 PHARMA DEVILS	**PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER**	**PROTOCOL No.:**

1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved .The protocol cannot be used for execution unless approved by the following authorities.

This performance qualification protocol of Becoater has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			QUALITY CONTROL		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The equipment working capacity is recommended by manufacturer challenged by charging the tablets with the maximum and minimum capacity of the pan.

2.3 SCOPE:

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of Becoater installed in coating area.

Once the performance qualification of Becoater has been completed successfully, the equipment shall be released for the production purposes.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Quality control , Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the performance qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Quality control / Production / Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory operation of the Becoater shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the Becoater is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Becoater. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 PREREQUISITE:

3.1 Approved Standard operating procedure of the equipment shall be available.

3.2 The maximum and minimum capacity of the equipment shall be verified by taking the batch/lot to suit the requirement.

3.3 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.

3.4 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.

3.5 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be revalidated if

- There are any major changes, which affect the performance of the equipment.
- Batch/lot size taken out of the range on which performance is done
- As per revalidation date and schedule

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 METHODOLOGY:

- **Pan Capacity Determination**

  Compressed tablets should be charged into the coating pan, start rotating the coating pan. None of the tablet should be coming out from the coating pan for maximum capacity.

- **Verification of Coating Process**

  Visual Inspection, Verify weight gain of Tablet after coating process.
  Establish coater capacity with Hardware and software to perform without any interruptions and trouble.

- **Purpose**

  The purpose of the coating system is to uniformly coat tablets with coating solution for minimum capacity and for maximum capacity (as per BMR Batch No. ----------) Critical process characteristics are monitored throughout the trials to ensure that coated product produced should have uniform coating & appearance. Tablets should not lose their characteristics during coating process.

- **Processing Steps**: The coating process is divided in the following process steps:

  Preparation of the coating solution.

  The coating solution sufficient for one batch of coating is prepared in a Solution Preparation vessel. The Solution shall be transferred into SS tank manually and connected to the Coating System

- **Coating Process**

- The uncoated Tablets are charged in the Coater. Coating solution is sprayed to coat the Tablets. Inlet air and exhaust system is provided to supply conditioned air and exhaust the solvent rich air.

- **Test Method**

Set process parameters for Coating System as determined in PQ BMR Parameters defined shall be appropriate to have airflow for uniform atomization.
Coating shall be done on caplet, oval and round shape tablets for minimum and maximum capacity verification for each shape.
Charge uncoated Tablets & prepare coating solution as per PQ BMR recipe and set process parameters, which includes a heating, a spraying and a cooling phase sequence.
Start the Coating System with the specified recipe.

Check the coating of the product bed visually every 15 minutes through sight glass.

On completion of the coating process discharge the coated tablets.

Record the test data and any observations throughout the process in the PQ BMR as well as PQ report

Samples of tablets are taken and tested as follows:

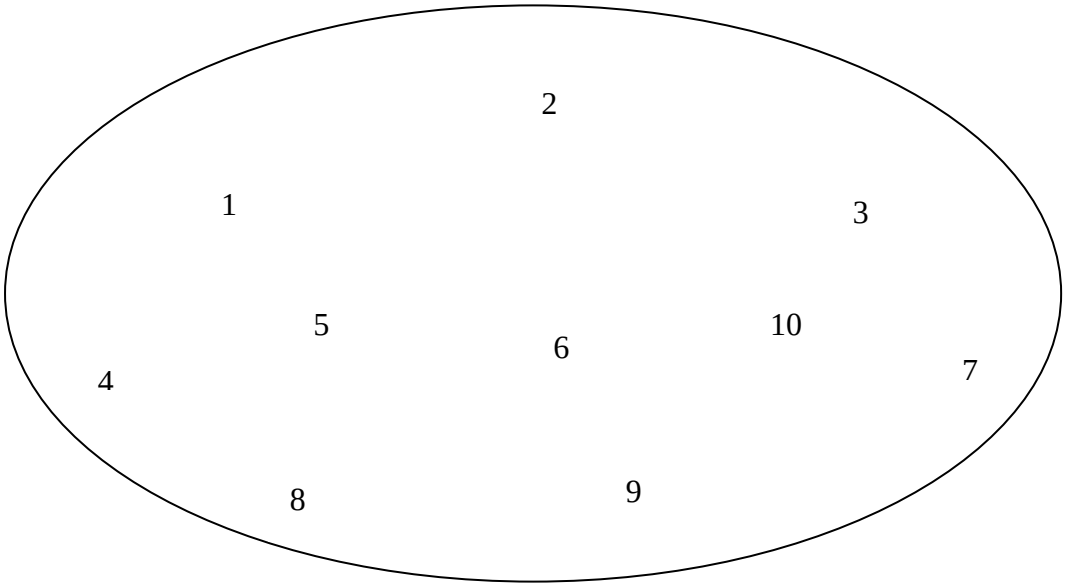
20 tablet composite from ten sampling locations to be collect and individually uniformity of weight to be performed to identify potential areas of poor coating. Samples are analyzed, according to applicable testing procedure for appearance and weight gain.

