validation criteria and justification for critical process parameters.

5.0 VALIDATION CRITERIA:

- Process validation batch shall be manufactured as per process steps given in the Master Manufacturing Formula.
- The batches manufactured during process validation shall meet the criteria defined in product specification.

6.0 REVALIDATION CRITERIA:

The process shall be revalidated whenever there shall be changes in:

- Manufacturing process and the product formula.
- Manufacturing site or location.
- Change in critical equipment in manufacturing process
- Change in batch size



	PROCES	S VALIDATION REPO	RT OF UN-COATED TABLET	
Batch	Batch Size: 1000000 Tablets		BMR No.: XXX/PRO/BMR/ZZ-00	
Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 5 of 73		Page No.: 5 of 73		
7.0	REASON FOR VALII	DATION:		
8.0	PRODUCT PROFIL	E:		
Name of the product :		:		
		: Each un-coated tablet contains:		
		API-1 (BP)	12 mg	
		API-2 (IP)	90 mg	
		API-3 (BP)	100 mg	
	Colours	: Sunset Yellow Supra		
	Shelf Life	: 24 Months		
	Appearance	: Reddish orange colour	red, circular, biconvex, un-coated tablets	
		having plain surface of	n both sides.	
	Storage Condition	: Store in cool and dry place. Protect from light.		



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PROCESS VALIDATION REPO	ORT OF UN-COATED TABLET
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00
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9.0 EQUIPMENT CALIBRATION / QUALIFICATION RECORD

BATCH NO.:

Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Balance						
Balance						
Balance						
Vibro Sifter			2			
RMG				- 1		
LPD for RMG						
Paste kettle	D	ares				
Fluid bed dryer						
Multimill						
Bin Blender						
Compression Machine	,					
De-duster cum Metal Detector		11:4-	STIO			
De-duster cum Metal Detector		\mathcal{J} li α e				_=

Reviewed by:	Date:
Validation	



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PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

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BATCH NO.:

Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Balance:						
Balance:						
Balance:						
Vibro Sifter						
RMG						
LPD for RMG				A		
Paste kettle						
Fluid bed dryer		are!	55			
Multimill						
Bin Blender						
Compression Machine						
De-duster cum Metal Detector						
De-duster cum Metal Detector		TRAFE	OITE			

Reviewed by:		Date:
	Validation	



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN-COATED TABLET			
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00		
Protocol No.: XXX/BBB/PVR/ZZ-00	Page No.: 8 of 73		

BATCH NO.:

Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Balance:						
Balance:						
Balance:						
Vibro Sifter						
RMG			2			
LPD for RMG				1		
Paste kettle						
Fluid bed dryer		are!	55			
Multimill						
Bin Blender						
Compression Machine						
De-duster cum Metal Detector						
De-duster cum Metal Detector		JIRA S	OITE			

Reviewed by:	Date:
Validation	1



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN-COATED TABLET			
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00		
Protocol No.: XXX/BBB/PVR/ZZ-00	Page No.: 9 of 73		

10.0 RAW MATERIALS RATIONALE:

API will be tested in accordance with the pre-defined specifications and test methods.

Raw Material	Reference	Name of	Analyti	Analytical Reference Number			
	Monograph	vendor	Batch No.	Batch No.	Batch No.		
API-1							
Microcrystalline cellulose (PH 112)							
Colloidal silicon dioxide							
Lactose (monohydrate)	416		2				
Povidone (K-30)	7			4			
Isopropyl alcohol			_				
API-2	Dec	res					
API-3	Mile						
Croscarmellose sodium							
Colloidal silicon dioxide							
Polacrilin potassium							
Magnesium Stearate			noi-				

Reviewed by :		Date:	
	Validation		



		VALIDATION REP					
	1000000 Tablets		BMR No.: XXX/PRO/BMR/ZZ-00				
Protocol No	.: XXX/BBB/PVR/Z	ZZ-00	Page No.: 10 of 73	<u> </u>			
11.0 USA	GE OF RAW MAT	TERIAL (ACTIVE):					
Active Material	B.No.	A. R. No.	API B.No.	Assay (%)	LOD / Water (%,w/w)		
API-1							
Acceptance	criteria:		Li	mit: NLT 98.0 NMT 102.0	Limit:NMT 0.5 % w/w		
API-2							
Acceptance	criteria:		Li	mit: NLT 98.0 NMT 102.0	Limit:NMT 0.5 % w/w		
			- C	A			
API-3		Proc					
Acceptance	criteria:		Li	mit: NLT 98.0 NMT 102.0	Limit:NMT 0.5 % w/w		
Reviewed by	<i>,</i>		Date:				
	Valida	tion	datio				



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN-COATED TABLET			
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00		
Protocol No.: XXX/BBB/PVR/ZZ-00	Page No.: 11 of 73		

12.0 GRANULATION STAGE:

12.1 RESULTS OF DRY MIXING:

DIFFERENT LOCATION SAMPLE:

Campla	Draw samples equivalent to between			Mixing U	niformity		
Sample Location	1-3 unit dose (XX mg to XX mg)	Batch	n No.	Batc	h No.	Bate	ch No.
	8/	LOTI	LOT II	LOTI	LOT II	LOTI	LOT II
T1							
T2							
Т3		- 1	10.	2			
M1		7					
M2							
М3				25			
B1		DITT	100				
B2		MARK					
В3							
B4						4	
Sampled by/date	/ 1						

COMPOSITE SAMPLE:

Product Name		1/2	Moral		
Speed	1	VO			

Sample.	Weight required	Weight taken (g)						
	(g)	Batch No.		В	Batch No.		Batch No.	
		LOT I	LOT II	LOT I	LOT II	LOT I	LOT II	
Composite	20 g							
Samp	led By / Date							



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN-COATED TABLET				
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00			
Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 12 of 73				
RESULT OF BULK DENSITY – UNTAPPED / TAPPED				

Batch No.	LOT	Untapped Bulk Density	Tapped Bulk Density	Checked By Sign &Date
	I			
	II			
	I			
	II			
	I			
1.1	II			

Reviewed by :		Date:	
	Validation	acass I	

12.2 RESULTS OF DURING WET GRANULATION:

Operation	on			RESU	ULTS		
Mixing		Bat	ch No.		tch No.	Bate	ch No.
		LOTI	LOT II	LOTI	LOT II	LOTI	LOT II
i) Time of Binder s addition	solution			atic			
ii) Granulation tim	e at			0.30.			
Agitator slow/fast	& chopper	100					
slow/fast (intermitt	ent)						
Agitator slow/fast	& chopper	1.					
slow/fast (intermitt	tent)						
iii) Amount of Ext	ra Isopropyl						
alcohol added							
Ampere reading	Agitator						
at end point Chopper							
Total Granulation	Гіте						
Checked by							

Checked by						
Reviewed by :			_	Date:		
	Validat	ion				



3.0 % - 4.0 %

w/w

5

6

PHARMA DEVILS

			Q	OMPTILL MASSONMACC			
	PF	ROCESS VAI	IDATION R	EPORT OF U	N-COATED T	TABLET	
Batch Siz	: 1000000 Ta	ablets		BMR No	: XXX/PRO/E	BMR/ZZ-00	
Protocol 1	No.: XXX/BB	B/PVR/ZZ-00)	Page No.	: 13 of 73		
	ESULTS OF I						
BULK S	AMPLE (Dri	ed Granules)					
Product							
Time of	Sampling		Afte	r Drying in FBI	D		
				Weight (taken (o)		
Sample	Weight required	Batc	h No.		h No.	Batc	h No.
	(g)	LOT I	LOT II	LOT I	LOT II	LOT I	LOT II
1	Approx 2 g						
2	Approx 2 g				2		
3	Approx 2 g						
4	Approx 2 g						
5	Approx 2 g			- A C C			
6	Approx 2 g			GRE			
Sample	ed By / Date			-5			
RESULT	OF LOD OF	BULK SAMPI	LES (Dried Gr	ranules)			
					OD in % w/w		
Sample	Acceptance criteria	Bate	h No.	Batcl	h No.	Batc	h No.
		LOT I	LOT II	LOTI	LOT II	LOT I	LOT II
1				6/2/1	TOTAL		
2	Limit: Till desired		VEI				_ =
3	LOD						
4	achieved						

Done by / Date					
Reviewed by :	Validation	 Date	e:	_	



Batch Size: 1000000 Tablets				R	BMR No.: XXX/PRO/BMR/ZZ-00				
Protocol No.: XXX/BBB/PVR/ZZ-00					age No.: 14 (
			IILLED GR	l					
Product									
Direction of t	he knives	3							
Speed									
				XX 7.03	Saha dalaan (a	.			
			<u> </u>		ight taken (g		D (1)		
Weight required (g)	Batch	No.		Batch No.		Batch	No.	
]	LOT I	LOT II	LOT	I LO	LII	LOT I	LOT II	
50 g	Д.				- 2				
Sampled By/Date									
•	SIEVE	ANALYSIS	S (Sifted/Mi	lled Granule	es)				
RESULT OF	SIEVE Sieve Size	ANALYSIS Microm eter		lled Granule	% w/w I	Retention h No.	Bat	ch No.	
RESULT OF	Sieve	Microm		arde	% w/w I		Bat LOT I	cch No.	
RESULT OF	Sieve	Microm eter	Batc	h No.	% w/w I	h No.			
RESULT OF	Sieve Size	Microm eter 850 μ 425 μ	Batc	h No.	% w/w I	h No.			
Acceptance Criteria	Sieve Size	Microm eter 850 μ 425 μ 250 μ	Batc	h No.	% w/w I	h No.			
RESULT OF	Sieve Size 20# 40#	Microm eter 850 μ 425 μ 250 μ 180 μ	Batc	h No.	% w/w I	h No.			
Acceptance Criteria	Sieve Size 20# 40# 60#	Microm eter 850 μ 425 μ 250 μ	Batc	h No.	% w/w I Batc LOT I	LOT II			
Acceptance Criteria For record	Sieve Size 20# 40# 60# 80# 100#	Microm eter 850 μ 425 μ 250 μ 180 μ 150 μ	Batc	h No.	% w/w I	LOT II			
Acceptance Criteria For record	Sieve Size 20# 40# 60# 80#	Microm eter 850 μ 425 μ 250 μ 180 μ	Batc	h No.	% w/w I Batc LOT I	LOT II			
Acceptance Criteria For record	Sieve Size 20# 40# 60# 80# 100#	Microm eter 850 μ 425 μ 250 μ 180 μ 150 μ	Batc	h No.	% w/w I Batc LOT I	LOT II			
Acceptance Criteria For record For record	Sieve Size 20# 40# 60# 80# 100#	Microm eter 850 μ 425 μ 250 μ 180 μ 150 μ	Batc LOT I	h No.	% w/w I Bate LOT I assed Throu	LOT II	LOTI		
Acceptance Criteria	Sieve Size 20# 40# 60# 100#	Microm eter 850 μ 425 μ 250 μ 180 μ 150 μ	Batc LOT I	h No.	% w/w I Bate LOT I assed Throu	h No. LOT II gh	LOTI		



		QUAL	ITY ASSURANCE		
Pl	ROCESS V.	ALIDATION REP	ORT OF UN-COAT	TED TABLET	
Batch Size: 1000000 T	ablets		BMR No.: XXX/I	PRO/BMR/ZZ-00	
Protocol No.: XXX/BE	BB/PVR/ZZ-	-00	Page No.: 15 of 73	3	
RESULT OF BULK D	ENSITY A	ND LOD (Sifted/M	(illed Granules)		
Batch No.	LOT	Tapped Bulk Density	Untapped Bulk Density	LOD	Checked By
	I				
	II				
	I				
	II				
	Ţ				

3.0 % - 4.0 % w/w

II

To record

Date:	
THE END OF SIFTING/MILLI	ING:
%Yield	Limit*
12110 dure	
()	NLT 99.5 %
ed after 10 or more production batche	es.
Date:	-
	THE END OF SIFTING/MILLI %Yield ed after 10 or more production batche



