PROCESS VALIDATION DRAFT TEMPLATES REPORT FOR UN-COATED TABLETS

PRODUCT NAME			
BATCH NO.			
DATE			
REPORT SUPERSEDES NO.	**NIL**		

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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			
Approved By	Head-QA			

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

7.0 REASON FOR VALIDATION:

……

……

8.0 PRODUCT PROFILE:

Name of the product : ……

Label Claim : 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 coloured, circular, biconvex, un-coated tablets having plain surface on both sides.

Storage Condition : Store in cool and dry place. Protect from light.

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						
RMG						
LPD for RMG						
Paste kettle						
Fluid bed dryer						
Multimill						
Bin Blender						
Compression Machine						
De-duster cum Metal Detector						
De-duster cum Metal Detector						

Reviewed by : _____ Date: _____

Validation

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						
Paste kettle						
Fluid bed dryer						
Multimill						
Bin Blender						
Compression Machine						
De-duster cum Metal Detector						
De-duster cum Metal Detector						

Reviewed by : _____ Date: _____

Validation

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						
Paste kettle						
Fluid bed dryer						
Multimill						
Bin Blender						
Compression Machine						
De-duster cum Metal Detector						
De-duster cum Metal Detector						

Reviewed by : _____ Date: _____

Validation

10.0 RAW MATERIALS RATIONALE:

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

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

Reviewed by : _____ Date: _____

Validation

11.0 USAGE OF RAW MATERIAL (ACTIVE):

Active Material	B.No.	A. R. No.	API B.No.	Assay (%)	LOD / Water (%,w/w)
API-1					
Acceptance criteria:				**Limit: NLT 98.0 NMT 102.0**	**Limit:NMT 0.5 % w/w**
API-2					
Acceptance criteria:				**Limit: NLT 98.0 NMT 102.0**	**Limit:NMT 0.5 % w/w**
API-3					
Acceptance criteria:				**Limit: NLT 98.0 NMT 102.0**	**Limit:NMT 0.5 % w/w**

Reviewed by : _____ Date: _____

Validation

12.0 GRANULATION STAGE:

12.1 RESULTS OF DRY MIXING:

DIFFERENT LOCATION SAMPLE:

Sample Location	Draw samples equivalent to between 1-3 unit dose (XX mg to XX mg)	Mixing Uniformity					
		Batch No.		Batch No.		Batch No.	
		LOT I	LOT II	LOT I	LOT II	LOT I	LOT II
T1							
T2							
T3							
M1							
M2							
M3							
B1							
B2							
B3							
B4							
Sampled by/date							

COMPOSITE SAMPLE:

Product Name	
Speed	

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

RESULT OF BULK DENSITY – UNTAPPED / TAPPED

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

Reviewed by : _____ Date: _____

Validation

12.2 RESULTS OF DURING WET GRANULATION:

Operation		RESULTS					
Mixing		Batch No.		Batch No.		Batch No.	
		LOT I	LOT II	LOT I	LOT II	LOT I	LOT II
i) Time of Binder solution addition							
ii) Granulation time at Agitator slow/fast & chopper slow/fast (intermittent) Agitator slow/fast & chopper slow/fast (intermittent)							
iii) Amount of Extra Isopropyl alcohol added							
Ampere reading at end point	Agitator						
	Chopper						
Total Granulation Time							
Checked by							

Reviewed by : _____ Date: _____

Validation

12.3 RESULTS OF DRYING:

BULK SAMPLE (Dried Granules)	
Product	
Time of Sampling	After Drying in FBD

Sample	**Weight required (g)**	**Weight taken (g)**					
		Batch No.		**Batch No.**		**Batch No.**	
		LOT I	**LOT II**	**LOT I**	**LOT II**	**LOT I**	**LOT II**
1	Approx 2 g						
2	Approx 2 g						
3	Approx 2 g						
4	Approx 2 g						
5	Approx 2 g						
6	Approx 2 g						
Sampled By / Date							

