PERFORMANCE QUALIFICATION PROTOCOL FOR RAPID MIXER GRANULATOR GRANULATION AREA (…… BLOCK)

SUPERSEDE PROTOCOL No.	
DATE OF QUALIFICATION	

PERFORMANCE QUALIFICATION PROTOCOL FOR RAPID MIXER GRANULATOR

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PERFORMANCE QUALIFICATION PROTOCOL FOR RAPID MIXER GRANULATOR

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION PROTOCOL 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/Qualification Team, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Protocol Activity • Monitoring of Performance Qualification Protocol Activity.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.

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5.0 EQUIPMENT DETAILS:

Equipment Name	RMG
Manufacturer's Name	
Location of Installation	Granulation Area
Equipment ID No.	

6.0 SYSTEM DESCRIPTION:

The RMG is used for mixing of dry powder as well as granulation of wet mass. It consists of main body, reverse switch, blade, shaft, mixing cabinet, gear box, motor. All the content part made of SS-316 material inside of mixer S.S blade is provided for proper mixing of dry powder or mixing of wet mass.

7.0 REASON FOR REQUALIFICATION:

Scheduled qualification is required as per qualification schedule and shall be performed according to detailed written procedures with the original qualification parameters and limits used as the evaluation criteria. The qualification studies shall be documented in detail and results of studies shall be compared to the original validation results and evaluated to the same extent. If the results are satisfactory, the equipment shall be certified. If the results are not satisfactory the modified system shall require new qualification studies.

8.0 SITE OF STUDY:

Granulation Area.

9.0 FREQUENCY OF RE-QUALIFICATION:

- Once in two year
- After any major breakdown or after major modification.
- After Change of Location

10.0 PRE QUALIFICATION REQUIREMENT:

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

11.0 TESTS AND CHECKS

11.1 Test

1. RPM
2. Assay

11.2 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.

12.0 REFERENCES:

The Principle Reference are the following:

- Validation Master Plan.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

The following references are used to give additional guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

13.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates
- QC Raw Data

14.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

All deviations, non conformances and out of specification results obtained shall be investigated in accordance with corresponding SOPs and documented in the qualification report.

16.0 CHANGE CONTROL, IF ANY:

Details of change controls initiated during the qualification activity, shall be documented in the qualification report.

17.0 ABBREVIATION:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
EU	:	European Union
PQ	:	Performance Qualification
mm	:	Millimeter
Amp.	:	Ampere
RMG	:	Rapid Mixer Granulator
GMP	:	Good Manufacturing Practices
ISPE	:	International Society for Pharmaceutical Engineering