	PROCESS VALIDATI	ON REPORT OF UN-COATE	D TABLET
Batch Size: 1000000		BMR No.: XXX/PR	O/BMR/ZZ-00
Protocol No.: XXX/I	BBB/PVR/ZZ-00	Page No.: 16 of 73	
12.5 RESULTS O	F LUBRICATION:		
BLEND UNII	FORMITY – PRE LUE	BRICATION	
Product Name			
Speed			
	Weigh	t taken (in g) for the time inter-	val (in minutes)
Sample Location↓	B. No.	B. No.	B. No.
	10 min	10 min	10 min
T1			
T2			
Т3		aress	
T4	THE PA		
M1			
M2			
M3			
M4		NOITEL IL	
B1		II lace.	
B2			
Sampled by/date			
1	- "		
Reviewed by:		Date:	
	Validation		



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN	N-COATED TABLE	Г
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Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 17 of 73

RESULT FOR BLEND UNIFORMITY – PRE-LUBRICATION

Blend Uniformity	% Blend uniformity						
	Batch No.	Batch No.	Batch No.				
	10 min	10 min	10 min				
T1							
T2							
Т3							
T4							
M1							
M2		-Aress					
M3							
M4							
B1							
B2							
Mean		u. Jatio					
Minimum		allace					
Maximum							
%RSD							
Checked By/ Date	- /						
Acceptance criteria	a: Average: 85.0-115.0	% and % RSD: NMT 6.0%					
Acceptance criteria	a: Average: 85.0-115.0	% and % RSD: NMT 6.0%					
Reviewed by:		Date:					
-	Validation						



atch Size: 1000000	Tablets	BMR No.: XXX/I	BMR No.: XXX/PRO/BMR/ZZ-00					
rotocol No.: XXX/F			Page No.: 18 of 73					
LEND UNIFORM	TTY – LUBRICATION							
Product Name								
Speed								
		taken (in g) for the time into						
Sample Location↓	B. No.	B. No.	B. No.					
T1	3 min	3 min	3 min					
T2								
T3								
T4		-^c5						
M1	Pr	06625						
M2								
M3								
M4		I FIO						
B1								
B2	N/C							
Sampled by/date								



QUALITY ASSURANCE

PROCESS	VAI	TION	REPORT	OF UN-COATE	DTARLET
	v /			~ / / 	

Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 19 of 73

RESULT FOR BLEND UNIFORMITY – LUBRICATION

		% Blend uniformity	
Blend Uniformity	Batch No.	Batch No.	Batch No.
	3 min	3 min	3 min
T1			
T2			
Т3			
T4			
M1			
M2		rass l	
M3	PIO		
M4			
B1			
B2			
Mean		: datiOil	
Minimum	Va	Icicio.	
Maximum			
%RSD			
Checked By/ Date	- "		
Acceptance criteri	a: Average: 85.0-115.0% and	% RSD: NMT 6.0%	
Reviewed by:	Validation	Date:	



		PR	ROCESS V	AL	IDATIO	N REPOI	RT (OF UN-CO	OATED TAB	BLET	
Batch Size:	100000	00 Ta	ablets				BM	R No.: XX	X/PRO/BMI	R/ZZ-00	
Protocol No	o.: XXX	K/BB	B/PVR/ZZ	-00			Pag	ge No.: 20 c	of 73		
COMPOS	ITE SA	MP	LE (Lubri	cate	d Granu	les)					
Product Na	me										
Speed											
		1	Weight					Weight 1	taken (g)		
Sampl	le.			Ba	tch No.			Batch No.	(g)	Batch No.	
Composite	Composite 50 g		50 g								
Sam	pled By	/ Da	ate								
RESULT OI Granules) Batch No.	F APPE		CE, ASSA	Y, B	Assay	NSITY – U		APPED / T. Untapped sulk Density	Tapped Bulk	LOD (Lubricate	Checked By/Date
Batch No.	Appear			API-1 API-2		API-3	_ B	uik Density	Density	gm of sample at	Dy/Date
			\ \ \							105° C)	
e (
Acceptance Criteria	Ligh Yello coloui	w	95.0 – 105 %			95.0 – 110 %	For r		ecord	3.0 % - 4.0 % w/w	
RESULT O			NALYSIS	(Lı	ıbricateo	l Granule	s)	- 24	_ \		
Acceptanc		eve	Micromet	ter		Parti	cle S	Size Distrib	ution (% w/v	w Retention)	
Criteria	Ana	lysis			B. No.		P	B. No.		B. No.	
	20)#	850μ		10						
	40)#	425μ								
For record 60)#	250μ								
	80)#	180 μ	1							
	10	0#	150μ								
		-			% w / w passed through						
For record	10	0#	150μ								
(Checked	By/ I	Date								
Reviewed by	y:		Validation				D	ate:			



Batch No. WYield Limit*			1	REPORT OF UN-COATED TABLET					
ERCENTAGE YIELD AT THE END OF LUBRICATION: Batch No.		R/77-00							
Batch No. %Yield Limit* NLT 99.5 % Yield Limit is tentative and will be finalized after 10 or more production batches. Eviewed by: Date: Validation			•	10					
NLT 99.5 % Vield Limit is tentative and will be finalized after 10 or more production batches. Validation		LE END OF ECDI		L imit*					
Tield Limit is tentative and will be finalized after 10 or more production batches. Viewed by: Date: Validation	Daten No.		/o i kid	Zinit					
viewed by: Date: Validation				NLT 99.5 %					
Validation	eld Limit is tentative and will	l be finalized after 1	10 or more production batch	es.					
Validation	eviewed by:		Date:						
Validation		on							



Pl	ROCESS V	ALIDATION REPO	ORT OF UN-COATED TABLE	Γ
Batch Size: 1000000 T	ablets		BMR No.: XXX/PRO/BMR/ZZ	Z-00
Protocol No.: XXX/BE	BB/PVR/ZZ	Z-00	Page No.: 22 of 73	
EVALUATION:				
	<u> </u>			
		Proc		
		Valid		
1				
Reviewed by:		Date	:	
	alidation			



PROCESS VALIDATION REPORT OF UN-COATED TABLET								
Batch Size: 1000000 Tablets	BMR No.: XXX/PRO/BMR/ZZ-00							
Protocol No.: XXX/BBB/PVR/ZZ-00	Page No.: 23 of 73							
13.0 COMPRESSION STAGE:								

13.1 SAMPLES DURING COMPRESSION CYCLE

Product	
Time of Sampling	Compression Run

	Batch No.		Batch No.		Batch No.		
Sample Details	Sample Quantity	Sampled By/Date	Sample Quantity	Sampled By/Date	Sample Quantity	Sampled By/Date	
Optimum hardness/ High speed							
Optimum hardness/ Low speed							
Optimum speed/ High hardness							
Optimum speed/ Low hardness		-00	e55		\		
Initial run / Full Hopper at optimum speed	V Vi	100					
Middle run at optimum speed							
End run / Half Hopper at optimum speed							

NOTE: In-process testing shall be carried out as per frequency in BMR and the recordings shall be done in the BMR and the results shall be evaluated.

		igh eed		ow eed		gh Iness	Lo Haro	ow Iness	Ini	tial	Mic	ldle	Eı	nd
Compression Batch No.	Speed	Force	Speed	Force	Speed	Force	Speed	Force	Speed	Force	Speed	Force	Speed	Force
\			1											

Reviewed by:				Date	e:				
	Valida	tion							



	PROCESS VA	ALIDATI(ON REP	ORT O	F UN-CO	ATED TAB	LET		
Batch Size: 1000000	Tablets			BMR No.: XXX/PRO/BMR/ZZ-00					
Protocol No.: XXX/I	BBB/PVR/ZZ-	00		Page	No.: 24 of	73			
12.2 INDIVIDUAL		ee green i	DATA	•					
13.2 INDIVIDUAL Batch Number:	L IN-PROCES			Samnlin	g: Maximur	n hardness () LHS	
Date:	Target Ha		Suge UI	-ampiiii		Thickness:		, 1110	
TESTS					RESULTS				
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (§ HARDNESS(N)	3)						Mean:		
THICKNESS (mm)							Min:	Max:	
FRIABILITY (% w/v	w)		•				•	•	
D.T. (min)		T 7 46							
		<u>Unit</u>	formity of	Weight	t (mg)				
	\								
				98	A. A.				
Capability Index									
Parameter LSL	USL	X		S	Ср	CpU	CpL	СрК	
Value →							4		
The capability index t	o be calculated	l for weigh	t sample	using fo	ollowing fo	rmula:			
			•						
Cp =	USL – LSL	C	CpU = -	USL –		$CpL = \frac{X - I}{-}$	LSL		
Ср –	6s		.ро =	3s		ср г	s		
	T	C.1 1	C C I		•				
CpK = min (CpU, Cp	L) (smallest of	t the value	s for CpU	and C ₁	pL)				
Where,									
USL = upper specific	ation limit for	weight							
LSL = lower specifica									
\		weight							
X = mean for weight									
s = Standard deviati	on.								
Reviewed by:				Dat	e:				
	Validation								



	PR	OCESS V	VALIDAT	ION REP	ORT OI	F UN-COA	ATED TAB	LET			
Batch Size: 10000	000 Tal	blets			BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.: XX	X/BBE	B/PVR/ZZ	Z-00		Page No.: 25 of 73						
Batch Number:				Stone of 6	of Sampling: Maximum hardness () RH						
Date:		Target I	Hardness:	Stage of S	Sampling: Maximum hardness () RHS Target Thickness:						
TESTS		Targett	iai uness.		F	RESULTS	1 mckness.				
APPEARANCE											
AVG WEIGHT (n	ng)										
GROUP WEIGHT	Γ (g)							L _			
HARDNESS(N)	-)							Mean:	M		
THICKNESS (mn FRIABILITY (%	,							Min:	Max:		
D.T. (min)	w/w)										
D.1. (IIII)		l	Ur	niformity of	Weight	(mg)					
						8/					
	\rightarrow										
						(
Capability Index			DY		92						
Parameter L	SL	USL	X		S	Ср	CpU	CpL	СрК		
Value →											
The capability inde	ex to be	e calculat	ed for weig	th sample	using fo	llowing for	rmula:				
)									
		JSL – LSL		G II	USL - X		X - 1	LSL			
Ср		6s		CpU = -	3s		CpL=3	· c			
		OS			33			3			
CpK = min (CpU,	CpL)	(smallest	of the valu	es for CpU	and Cp	L)					
Where,											
USL = upper speci	ficatio	n limit fo	r weight								
LSL = lower specia		n iimit io	r weight								
X = mean for we	ight										
s = Standard dev	iation.										
Reviewed by:					Date):					
110 vie vved 0 y	Va	lidation		-	שמו	·					



PR	OCESS VAL	IDATION RE	PORT C	F UN-COA	ATED TAB	LET				
Batch Size: 1000000 Ta	blets		BMI	R No.: XXX	K/PRO/BMR	2/ZZ-00				
Protocol No.: XXX/BB	B/PVR/ZZ-00		Page	Page No.: 26 of 73						
Batch Number:		Stage o	of Samplin	ng: Minimun	n hardness () LHS			
Date:	Target Hard		Target Thickness:							
TESTS				RESULTS						
APPEARANCE										
AVG WEIGHT (mg)										
GROUP WEIGHT (g)		1			r					
HARDNESS(N)						Mean:	12.5			
THICKNESS (mm)						Min:	Max:			
FRIABILITY (% w/w)										
D.T. (min)		Uniformity	of Woigh	t (ma)						
			or weigh	t (mg)						
				2						
				16						
Capability Index		Drok					I			
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК			
Value →										
The capability index to b	e calculated for	or weight samp	le using f	following fo	rmula:	4				
The supmerment moon to e		or weight sump	10 0001118 1	0110 (11118) 10	1110101					
	USL – LSL		USL –		X - 1	LSL				
Cp = -		CpU =	2-		$CpL = {}$					
	6s		3s		3	S				
CpK = min (CpU, CpL)	(smallest of th	ne values for C	pU and C	pL)						
	`			1						
Where,										
USL = upper specification	on limit for we	ight								
LSL = lower specification	on limit for we	ight								
X = mean for weight										
s = Standard deviation.										
Reviewed by:			Da	te:						
Va	alidation									