RESULT OF LOD OF BULK SAMPLES (Dried Granules)

Sample	**Acceptance criteria**	**Results of LOD in % w/w**					
		Batch No.		**Batch No.**		**Batch No.**	
		LOT I	**LOT II**	**LOT I**	**LOT II**	**LOT I**	**LOT II**
1	**Limit:** Till desired LOD achieved 3.0 % - 4.0 % w/w						
2							
3							
4							
5							
6							
Done by / Date							

Reviewed by : _____ Date: _____

Validation

12.4 RESULTS OF SIFTED/MILLED GRANULES:

Product	
Direction of the knives	
Speed	

Weight required (g)	**Weight taken (g)**					
	Batch No.		**Batch No.**		**Batch No.**	
	LOT I	**LOT II**	**LOT I**	**LOT II**	**LOT I**	**LOT II**
50 g						
Sampled By/Date						

RESULT OF SIEVE ANALYSIS (Sifted/Milled Granules)

Acceptance Criteria	**Sieve Size**	**Micrometer**	**% w/w Retention**					
			Batch No.		**Batch No.**		**Batch No.**	
			LOT I	**LOT II**	**LOT I**	**LOT II**	**LOT I**	**LOT II**
For record	20#	850 µ						
	40#	425 µ						
	60#	250 µ						
	80#	180 µ						
	100#	150 µ						
----	**% w/w Passed Through**							
For record	100 #	150 µ						

Reviewed by : _____ Date: _____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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RESULT OF BULK DENSITY AND LOD (Sifted/Milled Granules)

Batch No.	LOT	Tapped Bulk Density	Untapped Bulk Density	LOD	Checked By
	I				
	II				
	I				
	II				
	I				
	II				
To record				**3.0 % - 4.0 % w/w**	-----

Reviewed by: _____ Date:_____

Validation

PERCENTAGE BATCH YIELD AT THE END OF SIFTING/MILLING:

Batch no.	%Yield	Limit*
		NLT 99.5 %

* Yield Limit is tentative and will be finalized after 10 or more production batches.

Reviewed by: _____ Date:_____

Validation

12.5 RESULTS OF LUBRICATION:

BLEND UNIFORMITY – PRE LUBRICATION

Product Name	
Speed	

Sample Location↓	**Weight taken (in g) for the time interval (in minutes)**		
	B. No.	**B. No.**	**B. No.**
	10 min	**10 min**	**10 min**
T1			
T2			
T3			
T4			
M1			
M2			
M3			
M4			
B1			
B2			
Sampled by/date			

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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RESULT FOR BLEND UNIFORMITY – PRE-LUBRICATION

Blend Uniformity	**% Blend uniformity**		
	Batch No.	**Batch No.**	**Batch No.**
	10 min	**10 min**	**10 min**
T1			
T2			
T3			
T4			
M1			
M2			
M3			
M4			
B1			
B2			
Mean			
Minimum			
Maximum			
%RSD			
Checked By/ Date			
Acceptance criteria: Average: 85.0-115.0% and % RSD: NMT 6.0%			

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET	
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BLEND UNIFORMITY – LUBRICATION

Product Name	
Speed	

Sample Location↓	**Weight taken (in g) for the time interval (in minutes)**		
	B. No.	**B. No.**	**B. No.**
	3 min	**3 min**	**3 min**
T1			
T2			
T3			
T4			
M1			
M2			
M3			
M4			
B1			
B2			
Sampled by/date			

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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RESULT FOR BLEND UNIFORMITY – LUBRICATION

Blend Uniformity	**% Blend uniformity**		
	Batch No.	**Batch No.**	**Batch No.**
	3 min	**3 min**	**3 min**
T1			
T2			
T3			
T4			
M1			
M2			
M3			
M4			
B1			
B2			
Mean			
Minimum			
Maximum			
%RSD			
Checked By/ Date			
Acceptance criteria: Average: 85.0-115.0% and % RSD: NMT 6.0%			

