FACILITY QUALIFICATION

Prepared by:	Checked by:
Sign. & Date:	Sign. & Date:

CONTENTS

1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PREPARED BY				
Validation QA				
CHECKED BY				
Quality Assurance				
REVIEWED BY				
Production Head				
Warehouse Head				
Environment, health and safety				
Quality Control Head				
Engineering Head				
APPROVED BY				
QA Head				
Plant Head				

2.0 OBJECTIVE: To ensure that the critical attributes of the pharmaceutical manufacturing, packaging, storage and Microbiological testing Facility/area are designed, installed and functioning as per the designed specification throughout the anticipated operating ranges and meets the cGMP requirements and regulations.

3.0 SCOPE: The scope of this Facility Qualification is that the Receipt, Storage, dispensing, sampling, manufacturing, packaging, Microbiological testing and ancillary areas such as change rooms, corridors etc. are constructed according to specified design/required standards and regulation.

4.0 REASON FOR QUALIFICATION:

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following (☑):

New or refurbished area	☑
Major change in area/HVAC design	☐
Change in AHU/ AHU parameters	☐
Addition or removal of major equipment resulting in civil work	☐
Equipment replacement of different capacity	☐
Periodic Re-qualification	☐
Others (Specify)	☐

5.0 RESPONSIBILITY: Personnel involved in qualification activity.

Department	Name	Activity
User Department		To prepare the document as per the user Requirement and Design of area based on Process/Product, cGMP and Regulatory guidelines.
User Dept. Head		To verify and document all the critical aspects of Requirement and Design of area based on Process/Product, cGMP and Regulatory guidelines.
Engineering		To verify the Engineering and safety aspects of the Area
Environment, Health and Safety		To verify the Safety and Environment aspects of the Area
Quality Assurance		To be a part of team and review the documents
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

6.0 USER REQUIREMENT SPECIFICATION (URS):

6.1 Objective: The objective of URS is to provide the requirement and appropriate design to identify company needs and performance requirements of area including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP.

6.2 Reason for URS: To provide the requirements for Designing and installation of facility or area in _____ block for manufacturing, packaging, storage and Microbiological testing of pharmaceutical products.

6.3 Requirements: All the requirements are mentioned area wise as per respective attachments as listed in below table.

Refer Annexure No.	Area Code	Area Name
FQ/URS/B1/Annex-1		
FQ/URS/B1/Annex-2		
FQ/URS/B1/Annex-3		
FQ/URS/B1/Annex-4		
FQ/URS/B1/Annex-5		
FQ/URS/B1/Annex-6		
FQ/URS/B1/Annex-7		

6.4 Attachments: This section contains a list of all additional attachments which are required to be attached.

S.No.	Attachment Details	Refer Attachment No.
1.		FQ/URS/B1/Attachment-1
2.		FQ/URS/B1/Attachment-2
3.		FQ/URS/B1/Attachment-3

6.5 Recommendations/Conclusion:

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6.6 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
REVIEWED BY				
Production Head				
Warehouse Head				
EHS				
Engineering Head				
Quality Control Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

7.0 DESIGN QUALIFICATION (DQ):

7.1 Objective: To prepare the detailed specification (Design data) of area to ensure that the user requirement specification and Functional requirement specification or data sheet are achieved.

To design the area in conjunction with the design data in order to provide basis for the vendor, manufacturer, contractor and design engineer for designing the area when the project begins.

7.2 Reason for DQ: To provide a design for installation of facility or area in _____ block for production of pharmaceutical products.

7.3 Requirements: All the requirements are mentioned area wise as per respective attachments as listed in below table.

Refer Annexure No.	Area Code	Area Name
FQ/DQ/B1/Annex-1		
FQ/DQ/B1/Annex-2		
FQ/DQ/B1/Annex-3		
FQ/DQ/B1/Annex-4		
FQ/DQ/B1/Annex-5		
FQ/DQ/B1/Annex-6		
FQ/DQ/B1/Annex-7		

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2.		FQ/DQ/B1/Attachment-2
3.		FQ/DQ/B1/Attachment-3

7.5 Expected Documents and Drawings: A suggestive list (but not limited to), is as listed below:

S.No.	Document details	Required (✓ / ×)
1.	Design Specifications	☐
2.	Functional Specifications	☐
3.	As Built Area Layout	☐
4.	Instrument Listing	☐

