



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 1 of 14

**Pharmaceutical Guidelines
Performance Qualification
Equipment: Rapid Mixer Granulator
Equipment ID: PG/MFG/EQ/001
Document No: PG/PQ/001**



Pharmaceutical Guidelines

PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 2 of 14

TABLE OF CONTENTS

Sr. No.	Content	Page No.
1.0	Pre Approval	3
2.0	Purpose	4
3.0	Scope	4
4.0	Reference	4
5.0	Study of Qualification	4
6.0	Responsibility	5
7.0	Documentation	5
8.0	Machine Description	6
9.0	Procedure	6
10.0	Acceptance Criteria	6
11.0	Revalidation Criteria	7
12.0	Procedure	7
13.0	Sampling Procedure	7
13.1	First Run	7
13.2	Second Run	9
13.3	Third Run	11
14.0	Summary of Performance Qualification	12
14.1	Observed Deviation	12
14.2	Recommendations	13
14.3	Conclusion	13
15.0	Post Approval	14



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 3 of 14

1.0 PRE-APPROVAL:

Prepared by	Designation	Signature	Date

Reviewed By	Designation	Signature	Date
HOD Production			
HOD Engineering			
Executive Quality Assurance			
Unit Head			

Approved By	Designation	Signature	Date
HOD Quality Assurance			



Pharmaceutical Guidelines

PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 4 of 14

2.0 PURPOSE: To ensure that the Rapid Mixer Granulator is performing as per the required specifications.

3.0 SCOPE: This protocol is applicable for performance qualification of the Rapid Mixer Granulator. The performance qualification is an essential part of GMP documentation and serves as a base document for the validation activity.

3.1 INTENDED USE: For uniform mixing of powder.

3.2 LOCATION: ABC Pharmaceuticals Ltd. at Location.

4.0 REFERENCE: Operating Instruction Manual for Rapid Mixer Granulator RMG 150.

4.1 ATTACHMENTS: Purchase order and drawing

5.0 STUDIES FOR QUALIFICATION:

Design Qualification: To design, engineer, and supply the Rapid Mixer Granulator RMG 150 as per cGMP and cGEP and to provide assurance that the machine is manufactured as per the URS and it complies with the Scope of Supply.

This is a validation document for the machine, to prove that each operation proceeds as per the design specification prescribed there in the document.

Installation Qualification: To check that machine and accessories are supplied as per purchase order requirement.

To check that the machine is installed at its specified location

To check that the utilities required by the machine is provided

Operational Qualification: To measure the dimension wherever possible.

To ensure that all the instruments if any associated with the machine are calibrated before operational qualification.



Pharmaceutical Guidelines

PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 5 of 14

Performance Qualification: To operate the machine as per proposed procedure.

To challenge the operating parameters associated with the machine.

To challenge the safety features associated with the machine.

6.0 RESPONSIBILITY:

6.1 Pharmacist/ Officer Production and Engineering:

1. Carry out the activity as per protocol

2. Compile the results

3. Prepare summary report

6.2 HOD Production, HOD Engineering and General Manager:

Review the results

6.3 HOD- QA & QC

Conclude and approve the results

7.0 DOCUMENTATION:

All documentation work shall be completed concurrently during execution of the qualification. However the protocol does not define the sequence of the test/ documentation to be carried out.

1. Use indelible black ink for the recording.

2. Fill out complete information in the format provided.

3. Do not leave any blank space.

4. Correct the wrong entry by drawing single line through incorrect data, recording the correct data and then signing and dating the change.

5. Enter "N/A" in space that is not applicable.

6. During execution of the protocol any deviation must be implemented as per defined procedure.

7. During protocol execution, report shall be prepared with following details.

- Discussion of all study in observation column
- Qualification is successfully completed or not
- Conclusion
- Recommendation, if any.



Pharmaceutical Guidelines

PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 6 of 14

8.0 MACHINE DESCRIPTION:

The Rapid Mixer Granulator is a high shear machine, developed for mixing as well as granulation. The multibladed dual speed impeller & chopper performs the mixing and breaking of materials. The granulating solution is gently distributed in the base material as it is added.

The Impeller makes the uniform mixer of materials and binder. Impeller is designed to mix by circulating the materials from up to low and vice versa while running. The chopper set in the centerline of the material flow has the effect of constant cutting action by which it breaks the mass. The effect of the impeller blades is often to compact the material during discharge. So the Lumps can be easily crumbled but the dense particles that they are composed of retain their form.

9.0 PROCEDURE:

1. After completion of operation qualification initiate the performance qualification of the Rapid Mixer Granulator (150 lit.)
2. The effectiveness of mixing will be qualified by determining % assay & % LOD
3. Three product/lots will be taken for performance qualification of Rapid Mixer Granulator (150 lit.)
4. In case of any deviation inform to department head for necessary action.
5. Document the deviation details in Observed deviation section.
6. The Quality head and the department head will be decided whether deviation is acceptable or not.
7. If deviation is acceptable and it does not have impact on operation of the machine, provide final conclusion.
8. If deviation is not acceptable inform to concern department head and Quality head for necessary action.