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET	
Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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COMPOSITE SAMPLE (Lubricated Granules)

Product Name	
Speed	

Sample.	Weight required (g)	Weight taken (g)		
		Batch No.	Batch No.	Batch No.
Composite	50 g			
Sampled By / Date				

RESULT OF APPEARNCE, ASSAY, BULK DENSITY – UNTAPPED / TAPPED AND LOD (Lubricated Granules)

Batch No.	Appearance	Assay			Untapped Bulk Density	Tapped Bulk Density	LOD (Determined on 2 gm of sample at 105° C)	Checked By/Date
		API-1	API-2	API-3				
Acceptance Criteria	Light Yellow coloured	95.0 – 105 %	95.0 – 110 %	95.0 – 110 %	For record		3.0 % - 4.0 % w/w	------

RESULT OF SIEVE ANALYSIS (Lubricated Granules)

Acceptance Criteria	Sieve Analysis	Micrometer	Particle Size Distribution (% w / w Retention)		
			B. No.	B. No.	B. No.
For record	20#	850µ			
	40#	425µ			
	60#	250µ			
	80#	180 µ			
	100#	150µ			
----	---	---	% w / w passed through		
For record	100 #	150µ			
Checked By/ Date					

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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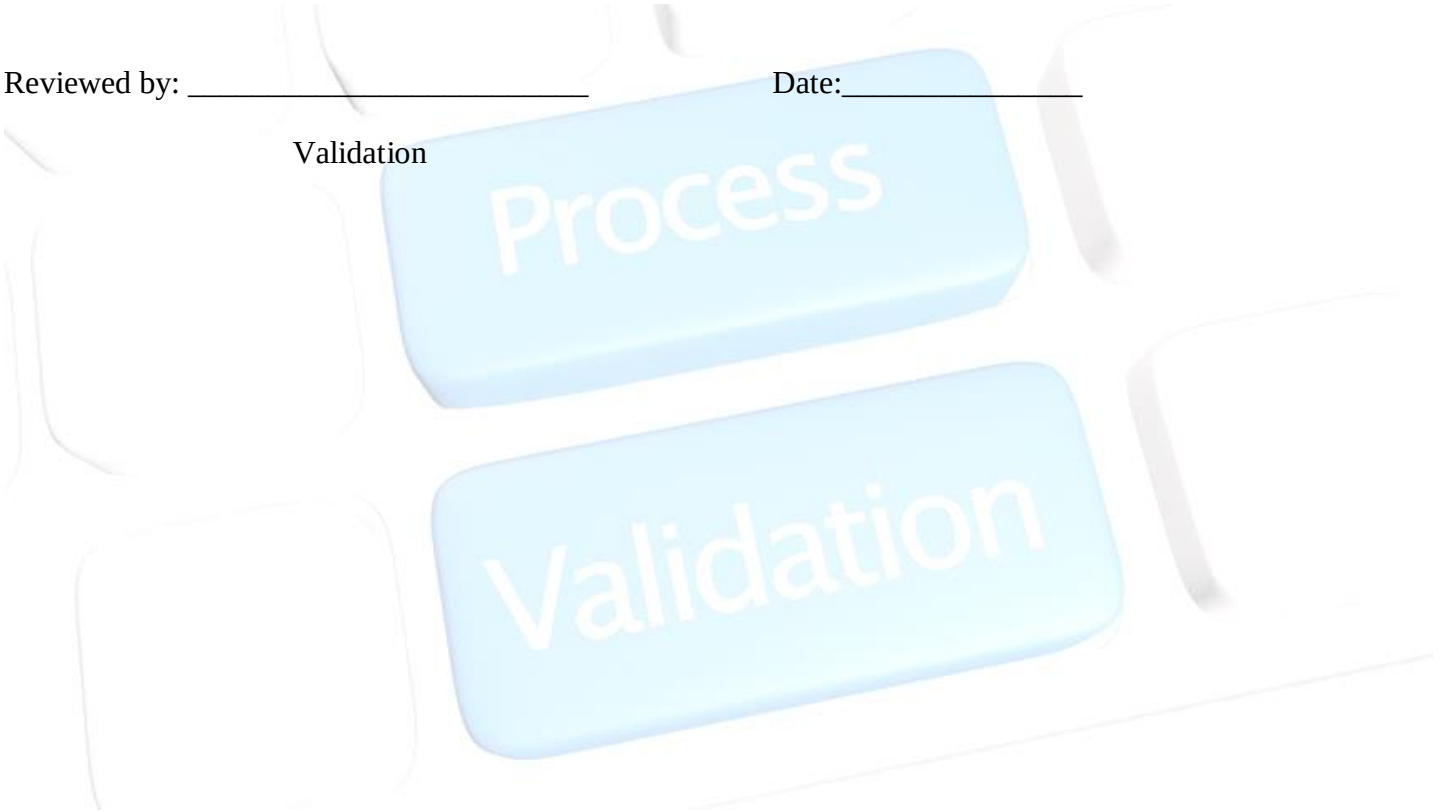
PERCENTAGE YIELD AT THE END OF LUBRICATION:

Batch No.	%Yield	Limit*
		NLT 99.5 %

* Yield Limit is tentative and will be finalized after 10 or more production batches.

Reviewed by: _____ Date:_____

Validation



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

Reviewed by: ___________________________ Date:________________

Validation

13.0 COMPRESSION STAGE:

13.1 SAMPLES DURING COMPRESSION CYCLE

Product	
Time of Sampling	Compression Run

Sample Details	**Batch No.**		**Batch No.**		**Batch No.**	
	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						
Initial run / Full Hopper at optimum speed						
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.

Compression Batch No.	**High speed**		**Low speed**		**High Hardness**		**Low Hardness**		**Initial**		**Middle**		**End**	
	Speed	**Force**	**Speed**	**Force**	**Speed**	**Force**	**Speed**	**Force**	**Speed**	**Force**	**Speed**	**Force**	**Speed**	**Force**

Reviewed by: _____ Date:_____

Validation

13.2 INDIVIDUAL IN-PROCESS TEST DATA

Batch Number:			**Stage of Sampling:** Maximum hardness ( ) **LHS**					
Date:	**Target Hardness:**			**Target Thickness:**				
TESTS	**RESULTS**							
APPEARANCE								
AVG WEIGHT (mg)								
GROUP WEIGHT (g)								
HARDNESS(N)							**Mean:**	
THICKNESS (mm)							**Min :**	**Max :**
FRIABILITY (% w/w)								
D.T. (min)								

Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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Batch Number:			**Stage of Sampling:** Maximum hardness ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

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Where,

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X = mean for weight

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Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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Batch Number:			**Stage of Sampling:** Minimum hardness ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

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CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

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LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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Batch Number:			**Stage of Sampling:** Minimum hardness ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

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X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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Batch Number:				**Stage of Sampling:** Maximum speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

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X = mean for weight

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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 Number:				**Stage of Sampling:** Maximum speed ( ) **RHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

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CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

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X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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Batch Number:				**Stage of Sampling:** Minimum speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

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X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

PROCESS VALIDATION REPORT OF UN-COATED TABLET

Batch Size: 1000000 Tablets	**BMR No.:** XXX/PRO/BMR/ZZ-00
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Batch Number:					**Stage of Sampling:** Minimum speed ( ) **RHS**				
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**		**API-3**				
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 32 of 73

Batch Number:			**Stage of Sampling:** Initial stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 33 of 73

Batch Number:			**Stage of Sampling:** Initial stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter	→ **LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value	→							