	PR	OCESS VAI	LIDATION RE	PORT O	F UN-COA	ATED TAB	LET				
Batch Size: 100	00000 Ta	blets		BMR	BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.: >	XXX/BBI	B/PVR/ZZ-00	0	Page	Page No.: 27 of 73						
Batch Number:	•		Stage	e of Sampling: Minimum hardness () RHS							
Date:	•	Target Har		Target Thickness:							
TESTS		Turget Hur		RESULTS							
APPEARANCI											
AVG WEIGHT											
GROUP WEIG HARDNESS(N							Mean:				
THICKNESS (,						Min :	Max:			
FRIABILITY (141111 •	IVIUA .			
D.T. (min)	,										
			Uniformity	of Weight	(mg)						
			10.00		9						
		(-								
	_74	1									
				- AC							
Capability Index	K										
Parameter	LSL	USL	X	S	Ср	CpU	CpL	СрК			
Value →											
The capability in	ndex to b	e calculated t	for weight samp	le using fo	ollowing fo	rmula:					
1											
	$Cp = -\frac{U}{2}$	USL – LSL	CpU =	USL – 2		CpL= X - I	_SL				
	Cp –	6s	Сро =	3s		3	s				
	~										
CpK = min (Cpt)	U, CpL)	(smallest of	the values for C ₁	pU and Cp	oL)						
Where,											
USL = upper sp	ecificatio	n limit for w	eight								
LSL = lower specific											
X = mean for		ii iiiiit 101 W	orgin								
	_										
s = Standard d	leviation.										
Reviewed by: _		11.1		Dat	e:						
	Va	alidation									



	PR	OCESS VA	LIDATI	ON REP	ORT OF	UN-CO	ATED TAB	LET					
Batch Size	: 1000000 Tal	blets			BMR N	No.: XX	X/PRO/BMR	$\overline{ZZ-00}$					
Protocol N	o.: XXX/BBI	B/PVR/ZZ-0	00		Page N	[o.: 28 o	f 73						
D 4 1 37	1		1	C4. 64		М .	1 /) I IIO				
Batch Nun Date:	nber:	Target Hai	rdness.	Stage of S	ge of Sampling: Maximum speed () LHS Target Thickness:								
TESTS		rarget Hal	uness.		RI	ESULTS							
APPEARA													
AVG WEI													
	VEIGHT (g)			T	<u> </u>	1		h. /r					
HARDNES THICKNE								Mean: Min :	Max:				
	TY (% w/w)			1		I		141111 •	IVIAA •				
D.T. (min)	· · · · · · · · · · · · · · · · · · ·												
Assay(%)		API-1			API-2		AP	I-3					
			Uni	iformity of	Weight (1	mg)							
				-									
	= "												
			3-2-41										
					SP.								
Capability I	ndex												
Parameter	→ LSL	USL	X		S	Ср	CpU	CpL	СрК				
Value	-							4					
The capabil	ity index to b	e calculated	for weig	ht sample	using foll	owing f	ormula:		1				
			J	ı		J							
	$Cp = \frac{U}{-}$	JSL – LSL		CpU = -	USL – X		$CpL = \frac{X - I}{}$	LSL					
	_	6s		Ср0 –	3s		3:	S					
O. K.		(11	.1		101								
CpK = min	(CpU, CpL)	(smallest of	the value	es for CpU	and CpL	4)							
Where,													
USL = uppe	er specificatio	n limit for v	veight										
	er specification												
X = mean	for weight												
	ard deviation.												
s – Standa	ara acviativii.												
_													
Reviewed b	y:	1' 1			Date:								
	Va	lidation											



	PD	OCESS V	ALIDATI	ON REP	ORT OF	· IIN-CO	ATED TAB	LET	
Ratch Sizes	: 1000000 Tal				1		X/PRO/BMR		
	o.: XXX/BBI		00			No.: 29 of		JZL-00	
I TOTOCOL IN	U·· AAA/DDI),1 VIN/LL-	00		1 age 1	1 0 47 01	. 1 J		
Batch Num	ıber:			Stage of S	Sampling	: Maximu	m speed () RHS
Date:		Target Ha	rdness:			Target	Thickness:		
TESTS					R	ESULTS			
APPEARA									
AVG WEI									
HARDNES	VEIGHT (g)							Mean:	
THICKNE								Min:	Max:
	TY (% w/w)						I	11222	172621
D.T. (min)	(111111)								
Assay(%)		API-1		A	API-2		AP	PI-3	
-			Uni	iformity of	Weight ((mg)			
	11.1						- /		
	=								
		. ()			A				
/									
Capability I	ndex								
Parameter	→ LSL	USL	X	l	S	Ср	CpU	CpL	СрК
Value	→							4	
The capabil	ity index to b	e calculated	l for weig	ht sample	using fol	llowing fo	rmula:		•
		JSL – LSL		C.II -	USL – X	_ ((X -]	LSL	
	Cp = -	6s	100	CpU = -	3s		CpL=3	<u> </u>	
							3		
CpK = min	(CpU, CpL)	(smallest o	f the value	es for CpU	J and Cpl	L)			
Where,									
USL = uppe	er specificatio	n limit for	weight						
LSL = lowe	er specification	n limit for v	weight						
X = mean	for weight								
s = Standa	ard deviation.								
Reviewed b	y:				Date	:			
	Va	lidation							



	PR	OCESS VA	LIDATI	ION REP	ORT OF	UN-CO	ATED TAB	LET				
Batch Size: 1000	0000 Ta	blets			BMR	No.: XXX	X/PRO/BMR	$\sqrt{ZZ-00}$				
Protocol No.: XX	XX/BBI	B/PVR/ZZ-0	00		Page No.: 30 of 73							
Dotah Number				Store of	Complin-	· Minimu	n anaad () LHS			
Batch Number: Date:		Target Hai	·dness·	stage of	ge of Sampling: Minimum speed () LHS Target Thickness:							
TESTS		Target Hai	uncss.		R	ESULTS	i i iiickiiess.					
APPEARANCE												
AVG WEIGHT												
GROUP WEIGH	HT (g)							h./				
HARDNESS(N) THICKNESS (m	ım)							Mean: Min :	Max:			
FRIABILITY (%								141111 •	wax .			
D.T. (min)	,											
Assay(%)		API-1			API-2		AP	PI-3				
	<u> </u>		Uni	<u>iformity o</u>	f Weight ((mg)	<u> </u>					
						150						
	3											
	="											
Capability Index												
Parameter	LSL	USL	X		S	Ср	CpU	CpL	СрК			
Value →								4				
The capability inc	dex to b	e calculated	for weig	ht sample	using fol	lowing fo	rmula:		1			
	т.	101 101			LICI X		X / 1	. CI				
C	p =	JSL – LSL		CpU =	USL – X		$CpL = \frac{X - I}{-}$	LSL				
	P	6s		СРС	3s		3	S				
Cak (Call	C-1)	(114 C	41	f C. I	I 1 C - I							
CpK = min (CpU	, CpL)	(smallest of	the value	es for Cpt	and Cpi	_)						
Where,												
USL = upper spec	cificatio	n limit for v	veight									
LSL = lower spec	ification	n limit for w	eight									
X = mean for w	eight											
s = Standard de	viation.											
Daviare d 1					D-4							
Reviewed by:	Va	lidation			Date	:						



	DD	OCESS V	AT IDAT	ION D	FDODT	OF UN CO	ATED TAB	IFT					
Ratch Size:	1000000 Ta		ALIVA I	TON K									
						BMR No.: XXX/PRO/BMR/ZZ-00							
Protocol No	o.: XXX/BBI	3/PVR/ZZ-	.00		Pag	Page No.: 31 of 73							
Batch Num	ber:			Stage (of Sampli	ng: Minimun	n speed () RHS				
Date:	aber.	Target Ha	ardness:	Buge (or Sumpin		t Thickness:) IXII O				
TESTS						RESULTS							
APPEARA	NCE												
AVG WEI	GHT (mg)												
GROUP W			T										
HARDNES								Mean:					
THICKNES								Min:	Max:				
	ΓΥ (% w/w)												
D.T. (min)		ADT 1			A DI 2		l A D	OT 2					
Assay(%)		API-1	IIn	iformit	API-2 y of Weig	ht (mg)	AP	1-3					
			Un	IIII TUITIIII (y or weig	nt (mg)							
						N e							
	-				A A L								
1			154		6 6								
Capability I	ndex		Fine										
Parameter	→ LSL	USL	X		S	Ср	CpU	CpL	СрК				
Value	→							-					
The conchili	ity inday to h	a anlandata	d for wais	rht com	nlo usina	following f	armula.						
The capabili	ity index to b	e calculated	i for weig	gni sam	pie using	ionowing io	ormula:						
		USL – LSL			USL	- X	X - I	LSL					
	Cp = -			CpU =	V = 10		CpL=						
		6s			3s		3	S					
$CnK = min \ell$	(CpU, CpL)	(smallest o	f the valu	es for (on∐ and o	CnL)							
	(CPC, CPL)	(Similar O	i die valu	05 101	cp c una v	CPL)							
Where,													
USL = uppe	r specificatio	n limit for	weight										
	r specificatio												
X = mean	_												
	_												
s – Standa	rd deviation.												
Daviana 1 1-					D	oto:							
keviewed by	y:	lidation		-	D	ate:							
	V 2	เมตะมาดท											



PR	OCESS VA	LIDATION R	EPORT (OF UN-CO	ATED TAB	LET					
Batch Size: 1000000 Ta	blets		BM	R No.: XX	X/PRO/BMR	2/ZZ-00					
Protocol No.: XXX/BB	B/PVR/ZZ-0	00	Page	Page No.: 32 of 73							
D 4 1 N 1		C4	• T '' 1	-4/T 11 T	I	C 1 /	·				
Batch Number:		Stage of Sampl	ing: Initial		* * *	mum Speed () LHS				
Date: TESTS	Target Hai	rdness:		RESULTS	t Thickness:						
APPEARANCE				KESUL 18)						
AVG WEIGHT (mg)											
GROUP WEIGHT (g)											
HARDNESS(N)						Mean:					
THICKNESS (mm)						Min:	Max:				
FRIABILITY (% w/w)											
D.T. (min) Assay(%)	API-1		API-2		AP	OT 2					
Assay(70)	AF1-1	I∃niformit	ty of Weigh	nt (mg)	Ar	1-3					
			y of weigh								
				- 2							
	\										
					. A.A.						
			PAC								
			U P								
Capability Index											
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК				
Value →						4					
The capability index to b	e calculated	for weight sam	ple using	following fo	ormula:						
			TIGE	**	.,						
Cp = -	USL – LSL	CpU =	USL –	X	$CpL = \frac{X - I}{}$	LSL ———					
_	6s	CpO =	3s			S					
CpK = min (CpU, CpL)	(smallest of	the values for	CpU and C	CpL)							
Where,											
USL = upper specification	n limit for v	veight									
LSL = lower specificatio	n limit for w	eight									
X = mean for weight											
s = Standard deviation.											
Reviewed by:			Da	ite:							
Va	alidation										



	PR	OCESS V	ALIDATIO	N REPORT	OF UN-CO	ATED TAB	LET	
Batch Size:	1000000 Tal	blets		BN	IR No.: XX	X/PRO/BMR	2/ZZ-00	
Protocol No	o.: XXX/BBI	3/PVR/ZZ	Z-00	Pag	ge No.: 33 of	f 73		
Batch Num	ıber:		Stage of Sam	ipling: Initial	stage/ Full Ho	opper at Optim	num Speed () RHS
Date:		Target H				t Thickness:		
TESTS					RESULTS			
APPEARA								
AVG WEIG	EIGHT (g)							
HARDNES							Mean:	
THICKNE	SS (mm)						Min:	Max:
	TY (% w/w)							
D.T. (min) Assay(%)		API-1		API-2		AP	PI-3	
- - Doug (/ 0)			Unifor	rmity of Weig	ht (mg)	111	- v	
				10				
Capability I	ndex							
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК
Value	→						4	
The capabili	ity index to b	e calculate	ed for weight	sample using	following fo	ormula:		ı
	7	ici ici		TICT	v	W.	ı CI	
	$Cp = \frac{0}{2}$	JSL – LSL	Cp	$U = \frac{USL}{}$	- X	$CpL = \frac{X - 1}{-1}$	LSL	
	ī	6s		3s		3	S	
CpK = min	(CpU, CpL)	(smallest	of the values	for CpU and	CpL)			
Where,	- ·							
USL = uppe	er specificatio	n limit for	weight					
	r specification							
X = mean	_							
s = Standa	ard deviation.							
Reviewed by	v .			ת	ate:			
KCAICMEN D	y Va	lidation		D	aic			
		-						