Test for Appearance, Weight Variation, Disintegration time & Thickness to be performed and note down in column provided.

One PQ batch must be tested as described before, in order to demonstrate consistent performance.

The different shaped tablet (Such as round shape, capsule, oval shape) used for coating pan verification and also minimum and maximum capacity to be verify taking the compressed tablet and process follows as per mentioned in PQ BMR.

Sampling Location Diagram of Auto Coater:



6.0 ACCEPTANCE CRITERIA:

6.1 Tablets should have uniform appearance as seen visibly.

6.2 **Weight Gain**

20 tablets shall be weighed from 10 different locations. The weight gain should not be less than 1.5 %. Results of weight of 20 tablets, disintegration time and thickness should be within the limit.

6.3 All hardware and software components shall perform without problems and interruptions while processing the complete batch for capacities as agreed with the equipment supplier

6.4 Appearance, Weight Variation, Thickness, should be with in limit as specified in PQ BMR.

7.0 MATERIAL REQUIRED FOR COATING:

- Raw Materials (Tablets) in sufficient quantity as per BMR Batch No. ----------
- Coating liquid in sufficient quantity
- Sample containers or sample bags.
- IPC

8.0 VALIDATION MATRIX

Pan size:
60" / 1525 mm (± 10 mm)

Pan working capacity:
Min. – 200 kg & Max. – 350 kg

Sr. No.	Shape of core tablets used for coating	Batch no to be taken	Wt. of core tablet taken for coating	Observed Avg. wt. Of core tablets	Checked by Sign& Date
1.	Round shape tablet for minimum capacity				
2.	Round shape tablet for maximum capacity				
3.	Capsule shape tablet for minimum capacity				
4.	Capsule shape tablet for maximum capacity				
5.	Oval shape tablet for minimum capacity				
6.	Oval shape tablet for maximum capacity				

9.0 In process specification for round oval and capsule shape tablet

INPROCESS SPECIFICATION

Sr. No.	Parameter	Specification for Round shape	Specification for Capsule shape	Specification for Oval shape
1	Appearance	Circular biconvex film coated tablets having plain surface on both sides.	Capsule shaped biconvex film coated tablets having plain surface on both sides.	Oval, biconvex film coated tablets having plain on both sides.
2	Weight of 20 tablets	7.18 g ± 2.5% (7.001 g – 7.360 g)	13.872 g ± 2.5% (13.526 – 14.219 g)	5.42 g ± 2.5% (5.285 g – 5.556 g)
3	Thickness	4.20 ± 0.30 mm (3.90 mm – 4.50 mm)	4.70 ± 0.20 mm (4.50 mm – 4.90 mm)	4.20 ± 0.20 mm (4.00 mm – 4.40 mm)
4	Disintegration time	NMT 30 Minutes	NMT 30 Minutes	NMT 30 Minutes
5	Uniformity of Weight	359.0 mg ± 5% (341.05 mg – 376.95 mg)	693.6 mg ± 5% (658.92 mg – 728.28 mg)	271.0 mg ± 5% (257.45 mg – 284.55 mg)
6	Average Weight	359.0 mg ± 2.5% (350.03 mg – 367.98 mg)	693.6 mg ± 2.5% (676.26 mg – 710.94 mg)	264.23 mg ± 2.5% (257.45 mg – 277.78 mg)