S.No.	Document details	Required (✓ / ×)
1.	Utility supply Piping and Instrumentation Diagram (P&ID)	☐
2.	MOC certificates	☐
3.	Test certificates of components/ instruments	☐
4.	Weld certificates (if any)	☐
5.	Electrical drawings	☐
6.	Other (Specify)	☐

✓: Applicable & required × : Not applicable

7.6 Recommendations/Conclusion:

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7.7 Post approval:

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Functional area	Name	Designation	Signature	Date
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Production Head				
Warehouse Head				
EHS				
Engineering Head				
Quality Control Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

8.0 INSTALLATION QUALIFICATION (IQ):

8.1 Objective: To ensure that all the critical attributes of area have been taken care and to establish that the area is constructed as per the approved design specification.

8.2 Reason for IQ: To verify the installation parameters of facility based on approved Design of facility or area in _____ block for production of pharmaceutical formulation.

8.3 Requirements: All the requirements are mentioned area wise as per respective attachments as listed in below table.

Refer Annexure No.	Area Code	Area Name
FQ/IQ/B1/Annex-1		
FQ/IQ/B1/Annex-2		
FQ/IQ/B1/Annex-3		
FQ/IQ/B1/Annex-4		
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S.No.	Document details	Required (✓ / ✗)
1.	Design Specifications	☐
2.	Functional Specifications	☐
3.	As Built Area Layout	☐
4.	Instrument Listing	☐
5.	Utility supply Piping and Instrumentation Diagram (P&ID)	☐

S.No.	Document details	Required (✓ / ×)
6.	MOC certificates	☐
7.	Test certificates of components/ instruments	☐
8.	Weld certificates (if any)	☐
9.	Electrical drawings	☐
10.	Other (Specify)	☐

✓: Applicable & required × : Not applicable

8.6 Deviations/Changes (if any):

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8.7 Recommendations/Conclusion:

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Warehouse Head				
EHS				
Engineering Head				
Quality Control Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

9.0 OPERATION QUALIFICATION (OQ):

9.1 Objective: To ensure that the critical attributes of the area are functioning as per the operational specification throughout the anticipated operating ranges.

9.2 Reason for OQ: To verify the operating parameters of facility based on the approved Design of facility or area in _____ block for production of pharmaceutical formulation.

9.3 Training: Personnel involved in qualification activity.

S.No.	Name	Training status	Training report availability	Checked by/ date

9.4 Verification of instruments for calibration status:

S.No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by Sign/ Date

9.5 Reference of Standard operating procedure (SOP):

S.No.	SOP Name	SOP No.	Checked by Sign/ Date

9.6 Operational Requirements: All the requirements are mentioned area wise as per respective attachments as listed in below table.

Refer Annexure No.	Area Code	Area Name
FQ/OQ/B1/Annex-1		
FQ/OQ/B1/Annex-2		
FQ/OQ/B1/Annex-3		
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9.8 Deviations/ Incident/ Changes (if any):

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9.9 Recommendations/ Conclusion:

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Warehouse Head				
EHS				
Engineering Head				
Quality Control Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

10.0 PERFORMANCE QUALIFICATION (PQ):

10.1 Objective: To confirm that the area/facility consistently meets the predetermined standards under normal and worst conditions.

10.2 Reason for PQ: To verify the performance of facility based on the approved Design, process, product and regulatory requirements of facility or area in _____ block for production of pharmaceutical formulation.

10.3 Training: Personnel involved in qualification activity.

S.No.	Name	Training status	Training report availability	Checked by/ date

10.4 Verification of instruments for calibration status:

S.No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by Sign/ Date

10.5 Performance Requirements: All the requirements are mentioned area wise as per respective attachments as listed in below table.

Refer Annexure No.	Area Code	Area Name
FQ/PQ/B1/Annex-1		
FQ/PQ/B1/Annex-2		
FQ/PQ/B1/Annex-3		
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7.		FQ/PQ/B1Attachment-7
8.		FQ/PQ/B1Attachment-8
9.		FQ/PQ/B1Attachment-9
10.		FQ/PQ/B1Attachment-10

10.7 Deviations/ Incident/ Changes/ OOS (if any):

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10.8 Recommendations/ Conclusion:

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