	PR	ROCESS	VALIDAT	TION RE	EPORT (OF UN-CO	DATED TAB	LET				
Batch Size:	: 1000000 Ta	ablets			BM	R No.: XX	XX/PRO/BMF	R/ZZ-00				
Protocol N	o.: XXX/BB	B/PVR/ZZ	Z-00		Page No.: 34 of 73							
Batch Num	nber:		Stage of	Samplin	g: Middle	stage/ Full	Hopper at Opt	imum Speed	() LHS			
Date:		Target I	Hardness:	- I	<u> </u>		et Thickness:					
TESTS						RESULTS						
APPEARA	NCE											
AVG WEI												
	VEIGHT (g)						<u>, </u>					
HARDNES								Mean:	T			
THICKNE								Min:	Max:			
D.T. (min)	TY (% w/w)											
Assay(%)		API-1			API-2		AT	PI-3				
Assay(70)		A1 1-1	U	niformity	of Weigl	nt (mg)	Al	. 1-3				
	T				or viergi	(1115)						
	+			-		- 9						
		\										
	=											
		- (-)				N. of						
					10%							
Capability I	ndex											
Parameter	→ LSL	USL	X		S	Ср	CpU	CpL	СрК			
Value	→							4				
The capabil	ity index to l	e calculat	ed for wei	ght samp	le using	following	formula:		1			
						***		T 01				
	Cp =	USL – LSL	_	CpU =	USL -	- X	$CpL = \frac{X - X}{-}$	LSL				
	Cp =	6s		СРС =	3s		3 S	Bs				
CpK = min	(CpU, CpL)	(smallest	of the value	ues for C	pU and C	CpL)						
Where,												
USL = uppe	er specification	on limit fo	r weight									
LSL = lowe	er specification	on limit fo	r weight									
X = mean	for weight											
s = Standa	ard deviation											
Reviewed b	y:			_	Da	ate:						
	V	alidation										



	PR	OCESS V	VALIDAT	TION F	REPORT	OF UN-CO	ATED TAB	LET				
Batch Size:	: 1000000 Tal			<u> </u>			X/PRO/BMR					
	o.: XXX/BBI		Z-00			ge No.: 35 of						
Batch Nun	nher•		Stage of	Samnlir	o: Middle	Middle stage/ Full Hopper at Optimum Speed () RHS						
Date:	11/11 •	Target F	Hardness:	շտուհոր	ig. Milduic		t Thickness:	nam specu (<i>)</i> K110			
TESTS		Targett	iai uiiess.			RESULTS						
APPEARA	NCE					ALDOLID						
AVG WEI												
	/EIGHT (g)		_									
HARDNES								Mean:	T			
THICKNE								Min:	Max:			
	TY (% w/w)											
D.T. (min) Assay(%)		API-1			API-2		AP	ντ_3				
135ay(70)		Af I-I	TI	niformi	ty of Weig	ht (mø)	AP	1-2				
				111011111	U WEIG	iii (iiig)						
	1					- 2						
	1	Ų.										
			-	100		U ed						
			I D I	10	(1)							
Capability I	ndex											
Parameter	→ LSL	USL	X		S	Ср	CpU	CpL	СрК			
Value	→							4				
The capabil	ity index to b	e calculat	ed for wei	ght san	nple using	following fo	ormula:		1			
	$Cp = \frac{U}{-}$	JSL – LSL		CpU =	USL -	- X	$CpL = \frac{X - I}{-}$	LSL				
	Cp –	6s		Сро –	3s		CpL= 3	S				
CpK = min	(CpU, CpL)	(smallest	of the val	ues for	CpU and (CpL)						
Where,												
	er specificatio	n limit fo	r weight									
	er specification	n nmit 101	weight									
X = mean	_											
s = Standa	ard deviation.											
Darriarra d L	***				D	oto.						
keviewea b	y:	lidation		_	D	ate:						
	va	muativii										



	ממ	OCECC VA	IDATION	DEDODE:	OF LIN CO	ATED TAP	LET					
. ~ .		OCESS VAI	LIDATION									
	1000000 Ta					X/PRO/BMR	R/ZZ-00					
Protocol No	o.: XXX/BBI	B/PVR/ZZ-00)	Pag	e No.: 36 of	73						
Batch Num	her:		Stage of Sam	nnling: End s	ing: End stage/ Full Hopper at Optimum Speed () LHS							
Date:	N-11	Target Har		-Luie, Dud	Target Thickness:							
TESTS		Target Har	uiicss.		RESULTS	i i iiicitiicss.						
APPEARA	NCE											
AVG WEI	GHT (mg)											
GROUP W		,	1		1	1						
HARDNES							Mean:	1				
THICKNES							Min:	Max:				
FRIABILIT D.T. (min)	I Y (% W/W)											
Assay(%)		API-1		API-2		AF	PI-3					
I I DOG (/ U)			Uniforn	nity of Weig	ht (mg)	AI						
			1									
	-											
	=											
	-			PAR								
1			240	10.00								
Capability In	ndex											
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК				
Value	→						4					
The capabili	ty index to b	e calculated	for weight sa	mple using	following fo	rmula:						
	•			1 0	C							
		USL – LSL	C II	USL -	- X	X -	LSL					
	Cp = -	6s	CpU:	= 3s		$CpL = \frac{\Lambda}{3}$	is .					
						J						
CpK = min ((CpU, CpL)	(smallest of	the values for	r CpU and (CpL)							
Where,												
ll'		1: '. C	. 1.									
	-	n limit for w										
LSL = lower	r specificatio	n limit for we	eight									
X = mean	for weight											
	rd deviation.											
s – Standa	iu ueviatioii.											
Reviewed by	y:			D	ate:							
	Va	lidation		D								



PR	OCESS V	ALIDATIO	ON REPO	RT OF	UN-COA'	TED TAB	LET			
Batch Size: 1000000 Ta	blets			BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.: XXX/BBI	B/PVR/ZZ	Z-00		Page N	o.: 37 of 7	3				
D 4 L M		G4 6.0	1· ·	74	T11 TT		C. 17) DIIG		
Batch Number:	Toward D		ampling: 1	and stage/		er at Optimu	m Speed () RHS		
Date: TESTS	Target H	lardness:		DI	Target ESULTS	Thickness:				
APPEARANCE				KI	LOULIS					
AVG WEIGHT (mg)										
GROUP WEIGHT (g)										
HARDNESS(N)							Mean:			
THICKNESS (mm)							Min:	Max:		
FRIABILITY (% w/w)										
D.T. (min)	API-1			PI-2		AP	T 2			
Assay(%)	API-I	I∃nif	formity of		ng)	AP	1-3			
				vveight (i	lig <i>)</i>			T		
					- 2					
	(
					-					
				SPA	4					
Capability Index										
Parameter LSL	USL	X	S		Ср	CpU	CpL	СрК		
Value →							4			
The capability index to b	e calculate	ed for weigh	nt sample u	sing foll	owing form	nula:				
	JSL – LSL			USL – X		X - I	CI			
$Cp = \frac{1}{2}$	JSL – LSL		CpU = -	USL – A	- C	$pL = \frac{X - 1}{}$				
7	6s			3s		38	S			
CpK = min (CpU, CpL)	(cmallect	of the value	s for CnII	and CnI)					
Where,	(smanest)	of the value	s for Cpo	and CpL)					
USL = upper specificatio	n limit for	weight								
LSL = lower specificatio	n limit for	weight								
X = mean for weight										
s = Standard deviation.										
Paviawad by				Data						
Reviewed by:Va	lidation			Date:						



PR	OCESS VALIDAT	ΓΙΟΝ REPC	RT OF U	JN-COA	TED TABI	LET					
Batch Size: 1000000 Tal	blets		BMR No.: XXX/PRO/BMR/ZZ-00								
Protocol No.: XXX/BBI	B/PVR/ZZ-00		Page No.: 38 of 73								
12.2 NVDIVIDIVA N	L PP C CEGG FEG	E D 4 E 4									
13.3 INDIVIDUAL IN Batch Number:	N-PROCESS TES	T DATA Stage of S	omnling. N	Marimum	handnaga () LHS				
Date:	Target Hardness:	Stage of S	amping: r		Thickness:) LHS				
TESTS	Target Haraness.		RES	SULTS	memicss.						
APPEARANCE				30215							
AVG WEIGHT (mg)											
GROUP WEIGHT (g)											
HARDNESS(N)						Mean:					
THICKNESS (mm)						Min:	Max:				
FRIABILITY (% w/w)											
D.T. (min)	T	miformity of	Waight (m	·~)							
		niformity of	weight (iii	<u>g)</u>							
Capability Index		Jec									
Parameter LSL	USL	K S		Ср	CpU	CpL	СрК				
Value →						4					
The capability index to be	e calculated for we	ight sample u	sing follo	wing for	nula:						
	JSL – LSL	CpU = -	USL – X	C	X - L	SL					
Cp = -	6s	СрО =	3s	C ₁	pL=						
CpK = min (CpU, CpL)	(smallest of the val	ues for CpU	and CpL)								
Where,											
USL = upper specificatio	n limit for weight										
LSL = lower specification											
X = mean for weight	C										
_											
s = Standard deviation.											
			_								
Reviewed by:	1.1	_	Date:_								
Va	lidation										



	PRO	OCESS V	ALIDAT	ION REPO	ORT O	F UN-COA	TED TAB	LET			
Batch Size: 100000	00 Tab	olets			BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.: XXX	K/BBE	B/PVR/ZZ	Z-00		Page No.: 39 of 73						
D / L N				G4 6.0	Sampling: Maximum hardness () RHS						
Batch Number: Date:	-	Target L	Iardness:	Stage of S	amplin		Thickness:) RHS		
TESTS		1 aiget f	iai uiiess:			RESULTS	1 mckness;				
APPEARANCE					<u> </u>	KLD CLID					
AVG WEIGHT (m	g)										
GROUP WEIGHT	(g)		1								
HARDNESS(N)	,							Mean:	13.5		
THICKNESS (mm FRIABILITY (% v	,							Min:	Max:		
D.T. (min)	W/W)										
D.1. (IIIII)			Ur	iformity of	Weight	t (m g)					
						(-8)					
	- 11										
	- '	_									
	17										
Capability Index			DY		SP.				1		
Parameter LS	SL	USL	X		5	Ср	CpU	CpL	СрК		
Value →											
The capability inde	x to be	e calculate	ed for weig	tht sample	using fo	ollowing for	mula:				
1 3				1	-	C					
		JSL – LSL		C.II	USL –		X -	LSL			
Cp =		6s		CpU = -	3s		CpL=	 Bs			
								,,,			
CpK = min (CpU, County)	CpL)	(smallest	of the valu	es for CpU	and C ₁	pL)					
Where,											
USL = upper specif	icatio	n limit fo	r weight								
LSL = lower specif		1 1111111 101	weight								
X = mean for wei	_										
s = Standard devi	ation.										
Reviewed by:				_	Dat	e:					
	Va	lidation									



	PR	OCESS V	ALIDAT	ION REPO	ORT O	F UN-COA	ATED TAB	LET			
Batch Size	: 1000000 Ta	blets			BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol N	o.: XXX/BB	B/PVR/ZZ	Z-00		Page	No.: 40 of	73				
Batch Nun	- l			C4aga af C	٠ائس	a. Minimum	1. a.d () I IIC		
Date:	nber:	Target H	lardness:	Stage of S	Sampling: Minimum hardness () LHS Target Thickness:						
TESTS		Target II	iai uness.		1	RESULTS	T HICKHESS.				
APPEARA	NCE					RESCEIS					
AVG WEI											
	VEIGHT (g)										
HARDNES	· '							Mean:			
THICKNE								Min:	Max:		
	TY (% w/w)										
D.T. (min)			T I w	niformity of	Waiabt	(mg)					
			UI		weight	(mg)	<u> </u>				
	0.1			10.0		-					
		/									
Capability I			124								
Parameter	→ LSL	USL	X	\$	3	Ср	CpU	CpL	СрК		
Value	→										
The capabil	ity index to b	e calculate	ed for weig	ght sample	using fo	ollowing for	rmula:				
		USL – LSL		CpU = -	USL – 2		X - I	LSL			
	Cp =	6s		Сро –	3s		$CpL = \frac{}{3}$	S			
CpK = min	(CpU, CpL)	(smallest	of the valu	es for CpU	and Cr	oL)					
Where,											
	er specification	on limit for	weight								
11/2	er specification										
	_	711 111111t 101	weight								
	for weight										
s = Standa	ard deviation	i									
Reviewed b	y:			_	Dat	e:					
	V	alidation									



