Report

For

Performance Qualification (PQ)

of

Dissolution Test Apparatus

Location : Wet Laboratory

Instrument Identification No. : QCD-001

Table of Contents

1.0 Report Preparation, Review and Approval :

1.1 Report Preparation :

Report Preparation of Performance Qualification (PQ) is responsibility of followings ;

Name	Designation	Department	Signature	Date
		Quality Control		
		Engineering		
		Quality Assurance		

1.2 Report Review :

Report Review of Performance Qualification (PQ) is responsibility of followings ;

Name	Designation	Department	Signature	Date
		Quality Control		
		Engineering		
		Quality Assurance		

1.3 Report Approval :

Report Approval of Performance Qualification (PQ) is responsibility of followings ;

Name	Designation	Department	Signature	Date
		Quality Control		
		Engineering		
		Quality Assurance		

2.0 Execution Team :

2.1 Personnel - Quality Control :

2.2 Personnel - Engineering :

2.3 Personnel - Quality Assurance :

3.0 Acceptance Criteria :

3.1 Number of revolutions check (RPM):

Number of revolutions (rpm)	Limits (rpm)
25	24 - 26
50	48 – 52
100	96 – 104
150	144 – 156

3.2 Temperature Check:

The observed temperature in each position of jars should be within ± 0.5 ° C of the set temperature.

3.3 Calibration of timer:

Set time	Tolerance
30 minutes	Between 29 min 24 secs. And 30 min. 36 secs.
60 minutes	Between 58 min 48 secs. And 61 min. 12 secs

3.4 Calibration for wobble check:

The tolerance for wobble is not more than 0.5 mm for paddles and 1 mm for basket.

3.5 Measurement of distance from shaft bottom to jar:

For the distance are 25 mm ± 2 mm

3.6 Distance between the shaft axis and vertical axis of the vessel:

Centring should be ≤ 2 mm

3.7 Head co planarity:

Head plate and the base plate should be perfectly horizontal.

3.8 Integrity check of the basket:

The mesh should be intact.

3.9 USP Calibration using Prednisone Tablets:

Acceptance Criteria: As per PVT current Lot Q0H398

4.0 Qualification / Re-Qualification Criteria :

Qualification / Re-Qualification of the Dissolution Test Apparatus shall be carried out periodically. In case of following, it shall be through the Change Control Procedure.

4.1	New Installation	☐
4.2	Modification or change in major component(s)	☐
4.3	Change in location	☐
4.3	Periodically (No change control required).	☐

5.0 Procedure :

5.1 Number of revolutions per minute check (RPM):

5.1.1 Shaft Rotation Speed :

Set RPM	Observed RPM (Vessel No.)					
	1	2	3	4	5	6
25						
50						
100						
150						

Acceptance Criteria :

For 25 RPM : 24 - 26 RPM
For 50 RPM : 48 - 52 RPM
For 100 RPM : 96-104 RPM
For 150 RPM : 144 - 156 RPM

5.2 Temperature Check:

5.2.1 Temperature of Vessels :

Time (Minutes)	Set Temp.	Observed Temperature (°C)							
		1	2	3	4	5	6	7	8
15	37°C								
30	37°C								
45	37°C								
60	37°C								

Acceptance Criteria :

The observed temperature in each position of vessels shall be in the range of 36.5° C to 37.5° C

5.3 Calibration of timer:

Set Time	30 Minutes	60 Minutes
Observed Time of Stop Watch		

Acceptance Criteria :

For 30 Minutes : 29 Minutes 24 Seconds to 30 Minutes 36 Seconds

For 60 Minutes : 58 Minutes 48 Seconds to 61 Minutes 12 Seconds

5.4 Calibration for wobble check:

5.4.1 Shaft Wobble Check :

a) Record of Wobbling for Paddle apparatus :

Vessel No.	1	2	3	4	5	6
Wobble reading 50 RPM						
Wobble reading 100 RPM						

Acceptance Criteria : Not more than 1.0 mm

b) Record of Wobbling for Basket apparatus :

Vessel No.	1	2	3	4	5	6
Wobble reading 50 RPM						
Wobble reading 100 RPM						

Acceptance Criteria : Not more than 1.0 mm

5.5 Measurement of distance from shaft bottom to jar:

5.5.1 Distance from Bottom of Paddle / Basket to the Bottom of Vessel :

a) Distance from Bottom of Paddle to the Bottom of Vessel :