10.0 VERIFICATION OF COATING INPROCESS PARAMETERS

10.1 Coating parameter for round shape for maximum batch size.

S. No	Parameter	Specification	Actual Observation	Checked By Sign
1.	Pan load (60")	Approx. 350 kg		
2.	Inlet Temperature	55 ± 5 ^{O}C		
3.	Exhaust Temperature	40 ± 5 ^{O}C		
4.	Pan RPM	____± ____		
5.	Spray rate	____ ± ____ g / minute / gun		
6.	Bed temperature	40 ± 4^{O}C		
7.	No of spray guns	06		
8.	Diameter of the nozzle of spray gun	1.0 mm		
9.	Distance between tablet bed & nozzle	___		

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (Production)										
Date	**Appearance**	Weight of 20 Tablets 7.18 g ± 2.5% (7.001 g – 7.359 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.30 mm (3.90 mm – 4.50 mm)					**Checked by**

Uniformity of weight coated tablets 359.0 mg ± 5% (341.05 mg – 376.95 mg) – By production									
Date:			**Time:**						
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**			**Average Weight in mg:**			
Checked by:									

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (QA)											
Date	**Appearance**	Weight of 20 Tablets 7.18 g ± 2.5% (7.001 g – 7.359 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.30 mm (3.90 mm – 4.50 mm)					**Checked by**

Uniformity of weight for coated tablets to be performed from different locations

Location - I

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - II

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - III

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - IV

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - V

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

Location - VI

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - VII

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - VIII

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - IX

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - X

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

RESULTS OF MAXIMUM ROUND SHAPE:

Tests	Acceptance Criteria	Observation	Checked By Sign/Date
Pan capacity Determination	According to the capacity as specified by supplier		
Visual Inspection Sample 20 tablets at each sampling location.	Uniform in appearance		
Verify weight gain of Tablet after coating. Composite 20 tab let Sample 10 location	The average wt. gain should not be less than 1.5%.		
Establish coater capacity with Hardware and software to perform without any interruptions and trouble.	Hardware and software to perform without any interruptions and trouble.		
Physical & chemical characteristics	Weight Variation, Thickness, Friability, Hardness, and disintegration should be within limits specified in PQ BMR.		

Remark :

Checked By (Sign/Date)

10.2 Coating parameter for round shape for minimum batch size.

S. No	Parameter	Specification	Actual Observation	Checked By Sign
1.	Pan load (60”)	Approx. 200 kg		
2.	Inlet Temperature	55 ± 5 ^{O}C		
3.	Exhaust Temperature	40 ± 5 ^{O}C		
4.	Pan RPM	____± ____		
5.	Spray rate	____ ± ____ g / minute / gun		
6.	Bed temperature	40 ± 4^{O}C		
7.	No of spray guns	06		
8.	Diameter of the nozzle of spray gun	1.0 mm		
9.	Distance between tablet bed & nozzle	___		

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (Production)										
Date	**Appearance**	Weight of 20 Tablets 7.18 g ± 2.5% (7.001 g – 7.359 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.30 mm (3.90 mm – 4.50 mm)					**Checked by**

Uniformity of weight coated tablets 359.0 mg ± 5% (341.05 mg – 376.95 mg) – By production									
Date:			**Time:**						
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**			**Average Weight in mg:**			
Checked by:									

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (QA)										
Date	**Appearance**	Weight of 20 Tablets 7.18 g ± 2.5% (7.001 g – 7.359 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.30 mm (3.90 mm – 4.50 mm)					**Checked by**

