



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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**PROCESS VALIDATION
DRAFT TEMPLATES
REPORT
FOR
COATED TABLETS**

PRODUCT NAME			
BATCH NO.			
DATE			
REPORT SUPERSEDES NO.	NIL		



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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			



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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



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7.0 REASON FOR VALIDATION:

.....
.....

8.0 PRODUCT PROFILE:

Name of the product :

Label Claim : Each enteric 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, enteric coated tablets having plain surface on both sides.

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



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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						
RMG						
LPD for RMG						
Paste kettle						
Fluid bed dryer						
Multimill						
Bin Blender						
Compression Machine						
De-duster cum Metal Detector						
De-duster cum Metal Detector						
Autocoater						
Colloid mill						
Vibrosifter						
Stirrer						
Tablet Inspection Belt						

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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						
Autocoater						
Colloid mill						
Vibrosifter						
Stirrer						
Tablet Inspection Belt						

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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						
Autocoater						
Colloid mill						
Vibrosifter						
Stirrer						
Tablet Inspection Belt						

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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					
Polacrillin potassium					
Magnesium Stearate					
Hydroxypropyl Methylcellulose (5 cps)					
Diethyl phthalate					
Isopropyl alcohol					
Dichloromethane					
Methacrylic acid copolymer Type A					
Isopropyl alcohol					
Acetone					
Talc					
Titanium dioxide					
Magnesium Stearate					
Sunset yellow Supra					
Purified water					
Diethyl phthalate					
Isopropyl alcohol					

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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: _____

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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							



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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



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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



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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



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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



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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: _____

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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: _____
Validation

Date: _____



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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: _____

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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: _____
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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 APPEARANCE, 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: _____

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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.

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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

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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.

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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:

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

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.

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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:

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

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.

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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
 - LSL = lower specification limit for weight
 - X = mean for weight
 - s = Standard deviation.

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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:

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

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 29 of 80

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



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 30 of 80

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: _____
Validation

Date: _____



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 31 of 80

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



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 32 of 80

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



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 33 of 80

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: _____
Validation

Date: _____



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 34 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 35 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 36 of 80

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



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 37 of 80

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



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 38 of 80

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: _____

Validation

Date: _____



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 39 of 80

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:

$$C_p = \frac{USL - LSL}{6s} \qquad C_{pU} = \frac{USL - X}{3s} \qquad C_{pL} = \frac{X - LSL}{3s}$$

$C_{pK} = \min(C_{pU}, C_{pL})$ (smallest of the values for C_{pU} and C_{pL})

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 40 of 80

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:

$$C_p = \frac{USL - LSL}{6s} \qquad C_{pU} = \frac{USL - X}{3s} \qquad C_{pL} = \frac{X - LSL}{3s}$$

$C_{pK} = \min(C_{pU}, C_{pL})$ (smallest of the values for C_{pU} and C_{pL})

Where,

USL = upper specification limit for weight

LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 41 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 42 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 43 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 44 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 45 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 46 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 47 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 48 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 49 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 50 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 51 of 80

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 COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 52 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 53 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 54 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 55 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 56 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 57 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 58 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 59 of 80

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



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QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 60 of 80

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: _____
Validation

Date: _____



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 61 of 80

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,

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LSL = lower specification limit for weight

X = mean for weight

s = Standard deviation.

Reviewed by: _____
Validation

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PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 62 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 63 of 80

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:

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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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 64 of 80

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



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 65 of 80

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: _____
Validation

Date: _____



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

Page No.: 66 of 80

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 Titrimetry] – mg/tablet –% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0			
	API-2 [By Titrimetry] – mg/tablet –% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0			
	API-3 [By Titrimetry] – 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%

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

Reviewed by: _____

Date: _____

Validation



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

Page No.: 68 of 80

14.0 COATING STAGE:

14.1 COATING PARAMETERS:

14.1.1 SEAL COATING PARAMETERS:

Parameters	Specified	Observation		
		Batch No.:	Batch No.:	Batch No.:
Inlet Temperature	40 °C to 50 °C			
Outlet Temperature	35 °C to 40 °C			
Pan Speed	_____			
Peristaltic pump Speed	_____			
Spray rate	_____			
Bed temperature	35°C to 40 °C			
No of spray guns	_____			
Diameter of the nozzle of spray gun	_____			
Atomizing pressure	_____			
Distance between guns and tablet bed	_____			

