



**PERFORMANCE  
QUALIFICATION REPORT  
FOR  
RAPID MIXER GRANULATOR  
(Granulation Area)**

<b>EQUIPMENT ID No.</b>	
<b>LOCATION</b>	
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	



**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**  
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**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**1.0 REPORT PRE -APPROVAL :**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			



**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**2.0 OBJECTIVE:**

- To demonstrate that the equipment will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the equipment.

**3.0 SCOPE:**

- The Protocol covers all aspects of Performance Qualification for the RMG being used at .....
- This Protocol will define the methods and documentation used to qualify the RMG for PQ.

**4.0 RESPONSIBILITY:**

The Validation Team, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Performance Qualification Report.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity</li><li>• Monitoring of Performance Qualification.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>



**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Rapid Mixer Granulator
<b>Manufacturer's Name</b>	
<b>Location of Installation</b>	Granulation Area
<b>Equipment ID No.</b>	

**6.0 PRE QUALIFICATION REQUIREMENT:**

- Calibrated Stop Watch for measuring Mixing Time
- Calibrated Tachometer for measuring RPM Impeller & Chopper

**7.0 TESTS AND CHECKS:**

**7.1 Test**

1. RPM
2. Assay

**7.2 Procedure:**

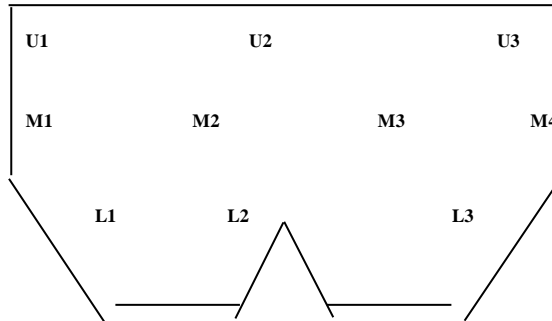
1. The test should be carried out for three batches
2. Switch ON the machine and operate as per SOP.
3. Run the machine at empty condition and verify the RPM of Impeller & Chopper at Slow and Fast Speed.
4. Load the product batch size with respect to capacity load.
5. Run the machine at set parameter of the product & sample from different location at end of mixing time. Upper 3 sampling point, Middle 4 sampling point and lower 3 sampling point.



**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**8.0 CHECKLIST OF ALL TESTS AND CHECKS:-**

The assay and content uniformity of the entire above batch sample with drawn from upper, middle and lower:



**RMG**

Quantity of Sample: Approx. 3 Times of Avg. weight of the tablet. From every sample point

No. of Samples: 3 Samples from Top Layer

4 Samples from Middle Layer

3 samples from Bottom Layer

Where,

U1= Upper Left  
U2= Upper Center  
U3= Upper Right

L1= Lower Left  
L2= Lower Center  
L3= Lower Right

M1= Middle Left  
M2= Middle Center 1  
M3= Middle Center 2  
M4= Middle Right



**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

Product Name						
Batch No						
Test Parameter	Standard Parameter	Observed Parameter	Standard Parameter	Observed Parameter	Standard Parameter	Observed Parameter
Impeller Slow Speed						
Impeller Fast Speed						
Chopper Slow Speed						
Chopper Fast Speed						

Done by:

Checked by:

A) PRODUCT NAME:

BATCH No.:

Name of API	Percentage of Assay											RSD NMT 5 %
	U1	U2	U3	M1	M2	M3	M4	U1	U2	U3	AVG	

Done by:

Checked by:

B) PRODUCT NAME:

BATCH No.:

Name of API	Percentage of Assay											RSD NMT 5 %
	U1	U2	U3	M1	M2	M3	M4	U1	U2	U3	AVG	

Done by:

Checked by:



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**C) PRODUCT NAME:**

**BATCH No:**

Name of API	Percentage of Assay											RSD NMT 5 %
	U1	U2	U3	M1	M2	M3	M4	U1	U2	U3	AVG	

**Done by:**

**Checked by:**

**Verified By**  
**Quality Assurance**  
**(Sign/Date).....**

**Inference:.....**  
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.....  
.....  
.....

**Reviewed By:**  
**Manager**  
**(Sign/Date).....**





**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**9.0 DOCUMENTS TO BE ATTACHED:**

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**10.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**11.0 NON COMPLIANCE:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY) :**

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**16.0 ABBREVIATION:**

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
PQ	:	Performance Qualification
RMG	:	Rapid Mixer Granulator



**PERFORMANCE QUALIFICATION REPORT FOR RAPID MIXER GRANULATOR**

**17.0 EXECUTED REPORT -APPROVAL**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			