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 34 of 73

Batch Number:			**Stage of Sampling:** Middle stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter	→ **LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value	→							

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 35 of 73

Batch Number:			**Stage of Sampling:** Middle stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 36 of 73

Batch Number:			**Stage of Sampling:** End stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 37 of 73

Batch Number:			**Stage of Sampling:** End stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter	→	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value	→								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

13.3 INDIVIDUAL IN-PROCESS TEST DATA

Batch Number:			**Stage of Sampling:** Maximum hardness ( ) **LHS**					
Date:	**Target Hardness:**			**Target Thickness:**				
TESTS	**RESULTS**							
APPEARANCE								
AVG WEIGHT (mg)								
GROUP WEIGHT (g)								
HARDNESS(N)							**Mean:**	
THICKNESS (mm)							**Min :**	**Max :**
FRIABILITY (% w/w)								
D.T. (min)								

Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 39 of 73

Batch Number:			**Stage of Sampling:** Maximum hardness ( ) **RHS**						
Date:	**Target Hardness:**					**Target Thickness:**			
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 40 of 73

Batch Number:			**Stage of Sampling:** Minimum hardness ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 41 of 73

Batch Number:			**Stage of Sampling:** Minimum hardness ( ) **RHS**					
Date:	**Target Hardness:**			**Target Thickness:**				
TESTS	**RESULTS**							
APPEARANCE								
AVG WEIGHT (mg)								
GROUP WEIGHT (g)								
HARDNESS(N)							**Mean:**	
THICKNESS (mm)							**Min :**	**Max :**
FRIABILITY (% w/w)								
D.T. (min)								
Uniformity of Weight (mg)								

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 42 of 73

Batch Number:				**Stage of Sampling:** Maximum speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 43 of 73

Batch Number:				**Stage of Sampling:** Maximum speed ( ) **RHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 44 of 73

Batch Number:				**Stage of Sampling:** Minimum speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 45 of 73

Batch Number:				**Stage of Sampling:** Minimum speed ( ) **RHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 46 of 73

Batch Number:			**Stage of Sampling:** Initial stage/ Full Hopper at Optimum Speed ( ) **LHS**					
Date:	**Target Hardness:**			**Target Thickness:**				
TESTS	**RESULTS**							
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**		**API-3**			

Uniformity of Weight (mg)									

Capability Index

Parameter	→ **LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value	→							

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 47 of 73

Batch Number:			**Stage of Sampling:** Initial stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 48 of 73

Batch Number:			**Stage of Sampling:** Middle stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 49 of 73

Batch Number:			**Stage of Sampling:** Middle stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 50 of 73

Batch Number:			**Stage of Sampling:** End stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 51 of 73

Batch Number:			**Stage of Sampling:** End stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 52 of 73

13.4 INDIVIDUAL IN-PROCESS TEST DATA

Batch Number:				**Stage of Sampling:** Maximum hardness ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**					
TESTS	**RESULTS**									
APPEARANCE										
AVG WEIGHT (mg)										
GROUP WEIGHT (g)										
HARDNESS(N)							**Mean:**			
THICKNESS (mm)							**Min :**	**Max :**		
FRIABILITY (% w/w)										
D.T. (min)										
Uniformity of Weight (mg)										

Capability Index

Parameter	→ **LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value	→							

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 53 of 73

Batch Number:			**Stage of Sampling:** Maximum hardness ( ) **RHS**						
Date:	**Target Hardness:**					**Target Thickness:**			
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 54 of 73

Batch Number:			**Stage of Sampling:** Minimum hardness ( ) **LHS**						
Date:	**Target Hardness:**					**Target Thickness:**			
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 55 of 73

Batch Number:			**Stage of Sampling:** Minimum hardness ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
APPEARANCE									
AVG WEIGHT (mg)									
GROUP WEIGHT (g)									
HARDNESS(N)							**Mean:**		
THICKNESS (mm)							**Min :**	**Max :**	
FRIABILITY (% w/w)									
D.T. (min)									
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 56 of 73