Uniformity of weight for coated tablets to be performed from different locations

Location - I

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - II

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - III

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - IV

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - V

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

Location - VI

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - VII

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - VIII

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - IX

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - X

Uniformity of weight coated tablets 359.0 mg ± 5%(341.05 mg – 376.95 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

RESULTS OF MINIMUM ROUND SHAPE:

Tests	Acceptance Criteria	Observation	Checked By Sign/Date
Pan capacity Determination	According to the capacity as specified by supplier		
Visual Inspection Sample 20 tablets at each sampling location.	Uniform in appearance		
Verify weight gain of Tablet after coating. Composite 20 tab let Sample 10 location	The average wt. gain should not be less than 1.5%.		
Establish coater capacity with Hardware and software to perform without any interruptions and trouble.	Hardware and software to perform without any interruptions and trouble.		
Physical & chemical characteristics	Weight Variation, Thickness, Friability, Hardness, and disintegration should be within limits specified in PQ BMR.		

Remark :

Checked By (Sign/Date)

10.3 Coating parameter for oval shape for Maximum batch size.

S. No	Parameter	Specification	Actual Observation	Checked By Sign
1.	Pan load (60”)	Approx. 350 kg		
2.	Inlet Temperature	55 ± 5 ^{O}C		
3.	Exhaust Temperature	40 ± 5 ^{O}C		
4.	Pan RPM	____± ____		
5.	Spray rate	____ ± ____ g / minute / gun		
6.	Bed temperature	40 ± 4^{O}C		
7.	No of spray guns	06		
8.	Diameter of the nozzle of spray gun	1.0 mm		
9.	Distance between tablet bed & nozzle	___		

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (Production)										
Date	**Appearance**	Weight of 20 Tablets 5.42 g ± 2.5% (5.285 g – 5.555 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.20 mm (4.00 mm – 4.40 mm)					**Checked by**

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By production									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				
Checked by:									

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (QA)											
Date	**Appearance**	Weight of 20 Tablets 5.42 g ± 2.5% (5.285 g – 5.555 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.20 mm (4.00 mm – 4.40 mm)					**Checked by**

Uniformity of weight for coated tablets to be performed from different locations

Location - I

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - II

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - III

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	

Min:	Max:	Average Weight in mg:	Checked by:

Location - IV

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - V

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - VI

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - VII

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - VIII

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - IX

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - X

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

RESULTS OF MAXIMUM OVAL SHAPE:

Tests	Acceptance Criteria	Observation	Checked By Sign/Date
Pan capacity Determination	According to the capacity as specified by supplier		
Visual Inspection Sample 20 tablets at each sampling location.	Uniform in appearance		
Verify weight gain of Tablet after coating. Composite 20 tab let Sample 10 location	The average wt. gain should not be less than 1.5%.		
Establish coater capacity with Hardware and software to perform without any interruptions and trouble.	Hardware and software to perform without any interruptions and trouble.		
Physical & chemical characteristics	Weight Variation, Thickness, Friability, Hardness, and disintegration should be within limits specified in PQ BMR.		

Remark :

Checked By (Sign/Date)

10.4 Coating parameter for oval shape for Minimum batch size.

S.No	Parameter	Specification	Actual Observation	Checked By Sign
1.	Pan load (60”)	Approx. 200 kg		
2.	Inlet Temperature	55 ± 5 ^{O}C		
3.	Exhaust Temperature	40 ± 5 ^{O}C		
4.	Pan RPM	____± ____		
5.	Spray rate	____ ± ____ g / minute / gun		
6.	Bed temperature	40 ± 4^{O}C		
7.	No of spray guns	06		
8.	Diameter of the nozzle of spray gun	1.0 mm		
9.	Distance between tablet bed & nozzle	___		

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (Production)										
Date	**Appearance**	Weight of 20 Tablets 5.42 g ± 2.5% (5.285 g – 5.555 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.20 mm (4.00 mm – 4.40 mm)					**Checked by**

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By production									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				
Checked by:									