	PR	OCESS VA	LIDAT	ION REP	ORT OF	UN-CO	ATED TAB	LET			
Batch Size:	1000000 Ta	blets			BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.	: XXX/BBI	B/PVR/ZZ-0	00		Page No.: 41 of 73						
Batch Numb				Stage of 9	Sampling	• Minimun	n hardness () RHS		
Date:)CI •	Target Ha	rdness:	Stage of t	amping		Thickness:) KIIS		
TESTS		Target Hu	i difess.		R	ESULTS	i inexitess:				
APPEARAN	ICE										
AVG WEIG	HT (mg)										
GROUP WI					•						
HARDNESS								Mean:	ľ		
THICKNES								Min:	Max:		
FRIABILIT	Y (% w/w)										
D.T. (min)			TI	:Co:4 of	Waiah4	()					
			Un	iformity of	weight	(mg)			<u> </u>		
				100							
		1									
Capability In	dex		P	0	92				1		
Parameter	→ LSL	USL	X	,	S	Ср	CpU	CpL	СрК		
Value	→										
The capabilit	y index to b	e calculated	for weig	ht sample	using fol	lowing fo	rmula:	4	•		
		USL – LSL		Call -	USL – X		X - I	LSL			
	Cp = -	6s		CpU =	3s		$CpL = \frac{}{3}$	S			
		OB			35						
CpK = min (0)	CpU, CpL)	(smallest of	the value	es for CpU	and Cpl	L)					
Where,											
USL = upper	specificatio	n limit for v	veight								
LSL = lower	specification	n limit for v	veight								
X = mean f	or weight										
s = Standar											
s – Standar	u ueviation.										
Reviewed by	:				Date	:					
•	Va	lidation									



PI	ROCESS VA	LIDATION 1	REPORT	OF UN-CO	ATED TAB	LET				
Batch Size: 1000000 T	ablets		BM	BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.: XXX/BB	BB/PVR/ZZ-0	00	Pag	Page No.: 42 of 73						
Batch Number:		Stag	e of Sampl	i ng: Maximur	n speed () LHS			
Date:	Target Har		,c or sumpr		Thickness:) 2210			
TESTS	luigeviiu	· caress ·		RESULTS	T THE THE SECTION OF					
APPEARANCE										
AVG WEIGHT (mg)										
GROUP WEIGHT (g)										
HARDNESS(N)						Mean:				
THICKNESS (mm)						Min:	Max:			
FRIABILITY (% w/w)										
D.T. (min)										
Assay(%)	API-1		API-2		AP	PI-3				
		Uniform	ity of Weig	ht (mg)						
	1									
	\				× 1					
Capability Index		Mile								
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК			
Value →						4				
The capability index to	be calculated	for weight sar	mple using	following fo	rmula:					
	USL – LSL		USL -		X - I	LSL				
Cp =	62	CpU =			$CpL = {}$					
	6s		3s		3	S				
CpK = min (CpU, CpL)	(smallest of	the values for	CnU and	CnL.)						
	(Sindinest of	the values for	epe una	3p 2)						
Where,										
USL = upper specificati	on limit for w	veight								
	1									
LSL = lower specification	on limit for w	eignt								
X = mean for weight										
s = Standard deviation	l .									
Reviewed by:			D	ate:						
V	alidation									



	PR	OCESS VA	LIDAT	ION RE	PORT C	OF UN-COA	ATED TAB	LET				
Batch Size:	1000000 Tal	blets			BM	BMR No.: XXX/PRO/BMR/ZZ-00						
Protocol No.			00			Page No.: 43 of 73						
D-4 1 37				C4	f Ca 1'	·) DHG			
Batch Numb	er:	Target Ha	rdnoss.	Stage of	Samplii	ng: Maximur	n speed (Thickness:) RHS			
TESTS		Target Ha	runess:			RESULTS	1 ilickiiess:					
APPEARAN	NCE											
AVG WEIG												
GROUP WI	EIGHT (g)											
HARDNESS								Mean:				
THICKNES								Min:	Max:			
FRIABILIT	Y (% w/w)											
D.T. (min) Assay(%)		API-1		I	API-2		AT	PI-3				
Assay(70)		AF1-1	I]n	niformity		t (mg)	Al	1-3				
				morning '	Vicigii	(mg)						
	1 1			-								
		\										
	= "											
					a C							
				YOU !								
Capability In	dex			- A								
Parameter	→ LSL	USL	X		S	Ср	CpU	CpL	СрК			
Value	→							4				
The capabilit	y index to b	e calculated	for weig	ght sampl	e using f	following fo	rmula:					
	т	ici ici			USL –	V	v	I CI				
	$Cp = \frac{C}{-}$	USL – LSL		CpU =	OSL -	<u> </u>	$CpL = \frac{X - }{}$	LOL				
		6s		1	3s		3	Bs				
O IZ		(11 .		6 6		T						
CpK = min (0)	CpU, CpL)	(smallest of	the valu	es for Cp	ou and C	pL)						
Where,												
USL = upper	specificatio	n limit for v	veight									
	_	1										
LSL = lower	_	n limit for w	eignt									
X = mean f	or weight											
s = Standar	d deviation.											
Reviewed by	•				Dα	te:						
Reviewed by	·	lidation		-	Da	<u> </u>						



PR	OCESS VA	LIDATION	REPORT	OF UN-CO	ATED TAR	LET	
Batch Size: 1000000 Ta		2011			X/PRO/BMR		
Protocol No.: XXX/BB		0		e No.: 44 of			
		ı					
Batch Number:	/D 4 TT		age of Sampl) LHS
Date: TESTS	Target Har	dness:		RESULTS	t Thickness:		
APPEARANCE				KESUL 15			
AVG WEIGHT (mg)							
GROUP WEIGHT (g)							
HARDNESS(N)						Mean:	
THICKNESS (mm)						Min:	Max:
FRIABILITY (% w/w)							
D.T. (min)	1 777 4		4.77.4				
Assay(%)	API-1	T	API-2	l-4 ()	AP	PI-3	
		Umiori	mity of Weig	nt (mg)			
			_				
	\.						
	1		YES		1		
Capability Index							
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК
Value →						4	
The capability index to b	e calculated	for weight sa	ample using	following fo	ormula:		
	USL – LSL	Call	USL -	- X	$CpL = \frac{X - 1}{-1}$	LSL	
Cp = -	6s	CpU	= 3s		CpL=3	s	
	OS		36		3	S	
CpK = min (CpU, CpL)	(smallest of	the values fo	or CpU and O	CpL)			
Where,							
USL = upper specification	on limit for w	eight					
LSL = lower specification							
X = mean for weight		8					
s = Standard deviation.	•						
Reviewed by:	1' 1		D	ate:			
V	alidation						



	PR	OCESS VA	LIDATION RE	EPORT ()F UN-COA	ATED TAR	LET	
Batch Size:	1000000 Tal				R No.: XXX			
	.: XXX/BBI		00		e No.: 45 of		22 00	
Batch Numl	ber:			f Samplin	ng: Minimum) RHS
Date:		Target Ha	rdness:			Thickness:		
TESTS APPEARAN	NCE				RESULTS			
AVG WEIG								
GROUP W								
HARDNES							Mean:	
THICKNES							Min:	Max:
FRIABILIT	TY (% w/w)			•	•	·	•	
D.T. (min)				1				
Assay(%)		API-1		API-2		AP	PI-3	
			Uniformity	of Weigl	nt (mg)			
					101			
	3 /							
				100				
	-	x ()	m. al					
Capability In	ndex		MA					1
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК
Value	→						4	
The capabilit	ty index to be	e calculated	for weight samp	le using	following for	rmula:		
	T			LICI	v	V	CI	
	$Cp = \frac{C}{-}$	JSL – LSL	CpU =	USL -		CpL=	LSL	
	Cp –	6s	Сро –	3s		3	S	
CpK = min (CpU, CpL)	(smallest of	the values for C	pU and C	CpL)			
Where,								
	, anaaifiaatia	n limit for v	vaiaht					
	r specificatio							
LSL = lower	specification	n limit for v	veight					
X = mean f	for weight							
s = Standar	rd deviation.							
, – Standar	a de viditon.							
Reviewed by	/:			Da	ate:			
,		lidation						



	PR	OCESS V	ALIDAT	ION REF	ORT O	F UN-COA	ATED TAB	LET				
Batch Size: 100			ALIDAT	LOIVINEI	BMR No.: XXX/PRO/BMR/ZZ-00							
Protocol No.: 2			Z-00		Page No.: 46 of 73							
Batch Number	-		Store of	Complin-	· Initial a	togo/ Ev11 II.	onnor at Onti-	mum Casal) LHS			
	•	Toward II		Sampling	g: Initial stage/ Full Hopper at Optimum Speed () LHS Target Thickness:							
Date: TESTS		Target H	araness:			RESULTS	1 nickness:					
APPEARANCI	F.					KESUL 18						
AVG WEIGHT												
GROUP WEIG												
HARDNESS(N	J)							Mean:				
THICKNESS (mm)							Min:	Max:			
FRIABILITY ((% w/w)											
D.T. (min)							T . =					
Assay(%)		API-1	T T		API-2	1 ()	AP	PI-3				
	<u> </u>		Un	iformity o	t Weight	t (mg)		<u> </u>				
						52						
	1											
						Ve						
					() ()							
Capability Index	X.											
Parameter	LSL	USL	X		S	Ср	CpU	CpL	СрК			
Value →	•							4				
The capability is	ndex to b	e calculate	ed for weig	tht sample	using fo	ollowing for	rmula:					
	т.	IOI I OI			LICI	3 7	X /	r or				
	$Cp = \frac{1}{2}$	JSL – LSL		CpU =	USL –	<u>X</u>	$CpL = \frac{X - 1}{-}$	LSL				
	Cp –	6s		СРС –	3s	1110	3	S				
CpK = min(Cp)	U, CpL)	(smallest	of the valu	es for Cp	U and C ₁	pL)						
Where,												
USL = upper sp	ecificatio	n limit for	weight									
LSL = lower sp												
X = mean for												
s = Standard c	leviation.											
Reviewed by: _					Dat	te:						
· · · · · · · · · · · · · · · · · · ·	Va	lidation		-	_ 30							



PR	OCESS V	VALIDATI	ON REPO	ORT OF U	UN-COAT	TED TAB	LET				
Batch Size: 1000000 Ta	blets			BMR No.: XXX/PRO/BMR/ZZ-00							
Protocol No.: XXX/BB	B/PVR/ZZ	Z-00		Page No.: 47 of 73							
		l a						,			
Batch Number:	T		ampling: I	nitial stage			um Speed () RHS			
Date:	Target I	Hardness:		D		hickness:					
TESTS APPEARANCE				<u> RE</u>	SULTS						
AVG WEIGHT (mg)											
GROUP WEIGHT (g)											
HARDNESS(N)							Mean:				
THICKNESS (mm)							Min:	Max:			
FRIABILITY (% w/w)											
D.T. (min)	A DI 1			DI A		A.D	T 2				
Assay(%)	API-1	Uni	formity of	PI-2 Weight (n	.a.)	AP	1-3				
T		UIII		weight (h	<u>lg)</u>	<u> </u>					
					-2						
	\										
				ACT							
				SEL							
Capability Index											
Parameter LSL	USL	X	S	S	Ср	CpU	CpL	СрК			
Value →							4				
The capability index to b	e calculat	ed for weigl	ht sample	using follo	owing forn	nula:					
Cp =	USL – LSL	_	CpU = -	USL – X	Cr	$DL = \frac{X - I}{-}$	LSL				
_	6s		сро –	3s	Cļ		S				
a				1163							
CpK = min (CpU, CpL)	(smallest	of the value	es for CpU	and CpL)							
Where,											
USL = upper specification	on limit fo	r weight									
LSL = lower specification											
X = mean for weight											
_											
s = Standard deviation.											
Reviewed by:				Date:							
Reviewed by:	alidation			2 u.o							