Batch Number:				**Stage of Sampling:** Maximum speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 57 of 73

Batch Number:				**Stage of Sampling:** Maximum speed ( ) **RHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 58 of 73

Batch Number:				**Stage of Sampling:** Minimum speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 59 of 73

Batch Number:				**Stage of Sampling:** Minimum speed ( ) **RHS**					
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 60 of 73

Batch Number:			**Stage of Sampling:** Initial stage/ Full Hopper at Optimum Speed ( ) **LHS**					
Date:	**Target Hardness:**				**Target Thickness:**			
TESTS	**RESULTS**							
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**		**API-3**			
Uniformity of Weight (mg)								

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 61 of 73

Batch Number:			**Stage of Sampling:** Initial stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 62 of 73

Batch Number:			**Stage of Sampling:** Middle stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 63 of 73

Batch Number:			**Stage of Sampling:** Middle stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 64 of 73

Batch Number:			**Stage of Sampling:** End stage/ Full Hopper at Optimum Speed ( ) **LHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

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.:** 65 of 73

Batch Number:			**Stage of Sampling:** End stage/ Full Hopper at Optimum Speed ( ) **RHS**						
Date:	**Target Hardness:**				**Target Thickness:**				
TESTS	**RESULTS**								
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**			**API-3**		
Uniformity of Weight (mg)									

Capability Index

Parameter →	**LSL**	**USL**	**X**	**S**	**Cp**	**CpU**	**CpL**	**CpK**
Value →								

The capability index to be calculated for weight sample using following formula:

$$Cp = \frac{USL - LSL}{6s} \qquad CpU = \frac{USL - X}{3s} \qquad CpL = \frac{X - LSL}{3s}$$

CpK = min (CpU, CpL) (smallest of the values for CpU and CpL)

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____ Date:_____

Validation

13.5 FINISHED PRODUCT ANALYSIS REPORT:

S. No.	Tests	Specification	Results (Batch Nos.)		
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 %			
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**				
	API-1 [By Titrymetry] ─ mg/tablet	NLT 85.5 to NMT 99.0			
	─% of label claim	NLT 95.0 to NMT 110.0			
	API-2 [By Titrymetry] ─ mg/tablet	NLT 85.5 to NMT 99.0			
	─% of label claim	NLT 95.0 to NMT 110.0			
	API-3 [By Titrymetry] ─ mg/tablet	NLT 85.5 to NMT 99.0			
	─% of label claim	NLT 95.0 to NMT 110.0			

YIELD DETAILS AT THE END OF COMPRESSION:

Batch No.	%Yield	Limit*
		NLT 99.0%

* Yield Limit is tentative and will be finalized after 10 or more production batches.

Reviewed by: _____ Date:_____

Validation

EVALUATION:

Reviewed by: ____________________________ Date:_________________

Validation

14.0 DESTRUCTION OF REMAINING VALIDATION SAMPLES:

All remaining samples of the batch are destroyed as per SOP No. ----------

Batch No.:	Destruction done by / Date	Checked by / Date

Reviewed by: _____ Date:_____

Validation

15.0 VALIDATION SUMMERY:

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.:** 71 of 73

Reviewed by: _____ Date:_____

Validation

16.0 CONCLUSION:

Product Batch Nos.:_____, _____and _____ manufactured in the facility as the validation batch meet the specification of tablets. The process of manufacturing was carried as per the approved Batch Manufacturing records and process of Manufacturing is validated.

The all process Validation batches has been manufactured and validated in full compliance with cGMP requirement.

Batch No.	A.R.No. of Finished Product

17.0 REPORT POST APPROVAL:

	HEAD – PRODUCTION	HEAD – QC	HEAD – QA
SIGN & DATE			

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