Vessel No.	1	2	3	4	5	6
Observed reading						

Acceptance Criteria : 25 ± 2 mm

b) Distance from Bottom of Basket to the Bottom of Vessel :

Vessel No.	1	2	3	4	5	6
Observed reading						

Acceptance Criteria : 25 ± 2 mm

5.6 Distance between the shaft axis and vertical axis of the vessel:

5.6.1 Measurement of Distance Between the Shaft axis and Vertical axis of the Vessel :

a) Measurement of Distance Between the shaft axis and Vertical axis of the Vessel : (Basket)

Vessel No.	1	2	3	4	5	6
Observed reading						

Acceptance Criteria : ± 2 mm

b) Measurement of Distance Between the shaft axis and Vertical axis of the Vessel : (Paddle)

Vessel No.	1	2	3	4	5	6
Observed reading						

Acceptance Criteria : ± 2 mm

5.7 Head coplanarity:

5.7.1 Measurement of Head Co-planarity for Paddle and Basket apparatus :

a) Measurement of Head Co-planarity :

	Record results at 2 points that are 90º apart (For Paddle apparatus)			
Shaft Verticality	1.1		1.2	
	2.1		2.2	
	3.1		3.2	
	4.1		4.2	
	5.1		5.2	
	6.1		6.2	

Acceptance Criteria : Not more than 0.5mm

b) Measurement of Head Co-planarity :

	Record results at 2 points that are 90º apart (For Basket apparatus)			
Shaft Verticality	**1.1**		**1.2**	
	2.1		**2.2**	
	3.1		**3.2**	
	4.1		**4.2**	
	5.1		**5.2**	
	6.1		**6.2**	

Acceptance Criteria : Not more than 0.5mm

5.8 Integrity check of the basket:

5.8.1 Sieve Integrity of Basket :

Observation :

Acceptance Criteria: Sieve mesh shall be Intact.

5.9 USP Calibration using Prednisone Tablets:

5.9.1 Calibration using prednisone tablets (Disintegrating type) for type I at 50 RPM.

a. Apparatus : USP Type -_____

b. Duration : _____min.

c. Speed : _____RPM

d. Temperature : _____ºC

e. Dissolution Medium : _____

f. Temperature :

Vessel No.	1	2	3	4	5	6
Initial						
Final						

$$\%\text{Released} = \frac{\text{Abs of sample} \times \text{Wt of std (mg)} \times 5 \times 500 \times 100 \times \text{Potency}}{\text{Abs of standard} \times 250 \times 50 \times 1 \times 10 \times 100}$$

Tablet No.	Absorbance at 242 nm	% Released	GM	% CV
1				
2				
3				
4				
5				
6				

5.9.2 Calibration using Prednisone tablet (Disintegrating type) for apparatus II at 50 RPM

a. Apparatus : USP Type -_____

b. Duration : _____min.

c. Speed :_____RPM

d. Temperature :_____ ^{o}C

e. Dissolution Medium : _____

f. Temperature :

Vessel No.	1	2	3	4	5	6
Initial						
Final						

Absorbance of std. Solution at 242 nm =_____

Tablet No.	Absorbance at 242 nm	% Released	GM	% CV
1				
2				
3				
4				
5				
6				

Calculation for GM and % CV

GM1= exp (average (Lnx_1: Lnx_n)

%CV1 = 100 x sqrt (exp(var(Lnx_1:Lnx_n))-1)

6.0 Document Check - List :

Sr. No.	Description	Attachment No.

7.0 Deficiency and Corrective Action :

7.1 Description of Deficiency and Date of Observation :

7.2 Person responsible for Corrective Action and Date Assigned :

7.3 Corrective Action taken and Date Conducted :

8.0 Final Report :

9.0 Abbreviation :

Describe the abbreviation(s) used in the document.

Abbreviated Form	Full Form
QA	Quality Assurance
QCD	Quality Control Department
ID	Identification

10.0 Certification :

Certificate

This is to certify that the **Dissolution Test Apparatus** installed in **Wet Laboratory (Instrument Identification No. : QCD-001)** of **Quality Control** is qualified for **Performance Qualification**. Hence it is authorized for routine use.

Signature : _____

(Head - Quality Assurance)

Date : _____