	PR	OCESS VA	LIDATION	REPORT	OF UN-CO	ATED TAB	LET	
Batch Size: 100	00000 Tal	blets		BM	IR No.: XXX	K/PRO/BMR	R/ZZ-00	
Protocol No.: X	XXX/BBE	B/PVR/ZZ-0	00	Pag	ge No.: 48 of	773		
Batch Number	•		Stage of Sam	nling: Middle	e stage/ Full H	Iopper at Opti	imum Speed	() LHS
Date:	•	Target Hai		71116 1111441		Thickness:	mam speed	() 2218
TESTS		Turget Hu	diess.		RESULTS	THERIESS:		
APPEARANCI	E				TESCETS.			
AVG WEIGHT								
GROUP WEIG								
HARDNESS(N	I)						Mean:	
THICKNESS (Min:	Max:
FRIABILITY ((% w/w)							
D.T. (min)		177.4		4.77.4				
Assay(%)		API-1	T1 •6	API-2		Al	PI-3	
			Unifori	nity of Weig	ht (mg)			
			. 11		9			
	1 /							
		1						
				100				
			Dire					
Capability Index	X							
Parameter	LSL	USL	X	S	Ср	CpU	CpL	СрК
Value →	•						4	
The capability is	ndex to be	e calculated	for weight sa	ample using	following fo	rmula:		
	т.	ICI ICI		LICI	V	V	I CI	
	$Cp = \frac{C}{-}$	JSL – LSL	CpU	= USL		$CpL = \frac{X - 1}{-}$	LSL	
	Cp –	6s	СрС	3s			s	
CpK = min (Cp)	U, CpL)	(smallest of	the values for	or CpU and	CpL)			
Where,								
USL = upper sp	ecificatio	n limit for v	veight					
LSL = lower sp								
X = mean for								
a - Standard a	loviotion							
s = Standard d	ieviation.							
Reviewed by:				D	ate:			
Reviewed by: _	Va	lidation		D				



P	ROCESS V	ALIDATION	REPORT	OF UN-CO	ATED TAR	LET	
Batch Size: 1000000 7				IR No.: XXX			
Protocol No.: XXX/B		Z-00		ge No.: 49 of		22 00	
D 4 L N L		C4	12 MC 1.11-	-4/ E-11 II		C 1 () DIIC
Batch Number:	Towast II	Stage of Samp	ing: Middle			num Speed () RHS
Date: TESTS	Target H	araness:		RESULTS	Thickness:		
APPEARANCE				RESULTS			
AVG WEIGHT (mg)							
GROUP WEIGHT (g)							
HARDNESS(N)						Mean:	
THICKNESS (mm)						Min:	Max:
FRIABILITY (% w/w))						
D.T. (min)			T				
Assay(%)	API-1	TI •6	API-2		AF	PI-3	
		Unitor	mity of Weig	ht (mg)	<u> </u>	<u> </u>	
			100	9			
	\.	1					
		1000	TO SA			\	
Capability Index							
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК
Value →						4	
The capability index to	be calculate	ed for weight s	ample using	following fo	rmula:		
	TIGI T.GI		1101	***	37	r or	
Cp =	USL – LSL	CpU	USL	<u> </u>	$CpL = \frac{X - 1}{-}$	LSL	
Cp –	6s	Срс	3s		3	S	
CpK = min (CpU, CpL)) (smallest	of the values for	or CpU and	CpL)			
Where,							
USL = upper specificat	ion limit for	weight					
LSL = lower specificat							
X = mean for weight	ion milit ioi	WOISIIL					
s = Standard deviatio	n.						
Reviewed by:			D	ate:			
•	Validation						



		O O E C C T T	ATTRACTOR	DEBORE	OF IN CC	A (DEE) COA	LEC	
			ALIDATION	1				
Batch Size:	1000000 Ta	blets		BM	R No.: XXX	X/PRO/BMR	2/ZZ-00	
Protocol No	o.: XXX/BBI	B/PVR/ZZ	-00	Pag	e No.: 50 of	£73		
Batch Num	hor		Stage of Sar	mpling: End s	rtage/ Full Ho	onner at Ontin	num Sneed () LHS
Date:	DCI.	Target H		inpinig. Life s		t Thickness:	ium specu () LIIG
TESTS		Target II	aruness.		RESULTS	t TilleRifess.		
APPEARA	NCE				RESCEIS			
AVG WEIG								
GROUP W						_		
HARDNES							Mean:	
THICKNE							Min:	Max:
	ΓΥ (% w/w)							
D.T. (min) Assay(%)		API-1		API-2		AT	PI-3	
Assay(70)		AF1-1	Unifor	mity of Weig	ht (mg)	AI	1-3	
				mity of Weigh				
			-11	-				
			J.					
					N. e.			
				100				
Capability In	ndex							
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК
Value	→						4	
The capabili	ty index to b	e calculate	d for weight s	ample using	following fo	rmula:		
			C		_			
		USL – LSL	C II	USL -	- X	X -1	LSL	
	Cp = -	6s	CpU	3s		CpL=	s	
		OS		36		3	S	
CpK = min	(CpU, CpL)	(smallest o	of the values for	or CpU and C	CpL)			
Where,								
ll'	r specificatio	n limit for	weight					
LSL = lower								
		11 1111111 101	weight					
	for weight							
s = Standa	rd deviation.							
Reviewed by	v:			D	ate:			
110 / 10 / 10 0		alidation		D				



	nn	OCEGG I		J DEDART A	OF LIM CO	ATED TAD	IFT	
D 4 1 C'			VALIDATION					
	1000000 Ta					X/PRO/BMR	Z/ZZ-00	
Protocol No	o.: XXX/BB	B/PVR/ZZ	Z-00	Pag	e No.: 51 of	73		
Batch Num	ber:		Stage of San	npling: End st	age/ Full Hor	pper at Optimi	ım Speed () RHS
Date:		Target I	Hardness:			t Thickness:	« F (,
TESTS					RESULTS			
APPEARA								
AVG WEIG								
GROUP W			1				h.,	
HARDNES							Mean:	Morra
THICKNE	55 (mm) FY (% w/w)						Min:	Max:
D.T. (min)	L1 (/0 W/W)							
Assay(%)		API-1		API-2		AP	PI-3	
		1	Unifor	mity of Weigl	nt (mg)			
	-			*		_		
	2	\						
				100				
	-	\ (TO CAL				
Capability I	ndex							
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК
Value	→				-		_	-
The capabili	tv index to b	e calculat	ed for weight s	sample using	l following fo	rmula:		
	.,		8		<i>8</i>			
		USL – LSL		USL -	- X	X - 1	LSL	
	Cp = -	6s	- Cpl	$J = {3s}$	T d Y O	$CpL = \frac{}{3}$	c c	
		OS		38		3	3	
CpK = min	(CpU, CpL)	(smallest	of the values f	or CpU and C	CpL)			
Where,								
USL = uppe	r specificatio	n limit fo	r weight					
LSL = lower								
		11 1111111 10	weight					
	for weight							
s = Standa	rd deviation.							
Reviewed by	y:			Da	ate:			
•		alidation						



	PR	OCESS V	ALIDAT	ION R	EPORT	OF U	JN-CO	ATED TAB	LET	
Batch Size:	1000000 Tal	blets			BN	MR No	o.: XXX	K/PRO/BMR	/ZZ-00	
Protocol No	.: XXX/BBI	B/PVR/ZZ	-00		Pa	ge No	.: 52 of	773		
13.4 IND	IVIDUAL II	N DDACE	ee Teet	грат	A					
Batch Num		V-PROCE	799 IE91			ling: N	Maximui	m hardness () LHS
Date:	ber.	Target H	ardness:	Suge	or Sump	77779		Thickness:) 2225
TESTS						RES	SULTS			
APPEARA										
AVG WEIG										
GROUP W									h.σ	
HARDNES THICKNES									Mean: Min :	Max:
FRIABILIT									171111 •	wax.
D.T. (min)	(/0 /// ///									
,			Ur	niformit	ty of Wei	ght (m	g)			
				- 1						
	- 1									
				W	7	5				
G 1994 7									0	
Capability In	ndex		Janu							
Parameter	→ LSL	USL	X		S		Ср	CpU	CpL	СрК
Value	→								4	
The capabili	ty index to b	e calculate	d for weig	ght sam	ple using	g follo	wing fo	rmula:		_
	-	TOT LOT			1101	37		X7 T	CI.	
	$Cp = \frac{0}{2}$	JSL – LSL		CpU =	USL	L – X		$CpL = \frac{X - I}{-}$	LSL 	
	Cp =	6s		Сро –	3s			39	S	
CaV min ((Call Cal)	(ama a 11 a a 4 a	£41 1	aa Can	Call and	Cal.)				
	(CpU, CpL)	(smanest c	or the valu	ies for t	CpO and	CpL)				
Where,										
USL = upper	r specificatio	n limit for	weight							
LSL = lower	r specification	n limit for	weight							
	for weight		J							
s = Standar	rd deviation.									
Reviewed by	y:	1.1		_	I	Date:_				
	Va	lidation								



nn	OCESS VA	I IDATIO	N REPORT	OF LINI COA	TED TAD	IFT	
Batch Size: 1000000 Ta		LIDATIO		R No.: XXX			
Protocol No.: XXX/BBI		0				VZZ-00	
1 TULUCUI NU.; AAA/BBI	D/FVK/LL-U	U	rag	e No.: 53 of	13		
Batch Number:			tage of Sampl) RHS
Date:	Target Har	dness:			Thickness:		
TESTS				RESULTS			
APPEARANCE AVG WEIGHT (mg)							
GROUP WEIGHT (g)							
HARDNESS(N)						Mean:	
THICKNESS (mm)						Min:	Max:
FRIABILITY (% w/w)			•	•			
D.T. (min)							
		Unifo	rmity of Weig	ht (mg)	1		
		-11	-	9			
	1						
			6				
Capability Index							
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК
Value →							
The capability index to b	e calculated	for weight	sample using	following for	rmula:		
$Cp = \frac{0}{2}$	USL – LSL	Cn	$U = \frac{USL}{}$		$CpL = \frac{X - X}{-}$	LSL	
Cp =	6s	Ср	3s		-	Bs	
CpK = min (CpU, CpL)	(smallest of	the values	for CpU and (CpL)			
Where,							
USL = upper specificatio	n limit for w	eight					
LSL = lower specificatio							
X = mean for weight	101 W	8-11					
s = Standard deviation.							
Daviawad by			D	nto:			
Reviewed by:Va	alidation		D	ate:			



	PR	OCESS VA	LIDATIO	N REPO	RT OF U	J N-COA	TED TAB	LET	
Batch Size:	1000000 Ta	blets			BMR N	o.: XXX	/PRO/BMR	ZZ-00	
Protocol No	: XXX/BBI	B/PVR/ZZ-0	0		Page No	.: 54 of 7	73		
D-4-1 N1				14000 of C		M::	handness () I IIC
Batch Numb	er:	Target Har		tage of Sa	ampling:		hardness (Thickness:) LHS
TESTS		Target Har	uness.		RE	SULTS	1 mckness.		
APPEARAN	NCE					00210			
AVG WEIG									
GROUP WI									
HARDNESS	` '							Mean:	
THICKNES								Min:	Max:
FRIABILIT	Y (% w/w)								
D.T. (min)			Unifo	rmity of V	Weight (m	na)			
					vveight (ii	<i>'s)</i>			
			r J			2			
	- 4								
						<u> </u>			
Capability In	dex								
Parameter	→ LSL	USL	X	S		Ср	CpU	CpL	СрК
Value	→								
The capabilit	y index to b	e calculated	for weight	sample u	sing follo	wing for	mula:		
	_								
	Cp = -	USL – LSL	Cr	U = -	USL – X	C	$CpL = \frac{X - I}{-}$	LSL 	
	Cp =	6s	Cp	/C =	3s	20	3:	S	
CpK = min (CpU, CpL)	(smallest of	the values	for CpU	and CpL)				
Where,									
USL = upper	enacificatio	n limit for w	voight						
	_		_						
LSL = lower	specificatio	n limit for w	eight						
X = mean f	or weight								
s = Standar	d deviation.								
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2									
Reviewed by	•				Doto				
Neviewed DV	•				Date:_				