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (QA)											
Date	**Appearance**	Weight of 20 Tablets 5.42 g ± 2.5% (5.285 g – 5.555 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.20 ± 0.20 mm (4.00 mm – 4.40 mm)					**Checked by**

Uniformity of weight for coated tablets to be performed from different locations

Location - I

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - II

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - III

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	

Min:	Max:	Average Weight in mg:	Checked by:

Location - IV

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - V

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - VI

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - VII

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - VIII

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - IX

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - X

Uniformity of weight coated tablets 271.0 mg ± 5%(257.45 mg – 284.55 mg) – By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

RESULTS OF MINIMUM OVAL SHAPE:

Tests	Acceptance Criteria	Observation	Checked By Sign/Date
Pan capacity Determination	According to the capacity as specified by supplier		
Visual Inspection Sample 20 tablets at each sampling location.	Uniform in appearance		
Verify weight gain of Tablet after coating. Composite 20 tab let Sample 10 location	The average wt. gain should not be less than 1.5%.		
Establish coater capacity with Hardware and software to perform without any interruptions and trouble.	Hardware and software to perform without any interruptions and trouble.		
Physical & chemical characteristics	Weight Variation, Thickness, Friability, Hardness, and disintegration should be within limits specified in PQ BMR.		

Remark :

Checked By (Sign/Date)

10.5 Coating parameter for capsule shape for Maximum batch size.

S.No.	Parameter	Specification	Actual Observation	Checked By Sign
1.	Pan load (60")	Approx. 350 kg		
2.	Inlet Temperature	55 ± 5 ^{O}C		
3.	Exhaust Temperature	40 ± 5 ^{O}C		
4.	Pan RPM	____± ____		
5.	Spray rate	____ ± ____ g / minute / gun		
6.	Bed temperature	40 ± 4^{O}C		
7.	No of spray guns	06		
8.	Diameter of the nozzle of spray gun	1.0 mm		
9.	Distance between tablet bed & nozzle	___		

Remark:

Reviewed by (Sign/Date)

 PHARMA DEVILS	**PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER**	**PROTOCOL No.:**

INPROCESS CHECKS (Production)										
Date	**Appearance**	Weight of 20 Tablets 13.872 g ± 2.5% (13.526 – 14.218 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.70 ± 0.20 mm (4.50 mm – 4.90 mm)					**Checked by**

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg) – By production									
Date:			**Time:**						
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				
Checked by:									

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (QA)											
Date	**Appearance**	Weight of 20 Tablets 13.872 g ± 2.5% (13.526 – 14.218 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.70 ± 0.20 mm (4.50 mm – 4.90 mm)					**Checked by**

Uniformity of weight for coated tablets to be performed from different locations

Location - I

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - II

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - III

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	

Min:	Max:	Average Weight in mg:	Checked by:

Location - IV

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - V

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - VI

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - VII

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

Location - VIII

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:				Checked by:

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

Location - IX

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - X

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

RESULTS OF MAXIMUM CAPSULE SHAPE:

Tests	Acceptance Criteria	Observation	Checked By Sign/Date
Pan capacity Determination	According to the capacity as specified by supplier		
Visual Inspection Sample 20 tablets at each sampling location.	Uniform in appearance		
Verify weight gain of Tablet after coating. Composite 20 tab let Sample 10 location	The average wt. gain should not be less than 1.5%.		
Establish coater capacity with Hardware and software to perform without any interruptions and trouble.	Hardware and software to perform without any interruptions and trouble.		
Physical & chemical characteristics	Weight Variation, Thickness, Friability, Hardness, and disintegration should be within limits specified in PQ BMR.		

