DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR INLINE HOMOGENIZER

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR INLINE HOMOGENIZER	PROTOCOL No.:

PROTOCOL CONTENTS

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1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of user requirement, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Inline Homogenizer (Make: ……)** to be installed in Oral Liquid Line.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of Design Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Design Qualification Protocol cum Report • Assist in the verification of Critical Process Parameters, Drawings as per the Specification.
Engineering	• Review of the Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features. • Review of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no unauthorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

6.0 BRIEF PROCESS DESCRIPTION:

Homogenizers are the device to form homogeneous solutions or dispersions of two different phases or even similar phases. For example, liquid - liquid mixing and dispersion, liquid – solid disintegration and dispersion, and liquid – gas dispersion.

The versatility built into this machine provides its users with new and more efficient approaches to traditional processing techniques. High-speed mechanical and hydraulic shear forces are the real key to the success of this machine. The close tolerance between the Rotor and Stator (In between 0.5 to 0.6 mm) generates a shearing action which ensures the materials being processed are subjected to thousands of shearing actions each minute.

S.No	Name of Component	Details
1.	Stator Rotor	Made up of SS material used for emulsification of the liquid
2.	Mechanical Seal	Used for cooling the high speed shaft
3.	Drive	12.5 HP motor with the shaft provide

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

Equipment Name	Inline Homogenizer
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Gross Volume	5500 Ltr.
Working Volume	5000 Ltr.
Model No.	
Sr. No.	
Location of Installation	Liquid Line

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Inline homogenizer is designed to uniform mixing of solution	Should be able to uniform mixing of solution	Process Requirement

8.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 415 V Frequency : 50 Hz Phase : 3	GMP Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	DESCRIPTION	SPECIFICATION
Mechanical Seal -01 No.		
1.	Type	Double cartridge
2.	Size	42 mm
3.	Manufacturer	Techno seal
4.	Seal face	Sic / carbon – R/satellite
Motor- 1 No.		
5.	Type	2HE2 163-0203
6.	Manufacturer	Hindustan Electric Motors
7.	Kw / HP	9.3/12.5
8.	Current	16.5 A
9.	Voltage	415 ± 10
10.	Speed	2800 RPM
Wheel- 1 No.		
11.	Type	Plate Type
12.	Mfg.	Ayaan Engineering
13.	Size	4” X 11/4”
14.	MOC	PU
Nozzles		
15.	N1	50 mm – Inlet
16.	N2	50 mm – Outlet
Capacity		
17.	Gross Volume	5500 Ltr.
18.	Working Volume	5000 Ltr.
Surface Finish		
19.	External	≤ 0.4 RA
20.	Internal	≤ 0.8 RA

8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Rotor	SS 316 L
2.	Stator	SS 316 L
3.	Clamp	SS 304
4.	Mesh	SS 316 L
5.	Covers	SS 304
6.	Stand	SS 304
7.	Wheel	PU
8.	Gasket	Silicon

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electric Safety	The VFD is provided with machine of appropriate capacity	Safety Requirement
When not in use	Wipe off dirt or dust on the controls of the power plug. At the time of cleaning the equipment do not apply water directly to any part of the equipment.	Safety Requirement
Electrical wiring and Earthing.	Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided.	Safety Requirement
Start On/Off switch: To Stop the process immediately.	Should be provided for equipment and operator safety.	Safety Requirement
Noise Level	Below 80 db	Safety Requirement

9.0 DOCUMENTS TO BE ATTACHED:

- Manual
- MOC certificate
- GA drawing
- P & ID drawing.
- Any other document

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
HP	:	Horse Power
Hz	:	Hertz
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
SS	:	Stainless Steel
URS	:	User requirement specification
V	:	Voltage
W	:	Watt

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (OPERATING DEPARTMENT)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			