	PF	ROCESS V	ALIDAT	TION REP	ORT OF	UN-COA	ATED TAB	LET	
Batch Size:	1000000 Ta	ablets			BMR	No.: XXX	X/PRO/BMR	/ZZ-00	
Protocol No	.: XXX/BB	B/PVR/ZZ	Z-00		Page N	No.: 55 of	73		
Dotals Name	h			Stage of	Camplina	• Minimum	houdness () DHC
Batch Num Date:	ber:	Torget H	lardness:	Stage of	Sampling		hardness (Thickness:) RHS
TESTS		Target	tai uness.		R	ESULTS	T IIICKIIESS.		
APPEARA	NCE					250215			
AVG WEIG									
GROUP W									
HARDNES	` '							Mean:	
THICKNES								Min:	Max:
FRIABILIT	<u> </u>								
D.T. (min)			TT.	niformity of	f Weight ((ma)			
			U.	miorimity of	vveigni ((mg)			
						2			
	k-1	/							
	<u> </u>								
					25	3			
Capability In	ndex								
Parameter	→ LSL	USL	X		S	Ср	CpU	CpL	СрК
Value	→								
The capabili	ty index to l	e calculate	ed for wei	ght sample	using fol	lowing for	rmula:		
		USL – LSL			USL – X		X - I	CI	
	Cp =	OSL – LSL		CpU =	USL - A		CpL= -X -1		
		6s		1000	3s		3	s	
CpK = min ((CpU, CpL)	(smallest	of the val	ues for CpU	J and Cpl	<u>(</u>)			
Where,									
USL = uppe	r specification	on limit fo	r weight						
LSL = lower	specification	on limit for	weight						
X = mean	for weight								
s = Standa	rd deviation								
5 – Standa	ra acviation	•							
D					-				
Reviewed by	y:	1.1		_	Date	:			
	V	alidation							



DI	PUCESS AV	I IDATI	ON REPORT	OF LIN-CO	ATED TAR	I FT	
Batch Size: 1000000 Ta		TIDAII			X/PRO/BMR		
Protocol No.: XXX/BB		00		e No.: 56 of			
			G. 6G 1	3.6	1./		\ T TT G
Batch Number:			Stage of Sampli) LHS
Date: TESTS	Target Har	rdness:		RESULTS	t Thickness:		
APPEARANCE				RESULIS			
AVG WEIGHT (mg)							
GROUP WEIGHT (g)							
HARDNESS(N)						Mean:	
THICKNESS (mm)						Min:	Max:
FRIABILITY (% w/w)				·	·		
D.T. (min)							
Assay(%)	API-1		API-2		AP	PI-3	
		Unif	cormity of Weig	nt (mg)			
				-			
	1		I A		a. 75		
	< ()	F-1-1	A PAR		1		
Capability Index							
Parameter	USL	X	S	Ср	CpU	CpL	СрК
Value →						4	
The capability index to	be calculated	for weigh	t sample using	following fo	rmula:		
	USL – LSL		USL -		X - 1	LSL	
Cp =	6s	C	$CpU = {3s}$	3710	CpL=3	e e	
					3	3	
CpK = min (CpU, CpL)	(smallest of	the value	s for CpU and (CpL)			
Where,							
N.							
USL = upper specificati	on limit for v	veight					
LSL = lower specification	on limit for w	eight					
X = mean for weight							
s = Standard deviation	l.						
Reviewed by:			D	ate:			
	'alidation						



QUALITY ASSURANCE

PROG Batch Size: 1000000 Table Protocol No.: XXX/BBB/I	CESS VAI	IDATION DED					
		LIDATION KEP	ORT OF	UN-CO	ATED TABI	LET	
Protocol No.: XXX/BBB/I	ets		BMR N	lo.: XXX	X/PRO/BMR/	ZZ-00	
	PVR/ZZ-00)	Page N	o.: 57 of	73		
D 4 L M L		C4	C1:) / · · · · · · · · · · · · · · · · ·	1 /		\ DHC
Batch Number: Date:	Farget Hard		Sampling:		Thickness:) RHS
TESTS	rarget Hart	mess.	RF	ESULTS	Tilless:		
APPEARANCE							
AVG WEIGHT (mg)							
GROUP WEIGHT (g)					.		
HARDNESS(N)						Mean:	3.4
THICKNESS (mm) FRIABILITY (% w/w)						Min:	Max:
D.T. (min)							
	API-1		API-2		API	[-3	
		Uniformity o		ng)			
					. /		
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \							
7							
Capability Index		Marc		•			-
Parameter	USL	X	S	Ср	CpU	CpL	СрК
Value →						4	
The capability index to be α	calculated f	or weight sample	using follo	owing fo	rmula:		
				J			
	L – LSL	Call –	USL – X		X - L	SL	
Cp =	6s	CpU =	3s		CpL= 3s		
				9.00			
CpK = min (CpU, CpL) (s	mallest of t	he values for Cpl	J and CpL)			
Where,							
USL = upper specification	limit for we	eight					
LSL = lower specification l		=					
LSL = lower specification I X = mean for weight							
\ -							

Validation



PR	OCESS V	ALIDAT	ION REP	ORT OF	UN-CO	ATED TABI	LET	
Batch Size: 1000000 Ta	blets			BMR N	No.: XXX	K/PRO/BMR	/ZZ-00	
Protocol No.: XXX/BB	B/PVR/ZZ-	-00		Page N	o.: 58 of	73		
Batch Number:			Stage of S	Sampling:) LHS
Date:	Target Ha	ardness:				Thickness:		
TESTS				RI	ESULTS			
APPEARANCE								
AVG WEIGHT (mg)								
GROUP WEIGHT (g)		ı	1	1				
HARDNESS(N)							Mean:	1
THICKNESS (mm)							Min:	Max:
FRIABILITY (% w/w)								
D.T. (min)	A DT 1		1.	DI 2		1 4 75	T 2	
Assay(%)	API-1	TI		PI-2	ma)	AP	1-3	
		Un	iformity of	vveight (1	ng)			
						z.,		
							+	
				ALG				
				BP.	1/			
Capability Index		M	A.C.					
Parameter	USL	X	!	S	Ср	CpU	CpL	СрК
Value →								
The capability index to b $Cp = -\frac{1}{2}$ $CpK = min (CpU, CpL)$ Where, $USL = upper specification LSL = lower specification X = mean for weight s = Standard deviation.$	On limit for on limit for	f the valu	CpU = -	USL – X	ojj	ormula: $CpL = \frac{X - I}{3s}$	_	
Reviewed by:V	alidation		-	Date:				



QUALITY ASSURANCE

Batch Size: 1000000 Tablets Protocol No.: XXX/BBB/PV Batch Number:		Stage of Sa	BMR No		ED TABL RO/BMR/2		
Batch Number: Date: Tan TESTS APPEARANCE	/R/ZZ-00	Stage of Sa		o.: XXX/P	RO/BMR/Z	77-00	
Protocol No.: XXX/BBB/PV Batch Number: Date: Tan TESTS APPEARANCE	/R/ZZ-00	Stage of Sa					
Batch Number: Date: Tan TESTS APPEARANCE		Stage of Sa	8- 10	.: 59 of 73			
Date: Tai TESTS APPEARANCE	rget Hardness:	Stage of Sa					
TESTS APPEARANCE	rget Hardness:		mpling: M		•)	RHS
APPEARANCE			DEC	Target Th	nickness:		
			KES	SULTS			
GROUP WEIGHT (g)							
HARDNESS(N)						Mean:	1
THICKNESS (mm)						Min:	Max:
FRIABILITY (% w/w) D.T. (min)							
Assay(%) AP	PI-1	Α	PI-2		API-	-3	
		niformity of		g)			
			15-17				
Capability Index		To Co					
Parameter	USL X	S	S	Ср	CpU	CpL	СрК
Value →						4	
The capability index to be cal	lculated for wei	ght sample i	using follo	wing form	ula:		
apacint, mach to be car	101 WO	one sample (
USL -	– LSL	G II	USL-X		X - LS	SL	
$Cp = \phantom{aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa$	S	CpU = -	3s	Cpl	_=		
					38		
CpK = min (CpU, CpL) (small)	allest of the val	ues for CpU	and CpL)				
Where,							
USL = upper specification lin	nit for weight						
LSL = lower specification lim							
- I	8						
X = mean for weight							
X = mean for weight s = Standard deviation.							

Validation



	PR	OCESS V	ALIDATION	REPORT	OF UN-COA	ATED TAB	LET	
Batch Size:	1000000 Tal	blets		BM	R No.: XXX	K/PRO/BMR	/ZZ-00	
Protocol No	.: XXX/BBI	B/PVR/ZZ-	-00	Pag	ge No.: 60 of	73		
Batch Num	ber:		Stage of Sam	pling: Initial	stage/ Full Ho	opper at Opti	mum Speed () LHS
Date:	~~~	Target Ha		T8:		Thickness:	(,
TESTS		Target III	ii uness.		RESULTS	TimeRifess.		
APPEARA	NCE				TESCEIS.			
AVG WEIG								
GROUP W	· · ·							
HARDNES	,O/						Mean:	
THICKNES							Min:	Max:
FRIABILIT			1	•	- 1	•	<u> </u>	•
D.T. (min)	, , ,							
Assay(%)		API-1		API-2		AP	PI-3	
•			Unifori	nity of Weig	ht (mg)			
			-13	-				
			J					
	=							
					N/e			
				TOSA				
Capability Ir	ndex							
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК
Value	→						4	
The capabili	ty index to be	e calculated	d for weight sa	ample using	following for	rmula:		•
		JSL – LSL		USL -	– X	X -]	LSL	
	Cp = -	6s	CpU	= 3s		$CpL = \frac{}{3}$		
		US		38		3	5	
CpK = min	CpU, CpL)	(smallest o	f the values fo	or CpU and O	CpL)			
		` A. V		1	1 /			
Where,								
USL = upper	r specificatio	n limit for	weight					
1	specification							
X = mean	•		C					
	_							
s = Standar	rd deviation.							
Reviewed by	/:			D	ate:			
	Va	lidation						



	DD	OODGG T	7AT ID AUTON	I DEDARE	OF IN CO		TEC		
PROCESS VALIDATION REPORT OF UN-COATED TABI									
Batch Size:	1000000 Ta	blets		BM	BMR No.: XXX/PRO/BMR/ZZ-00				
Protocol No	o.: XXX/BB	B/PVR/ZZ	Z-00	Pag	e No.: 61 of	73			
Batch Num	hor:		Stage of Samp	nling. Initial s	tage/ Full Ho	nner at Ontin	num Sneed () RHS	
Date:	DCI.	Target H	Iardness:	pinig. Initial s		t Thickness:	ium specu () KIIS	
TESTS		Targett	taruness.		RESULTS	i i ilickiiess.			
APPEARA	NCE				RESCEIS				
AVG WEIG	GHT (mg)								
GROUP W									
HARDNES							Mean:	T= -	
THICKNE							Min:	Max:	
D.T. (min)	ΓΥ (% w/w)								
Assay(%)		API-1		API-2		ΔI	PI-3		
Assay (70)		AII-I	Unifor	mity of Weig	ht (mg)	All	1-3		
					-				
	-		- 1						
	-1	\							
				VAR					
				He er					
Capability In	ndex								
Parameter	→ LSL	USL	X	S	Ср	CpU	CpL	СрК	
Value	→						4		
The capabili	ty index to b	e calculat	ed for weight s	ample using	following fo	rmula:			
						.A.			
	Cp = -	USL – LSL	· CpU	USL -	- X	$CpL = \frac{X - 1}{-1}$	LSL		
	Cp =	6s	Срс	3s			s		
CpK = min	(CpU, CpL)	(smallest	of the values for	or CpU and C	CpL)				
Where,									
USL = uppe	r specificatio	on limit fo	r weight						
LSL = lower									
	for weight		. ,, 0.8						
	rd deviation.								
s = Standa	ra acviativii.								
Reviewed by				D	ate:				
	Va	alidation							