10.0 ACCEPTANCE CRITERIA:

1. % RSD (Relative Standard Deviation) of assay should not be more than 6 %
2. % RSD (Relative Standard Deviation) of LOD should not be more than 6 %
3. The equipment should work smoothly with minimum noise while operating



Pharmaceutical Guidelines

PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 7 of 14

- The equipment should produce intended outputs with respect to quality & quantity consistently.

11.0 REVALIDATION CRITERIA:

The equipment shall be revalidated, in case

- Location of the equipment is changed.
- Any spares/parts of the equipment are replaced that have a direct bearing on the performance of the equipment.
- At normal revalidation schedule.

12.0 PROCEDURE:

- Follow the procedure as mentioned in the BMR of the selected product for Performance qualification.
- Load the material in the Rapid mixer granulator
- Collect the sample as per sampling procedure after pre-mixing for % assay determination.
- Collect the sample as per sampling procedure after wet milling for % LOD determination.
- Note down the ampere reading for mixer & chopper during the process.

13.0 SAMPLING PROCEDURE:

- Wear nose mask, hand gloves before sampling.
- Label the sample bag with details as Product name, stage, beater speed, date, time, sign.
- Collect approx. 2.0 gm composite sample from top, middle & bottom after pre-mixing.
- Collect approx. 5.0 gm composite sample from top, middle & bottom after wet granulation.
- Record the details of sampling & analysis.

13.1 FIRST RUN:

PRODUCT DETAIL-FIRST RUN		
Date	:	
Product	:	
Batch No.	:	
Batch Size	:	



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 8 of 14

BILL OF MATERIAL

Sr. No.	Item Description	Qty. (in KG)					
Stage : Pre mixing							
01							
02							
03							
04							
05							
06							
07							
08							
09							
Stage : Binder							
1							
2							
3							
4							
Remarks:							
Performed By		Date		Checked By		Date	

PROCESS DETAILS

Stage	Time		Speed		Ampere load		
	From	To	Beater	Chopper	Beater	Chopper	
Pre - mixing							
Wet granulation							
Remarks:							
Performed By		Date		Checked By		Date	



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 9 of 14

ANALYSIS DETAILS

Sampling location	In- process parameter	Specification	Results	% RSD Limit (NMT 6 %)
Stage : Pre mixing				
Top	Assay			
Middle				
Bottom				
Stage : Wet granulation				
Top	LOD	NA		
Middle				
Bottom				
Remarks:				
Performed By		Date	Checked By	Date

13.2 SECOND RUN:

PRODUCT DETAIL-SECOND RUN	
Date	:
Product	:
Batch No.	:
Batch Size	:

BILL OF MATERIAL

Sr. No.	Item Description	Qty. (in KG)
Stage : Pre mixing		
01		
02		
03		
04		
05		
06		
07		



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 10 of 14

08		
09		
Stage : Binder		
1		
2		
3		
4		
Remarks:		
Performed By	Date	Checked By

PROCESS DETAILS

Stage	Time		Speed		Ampere load	
	From	To	Beater	Chopper	Beater	Chopper
Pre – mixing						
Wet granulation						
Remarks:						
Performed By	Date	Checked By	Date			

ANALYSIS DETAILS

Sampling location	In- process parameter	Specification	Results	% RSD Limit (NMT 6 %)
Stage : Pre mixing				
Top	Assay			
Middle				
Bottom				
Stage : Wet granulation				
Top	LOD	NA		
Middle				



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 11 of 14

Bottom					
Remarks:					
Performed By		Date		Checked By	Date

13.3 THIRD RUN:

PRODUCT DETAIL-THIRD RUN	
Date	:
Product	:
Batch No.	:
Batch Size	:

BILL OF MATERIAL

Sr. No.	Item Description	Qty. (in KG)					
Stage : Pre mixing							
01							
02							
03							
04							
05							
06							
07							
08							
09							
Stage : Binder							
1							
2							
3							
4							
Remarks:							
Performed By		Date		Checked By		Date	



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 12 of 14

PROCESS DETAILS

Stage	Time		Speed		Ampere load	
	From	To	Beater	Chopper	Beater	Chopper
Pre – mixing						
Wet granulation						
Remarks:						
Performed By		Date		Checked By		Date

ANALYSIS DETAILS

Sampling location	In- process parameter	Specification	Results	% RSD Limit (NMT 6 %)		
Stage : Pre mixing						
Top	Assay					
Middle						
Bottom						
Stage : Wet granulation						
Top	LOD	NA				
Middle						
Bottom						
Remarks:						
Performed By		Date		Checked By		Date

14.0 SUMMARY OF PERFORMANCE QUALIFICATION:

14.1 OBSERVED DEVIATION:



Pharmaceutical Guidelines

PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 13 of 14

14.2 RECOMMENDATIONS:

--

14.3 CONCLUSION:

--



Pharmaceutical Guidelines PERFORMANCE QUALIFICATION

RAPID MIXER GRANULATOR (150 Liters)

Document No: PG/PQ/001

Page no 14 of 14

15.0 POST APPROVAL:

Reviewed By	Designation	Signature	Date
HOD Engineering			
HOD Production			
Executive Quality Assurance			
Unit Head			

Approved By	Designation	Signature	Date
HOD Quality Assurance			