Process Performance Qualification Protocol

Name of Product:

Stage:

Product Code:

Plant:

Process Performance Qualification Protocol			
Company Name			**Company Logo**
Document No. : PPQP/ Product Code-XXX/NN *			
Effective Date		**Revision No. :**	

1.0 Purpose :

The purpose of this Process Performance Qualification Protocol is to produce consistent quality of product by given sets of Equipments & Process Conditions by using Batch Manufacturing record (BMR).

2.0 Scope :

This Process Performance Qualification Protocol is applicable for the _____(Product Name / Stage), manufacturing at _____(Plant Name / Company Name).

- Batch Size:
- Type of Validation : (Prospective /Retrospective / Concurrent)
- Product Code :
- Retest Period :

3.0 Approval Signatures:

Following personnels are responsible for preparation, review and approval of Process Performance Qualification Protocol.

	Name/ Designation	Signature	Date
Prepared by			

	Name/ Designation	Signature	Date
Reviewed By			

	Name/ Designation	Signature	Date
Approved By			

4.0 Responsibilities :

The responsibilities and functions are as tabulated below.

Team	Responsibility
Validation Dept.	To develop necessary documents (Validation Master Plan, protocol, and summery reports) guide and share responsibility of validation team along with plant manager. To provide training to concerns, to execute the protocols and monitor validation efforts, to ensure completion of schedule. To prepare summary reports for final management approval. To get approval of all documents from the validation team members.
Engineer Projects/ Maintenance	To assist in supplying documents (procedure for equipment operation, data, manuals and drawings) necessary for execution of protocol. To provide additional staff when needed to assist the inspection and operation of an equipment and system. To provide personnel when necessary to calibrate or check calibration of measuring /recording & controlling instruments. Calibration of instrument, incorporated into the system, prior to validation. Maintenance and calibration of validation equipment / instrument. Storage and maintenance of the calibration documents.
Plant Manager	To plan all the execution of validation programme. To guide and supervise, the shift in charges and operators in performing actual operation as described in SOP/BMR. To check and record all the detailed observation and data collected by shift supervisor. To record the observation and deviation (if any).
Production In Charge	To actually perform / operate the equipment and equipment system as per SOP/ BMR. To collect the necessary data and samples as described in the protocol. To notice abnormality and deviation (if any), during the operation.
Quality Assurance	To monitor & co-ordinate the whole validation program To review all executed protocols. To check / calculate / analyse various data collected during the executive of protocol. To maintain all the document related to the validation efforts.
Quality Unit	To provide laboratory services for testing sample and provide test results. To collect the sample as per the procedure. To assist validation team, by providing all related documents i.e. SOPs, test procedure, BMR, sampling plan and validation / qualification procedure. To check, calculate and analyse various data collected during the validation studies. To maintain all the documents related to the validation studies for review and presentation to the auditors / inspectors. (all original to be maintained)

5.0 Introduction :

- Brief description of Process, its stages and how many batches shall be produced with respect to this protocol & their batch size.

6.0 Details of Raw Materials :

Raw Materials	Batch No.	Vendors	Qualification Status

7.0 Details of Packing Materials :

Packing Materials	Batch No.	Vendors	Qualification Status

8.0 Utilities & Equipment Qualification Details :

Utilities:

Name of Utility	Batch No.	Qualification Status

Equipment Qualification Details:

Equipments	Equipment Tags	Qualification Date	Due Date

9.0 Reference Documents:

Mention list of following documents related with Product.

- Batch manufacturing record:
- Specifications :
- SOPs :

10.0 Process Performance Qualification programme :

10.1 Pre qualification requirement:

The following pre qualification requirement shall be complied prior to execution of this protocol.

- Verify that Validation master plan has been completed and approved.
- Verify that the equipment qualifications (DQ, IQ, OQ) have been completed.

- Verify that all equipment cleaning operations have been completed prior to the start of validation programme.
- Process Flow Diagram

10.2 CPP, Non CPP & IP Controls :

a) Critical Process Parameters:

BMR Step No.	Manufacturing Stage	Process Parameters	Limits

b) Non Critical Process Parameters:

BMR Step No.	Manufacturing Stage	Process Parameters	Limits

c) In Process Controls:

In Process Tests	Specification Limit	Observed Limit	Remarks

11.0 Sampling & Testing Plan :

a) Centrifuge Process Validation :

- Shall be carried out for ensuring Homogeneity of Material
- Samples shall be withdrawn from Top, Middle & Bottom of Centrifuge.

b) Drying Process Validation

- Shall be carried out to ensure uniform drying of material across the dryer.
- Samples shall be withdrawn from different locations as defined in Sampling location Diagram

c) Blending Process Validation

- Shall be carried out to ensure uniform blending of material.
- Samples shall be withdrawn from different locations as defined in Sampling location Diagram

Note:

- 2 sets of samples shall be withdrawn, one for analysis & second for if any abnormal results of first sample is observed.

- Withdraw equal amount of sample from different defined locations, mix well & treat that sample as "Composite Sample"
- Sample shall be collected in fresh poly bag with self seal / lock.
- Sample Quantity shall be aprox. 10 gm.

12.0 Sampling Location Diagram :

- Define the sampling locations diagram for Centrifuge, Dryer &/or Blender from which samples for validations shall be withdrawn.

13.0 Revalidation Criteria :

- Change in process parameters
- Change in the equipment and instruments type, specification design and MOC.
- Change in the any major component of Equipment

14.0 Abbreviations :

- BMR : Batch Manufacturing Record
- SOP: Standard Operating Procedure.
- MOC : Material of Construction
- PPQP : Process Performance Qualification Protocol

15.0 History :

Revision No.	Effective Date	Reason for Revision

16.0 Annexures :

Sr. No.	Annexure

***** Where XXX stands for the sequential no. for Protocol
NN stands for revision no.

Where F1 stands for Format No.
AAA stands for Dept. Code
BBB stands for SOP No.
NN stands for revision no.