Remark :

Checked By (Sign/Date)

10.6 Coating parameter for capsule shape for minimum batch size.

S.No.	Parameter	Specification	Actual Observation	Checked By Sign
1.	Pan load (60")	Approx. 200 kg		
2.	Inlet Temperature	55 ± 5 ^{O}C		
3.	Exhaust Temperature	40 ± 5 ^{O}C		
4.	Pan RPM	____± ____		
5.	Spray rate	____ ± ____ g / minute / gun		
6.	Bed temperature	40 ± 4^{O}C		
7.	No of spray guns	06		
8.	Diameter of the nozzle of spray gun	1.0 mm		
9.	Distance between tablet bed & nozzle	___		

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (Production)										
Date	**Appearance**	Weight of 20 Tablets 13.872 g ± 2.5% (13.526 – 14.218 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.70 ± 0.20 mm (4.50 mm – 4.90 mm)					**Checked by**

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg) – By production									
Date:			**Time:**						
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				
Checked by:									

Remark:

Reviewed by (Sign/Date)

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

INPROCESS CHECKS (QA)											
Date	**Appearance**	Weight of 20 Tablets 13.872 g ± 2.5% (13.526 – 14.218 g)	**Disintegration Time** Limit: NMT 30 minutes	**Thickness** 4.70 ± 0.20 mm (4.50 mm – 4.90 mm)					**Checked by**

Uniformity of weight for coated tablets to be performed from different locations

Location - I

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - II

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - III

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	

Min:	Max:	Average Weight in mg:	Checked by:

Location - IV

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

Location - V

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				Time:					
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:		Max:		Average Weight in mg:				Checked by:	

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

Location - VI

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - VII

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - VIII

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:				**Time:**					
Tablet weight in mg									
1		**5**		**9**		**13**		**17**	
2		**6**		**10**		**14**		**18**	
3		**7**		**11**		**15**		**19**	
4		**8**		**12**		**16**		**20**	
Min:			**Max:**		**Average Weight in mg:**				**Checked by:**

Location - IX

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:			Time:						
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:			Checked by:	

Location - X

Uniformity of weight coated tablets 693.6 mg ± 5% (658.92 mg – 728.28 mg)– By QA									
Date:			Time:						
Tablet weight in mg									
1		5		9		13		17	
2		6		10		14		18	
3		7		11		15		19	
4		8		12		16		20	
Min:			Max:		Average Weight in mg:			Checked by:	

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL REPORT FOR BECOATER	PROTOCOL No.:

RESULTS OF MINIMUM CAPSULE SHAPE:

Tests	Acceptance Criteria	Observation	Checked By Sign/Date
Pan capacity Determination	According to the capacity as specified by supplier		
Visual Inspection Sample 20 tablets at each sampling location.	Uniform in appearance		
Verify weight gain of Tablet after coating. Composite 20 tab let Sample 10 location	The average wt. gain should not be less than 1.5%.		
Establish coater capacity with Hardware and software to perform without any interruptions and trouble.	Hardware and software to perform without any interruptions and trouble.		
Physical & chemical characteristics	Weight Variation, Thickness, Friability, Hardness, and disintegration should be within limits specified in PQ BMR.		

Remark :

Checked By (Sign/Date)

10.7 Composite assay result of coated tablet

Collect the composite tablet for assay test from each lot of coating and send to QC for analysis.

S.No.	Shape	Quantity of Sample given to QC	Assay result	Remark
I.	Round shape Maximum			
II.	Round shape Minimum			
III.	Oval shape Maximum			
IV.	Oval shape Minimum			
V.	Capsule shape Maximum			
VI.	Capsule shape Minimum			

Remark :

Checked By (Sign/Date)

11.0 DEFFICIENCY AND CORRECTIVE ACTIONS

Following deficiency was verified and corrective actions taken in consultation with the validation team.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

12.0 ANNEXURE (S):

S.No.	Annexure No.	Title of Annexure

Remarks (if any)**:**

Done By & Date: **Verified By & Date:**

13.0 PERFORMANCE QUALIFICATION FINAL REPORT:

13.1 SUMMARY:

13.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

13.3 FINAL REPORT APPROVAL:

It has been verified that all tests required by this report are completed, reconciled and attached to this protocol or included in the performance qualification summary report. All amendments and discrepancies are documented, approved and attached to this protocol. (If applicable)

Signature in the block below indicate that all items in this qualification report of Becoater have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		