Reviewed by: _____

Date: _____

Validation

14.1.2 ENTERIC COATING PARAMETERS

Parameters	Specified	Observation		
		Batch No.:	Batch No.:	Batch No.:
Inlet Temperature	35 °C to 45 °C			
Outlet Temperature	30 °C to 35 °C			
Pan Speed	_____			
Peristaltic pump Speed	_____			
Spray rate	_____			
Bed temperature	30°C to 35 °C			
No of spray guns	_____			
Diameter of the nozzle of spray gun	_____			
Atomizing pressure	_____			
Distance between guns and tablet bed	_____			

Reviewed by: _____

Date: _____

Validation



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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14.2 RESULTS OF FILM COATED TABLET:

14.2.1 RESULTS FOR COATING CYCLE:

Batch Number :

Stage of Sampling: Completion of Enteric coating

Date :

TESTS	RESULTS								
APPEARANCE									
D.T. (min)									
THICKNESS (mm)								Min:	Max:
Uniformity of weight (mg)							Group wt.	Average wt.	

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: _____
Validation

Date: _____



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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14.2.2 RESULTS FOR COATING CYCLE:

Batch Number :

Stage of Sampling: Completion of Enteric coating

Date :

TESTS	RESULTS								
APPEARANCE									
D.T. (min)									
THICKNESS (mm)								Min:	Max:
Uniformity of weight (mg)							Group wt.	Average wt.	

Capability Index

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

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

$$Cp = \frac{USL - LSL}{6s}$$

$$CpU = \frac{USL - X}{3s}$$

$$CpL = \frac{X - LSL}{3s}$$

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: _____

Validation

Date: _____



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets	BMR No. : XXX/PRO/BMR/ZZ-00
Report No.: XXX/BBB/PPV/ZZ-00	Page No.: 71 of 80

14.2.3 RESULTS FOR COATING CYCLE:

Batch Number :	Stage of Sampling: Completion of Enteric coating
-----------------------	---

Date :

TESTS	RESULTS								
APPEARANCE									
D.T. (min)									
THICKNESS (mm)								Min:	Max:
Uniformity of weight (mg)							Group wt.	Average wt.	

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: _____
Validation

Date: _____



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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14.3 FINISHED PRODUCT ANALYSIS REPORT:

S. No.	Tests	Specification	Results (Batch Nos.)		
1.0	Description	Reddish orange coloured, circular, biconvex, enteric coated tablets having plain surface on both sides.			
2.0	Identification For API-3 (By UV)	The UV absorption spectrum of the standard and sample preparation should be concordant.			
3.0	Average weight (mg)	451.0 ± 2.5 % (439.73 – 462.28)			
4.0	Uniformity of weight (%)	Not more than 2 of the individual weights deviates from the average weight by more than ± 5% and none deviates by more than ±10%			
5.0	Disintegration Time In 0.1 N Hydrochloric acid In mixed phosphate buffer pH 6.8	Tablets should not disintegrate in 2 hours. Not more than 60 minutes			
6.0	Assay				
	API-1 [By Titrimetry] – mg/tablet –% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0			
	API-2 [By Titrimetry] – mg/tablet –% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0			
	API-3 [By UV] – mg/tablet –% of label claim	NLT 85.5 to NMT 99.0 NLT 95.0 to NMT 110.0			
7.0	Microbial Analysis	As per Specification.			

Reviewed by: _____

Date: _____

Validation



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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14.4 YIELD DETAILS AT THE END OF ENTERIC COATING:

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

14.5 YIELD DETAILS AT THE END OF INSPECTION:

Batch No.	%Yield	Limit*
		NLT 98.5%

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

Reviewed by: _____

Date: _____

Validation



PHARMA DEVILS

QUALITY ASSURANCE

PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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15.0 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



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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17.0 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

18.0 REPORT POST APPROVAL:

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



PROCESS VALIDATION REPORT OF COATED TABLET

Batch Size : 1000000 Tablets

BMR No. : XXX/PRO/BMR/ZZ-00

Report No.: XXX/BBB/PPV/ZZ-00

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19.0 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