	nn.		I ID A TION	DEDODE	OF LINE CO.		TET		
D . 4.1.69			LIDATION						
Batch Size:					BMR No.: XXX/PRO/BMR/ZZ-00				
Protocol No.	: XXX/BBI	B/PVR/ZZ-0	00	Pag	Page No.: 62 of 73				
Batch Numb	er:	<u> </u>	Stage of Samp	oling: Middle	e stage/ Full H	Iopper at Opti	imum Speed	() LHS	
Date:		Target Har		-		Thickness:		· · · · · · · · · · · · · · · · · · ·	
TESTS					RESULTS				
APPEARAN									
AVG WEIG	` ' '								
GROUP WEIGHT (g)									
HARDNESS THICKNES							Mean: Min :	Max:	
FRIABILIT							IVIIII ;	Max:	
D.T. (min)	1 (/0 W/W)								
Assay(%)		API-1		API-2		AF	PI-3		
* ` ′			Uniforn	nity of Weig	ht (mg)	,			
	1		17						
			-/-						
				1	_ (
	-	X (TO SA					
Capability Inc	dex		India		•			- 1	
Parameter	→ _{LSL}	USL	X	S	Ср	CpU	CpL	СрК	
Value	→						4		
The capability	v index to be	e calculated	for weight sa	ample using	following fo	rmula:			
			8	. r 8	<i>8</i>				
		JSL – LSL		USL -	- X	X -1	LSL		
	Cp = -	6s	CpU	= 3s		CpL= -3	S		
CpK = min (C)	CpU, CpL)	(smallest of	the values fo	r CpU and (CpL)				
Where,									
USL = upper	specification	n limit for w	voight						
LSL = lower		ii iiiiiit 101 w	eigin						
X = mean for	_								
s = Standar	d deviation.								
Reviewed by:	·			D	ate:				
•	Va	lidation							



pi	ROCESS V	ALIDATION	REPORT	OF UN.CO	ATED TAR	LET		
Batch Size: 1000000 T								
Protocol No.: XXX/BE		-00		BMR No.: XXX/PRO/BMR/ZZ-00 Page No.: 63 of 73				
Dotah WL	1	Stage of S				num C 1 (\ DIIG	
Batch Number:	Target H	Stage of Samp	ung: Middle			num Speed () RHS	
Date: TESTS		RESULTS	Thickness:					
APPEARANCE				RESULIS				
AVG WEIGHT (mg)								
GROUP WEIGHT (g)								
HARDNESS(N)						Mean:		
THICKNESS (mm)						Min:	Max:	
FRIABILITY (% w/w)								
D.T. (min)			1					
Assay(%)	API-1	77.10	API-2	•	AP	PI-3		
		Unifor	mity of Weig	ht (mg)				
		. 111	100	54				
	1	J						
		1000	TO SA					
Capability Index								
Parameter LSL	USL	X	S	Ср	CpU	CpL	СрК	
Value →						4		
The capability index to	be calculate	d for weight s	ample using	following fo	rmula:			
	TIGI I GI		1101	V	X / 1	. OI		
Cp =	USL – LSL	CpU	USL —	- X	$CpL = \frac{X - I}{-}$	LSL		
Sp.	6s	Сро	3s		3	S		
(
CpK = min (CpU, CpL)	(smallest	of the values for	or CpU and	CpL)				
Where,								
USL = upper specificati	ion limit for	weight						
LSL = lower specificati								
X = mean for weight	101	0.5						
s = Standard deviation	1.							
Reviewed by:			D	ate:				
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	/alidation		D					



	PR	OCESS V	ALIDATION	N REPORT	OF UN-COA	ATED TAB	LET		
Batch Size: 1000	0000 Tal	blets		BM	BMR No.: XXX/PRO/BMR/ZZ-00				
Protocol No.: X	XX/BBE	B/PVR/ZZ-	00	Pag	Page No.: 64 of 73				
Batch Number:			Stage of Sa	mpling: End	stage/ Full Ho	nner at Ontin	num Speed () LHS	
		Toward II.		inpinig. End			ium speed () LIIS	
Date: TESTS		Target Ha	iraness:		RESULTS	Thickness:			
APPEARANCE					RESULIS				
AVG WEIGHT									
GROUP WEIGH									
HARDNESS(N)	(<u>s</u>)						Mean:		
THICKNESS (n	nm)						Min:	Max:	
FRIABILITY (%			l I	I	I		111222	172422	
D.T. (min)	• ,								
Assay(%)		API-1		API-2		AF	PI-3		
			Unifor	mity of Weig	ht (mg)	•			
				·					
	- + +			-	- 2				
			- 7						
	= 1								
			Dir						
Capability Index									
Parameter	LSL	USL	X	S	Ср	CpU	CpL	СрК	
Value →							4		
The capability in	dex to be	e calculated	d for weight s	sample using	following fo	rmula:		•	
				LICI	37	37.	r or		
	$Cp = -\frac{C}{T}$	JSL – LSL	CpU	USL -		$CpL = \frac{X - 1}{-}$			
		6s	Срс	3s			s		
CpK = min (CpU	(, CpL)	(smallest o	f the values for	or CpU and O	CpL)				
Where,									
USL = upper spe	cificatio	n limit for	weight						
LSL = lower spectors	cificatio	n limit for	weight						
X = mean for w	veight								
s = Standard de	eviation.								
Reviewed by:				D	ate:				
icoviewed by	Va	lidation		D	u.v				



	DD 0 0700	*** * *** * ***	10N B==	000000	IN CC : -			
		VALIDAT	ION REP					
Batch Size: 100000	0 Tablets			BMR No.: XXX/PRO/BMR/ZZ-00				
Protocol No.: XXX	/BBB/PVR/Z	ZZ-00		Page No	65 of 73	3		
Batch Number:		Stage of	Sampling:	End stage/	Full Hoppe	er at Optimu	ım Speed () RHS
Date:	Target	Hardness:	1,8,			hickness:	F 355 (,
TESTS	Turget			RE	SULTS			
APPEARANCE								
AVG WEIGHT (mg	-							
GROUP WEIGHT	(g)			1				
HARDNESS(N)							Mean:	3.6
THICKNESS (mm)	/ >						Min:	Max:
FRIABILITY (% w D.T. (min)	/w)							
Assay(%)	API-1			API-2		AP	I-3	
	1 1 1 1 1	Un		Weight (m	ıg)	111	<u>- v</u>	
			•	<u> </u>	<i>S</i> /			
	11							
						4		
					1			
			100					
Capability Index								
Parameter LS	L USI	L X		S	Ср	CpU	CpL	СрК
Value -	L USI	A .	'	3	СР	Сро	CpL	СрК
	. 1 1 1	1.0	1, 1	· C 11	· c			
The capability index	to be calcula	ated for weig	int sample	using follo	wing forn	nuia:		
	USL – LS	I/		USL – X		X - I	SL	
Cp =	-	-	CpU =		Cp	L=	_	
	6s			3s		38	S	
CpK = min (CpU, C	nI.) (smalles	at of the valu	es for CnI	and CnL)				
	pr) (smanes	or the valu	es for CpC	and CpL)				
Where,								
USL = upper specific	cation limit f	for weight						
LSL = lower specific	cation limit f	or weight						
X = mean for weight								
s = Standard devia								
s – Standard devia	uon.							
Reviewed by:			-	Date:_				
	Validation							



QUALITY ASSURANCE

PROCESS	VALIDA	ATION REPOR	ET OF UN.	COATED	TARLET
1 1/1 // 1/1/1/1/1/1/1/1/1/1/1/1/1/1/1/) V /~\ _ / /	~ I I\/	~ 1 ~ 71 , ~ 1,1, ~ -	'\ \\ <i>\\</i> \ \\	

Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 66 of 73

13.5 FINISHED PRODUCT ANALYSIS REPORT:

S. No.	Tests	Specification	Re	esults (Batch Nos.)
S. 140.	Tests	Specification		
1.0	Description	Light yellow circular, biconvex uncoated tablet having plain surface on both sides.		
2.0	Identification API-1 (By UV)	The UV absorption spectrum of the standard and sample preparation should be concordant.		
3.0	Average weight (mg)	410.0 ± 2.5 % (399.8 – 420.3)		
4.0	Uniformity of weight	Not more than two of the individual weights deviate from		
	(%)	the average weight by more than ± 5 % and none should deviate by more than ± 10 %	30	
5.0	Disintegration Time	Not more than 30		
6.0	Hardness (N)	NLT 6.0 kg/cm ²		
7.0	Friability (% w/w)	NMT 1.0		
8.0	Assay		rion	
	API-1 [By Titrymetry] - mg/tablet -% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0		
	API-2 [By Titrymetry] - mg/tablet -% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0		
\	API-3 [By Titrymetry] - mg/tablet -% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0		

YIELD DETAILS AT THE END OF COMPRESSION:

Batch No.	%Yield	Limit*
		NLT 99.0%
* Vield Limit is tentative and	d will be finalized after 10 or more production b	natches

			1121 >>1070
* Yield Limit is tentative and	d will be finalized after 10	or more production b	patches.
Reviewed by:		Date:	
Valida	ation		



_	PROCESS	VALIDATION REPO	ORT OF UN-COATED TABLET
Batch Size: 10000	00 Tablets		BMR No.: XXX/PRO/BMR/ZZ-00
Protocol No.: XXX	X/BBB/PVR/Z	ZZ-00	Page No.: 67 of 73
EVALUATION:			
	44		
		Drac	255
<u> </u>		The state of the s	
<u> </u>			
 			
	3		Hariloit III
		MSV	
Reviewed by:	Validation	Date	:



tch Size: 100		ATED TABLET X/PRO/BMR/ZZ-00		
tocol No.: X	XX/BBB/PVR/ZZ-	00	Page No.: 68 of	73
			DATION SAMPLES as per SOP No	
Batch No.:		Destruction	done by / Date	Checked by / Date
ed by:			Date:	
, —	Validation	Pro	tess	



	PROCESS	VALIDATION REPO	ORT OF UN-COATED TABLET
Batch	Size: 1000000 Tablets		BMR No.: XXX/PRO/BMR/ZZ-00
Proto	col No.: XXX/BBB/PVR/Z	Z-00	Page No.: 69 of 73
15.0	VALIDATION SUMME	RY:	
\		DroG	255
H			
		Valid	lation)



PROCESS	VALIDATION REPO	RT OF UN-COATED TABLET		
Batch Size: 1000000 Tablets		BMR No.: XXX/PRO/BMR/ZZ-00		
Protocol No.: XXX/BBB/PVR/Z	ZZ-00	Page No.: 70 of 73		
	Proc	399		
T	<u> </u>			
<u> </u>				
		ACC-C-		



PROCESS VALIDATION REPORT OF UN-COATED TABLET							
Batch Size: 1000000	O Tablets	BMR No.: XXX/PRO/BMR/ZZ-00					
Protocol No.: XXX/	/BBB/PVR/ZZ-00	Page No.: 71 of 73					
	1.1						
1	Proc	899					
	The warm						
Reviewed by:	Dat	e:					
	, ariounion						



	PROCESS VALIDAT	TON REPORT OF	UN-COATEI	D TABLET		
Batch Size: 1000000 Tablets			BMR No.: XXX/PRO/BMR/ZZ-00			
Protocol No.: XXX/BBB/PVR/ZZ-00			Page No.: 72 of 73			
16.0 CO	NCLUSION:					
Product Bat	tch Nos.:,an	nd manufa	actured in the fa	acility as the validation batch meet		
the specifica	ation of tablets. The process of man	afacturing was carried	as per the appro	oved Batch Manufacturing records		
and process	of Manufacturing is validated.					
The all proc	ess Validation batches has been man	afactured and validated	l in full complia	ance with cGMP requirement.		
Batch No.		A.R.No. of Finished Product				
	1.1		2			
				A		
		~COS	<u> </u>			
17.0 RE	PORT POST APPROVAL:					
	HEAD – PRODUCTION	HEAD – QC		HEAD – QA		
SIGN & DATE		alidat	Yojj			



QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets BMR No.: XXX/PRO/BMR/ZZ-00

Protocol No.: XXX/BBB/PVR/ZZ-00 Page No.: 73 of 73

18.0 ABBREVIATIONS

QA : Quality Assurance

QC : Quality Control

OOS : Out of Specification

SOP : Standard Operating Procedure

LOD : Loss on Drying

BMR : Batch Manufacturing Record

MMF : Master Manufacturing Formula

A.R. No. : Analytical Report Number

NLT : Not Less Than

NMT : Not More Than

FBD : Fluid Bed Dryer

RMG : Rapid Mixer Granulator

PVR : Process validation report

ASTM : American Society for Testing and Materials

IRMB : Infra Red Moisture Balance

API : Active Pharmaceutical Ingredient