



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER
FILLING MACHINE**

DATE OF QUALIFICATION

SUPERSEDES PROTOCOL No.

NIL



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol pre-Approval	03
2.0	Objective	04
3.0	Scope	04
4.0	Responsibility	05
5.0	Project requirements	06
6.0	Brief process description	06
7.0	Equipment specification	06-07
8.0	Critical Variables to be Met	07
8.1	Process/product parameters	07
8.2	Utility requirements/location suitability	08
8.3	Technical specifications/Key Design Features	08-10
8.4	Material of Construction	11
8.5	Safety	11
8.6	Vendor selection	12
9.0	Documents to be Attached	12
10.0	Review (inclusive of follow up action, if any)	12
11.0	Any changes made against the formally agreed parameters	12
12.0	Recommendation	13
13.0	Abbreviations	13
14.0	Reviewed by	14



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

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)			



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

2.0 OBJECTIVE:

- To prepare the Design Qualification on basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment / Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Single Head Automatic Powder Filling Machine procured from DMEC Process Equipment.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



PHARMA DEVILS


**DESIGN QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
 SINGLE HEAD AUTOMATIC POWDER FILLING
 MACHINE**

PROTOCOL No.:

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	<ul style="list-style-type: none"> • Preparation, Review and Authorization of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none"> • Review & Approval of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. <ul style="list-style-type: none"> • GA Drawing • Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures. • Details of Utilities • Identification of components for Calibration • Material of Construction of all components • Brief Equipment Description • Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

 <p>PHARMA DEVILS</p>	<p>DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD AUTOMATIC POWDER FILLING MACHINE</p>	<p>PROTOCOL No.:</p>
--	---	-----------------------------

5.0 PROJECT REQUIREMENTS:

To ensure that no Unauthorized and / 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. The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical. Products in accordance with cGMP principles. To ensure the safe delivery of the Equipment from the supplier Site.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Modal SHPF-1 Single Head Powder Filling Machine is designed to fill powder in pharmaceutical bottles. The basic machine has a fabricated frame with SS claded table top. The table is fitted with SS covers all around.it houses Electrical Motor, Gear Box, Electrical Panel Box and Control station at convenient place. The Conveyor has adjustable size to match with bottle size.

Empty sterile bottles are conveyor fed via turn table to the star wheel which conveyors bottles from conveyor to the filling head for till the desired quantity of powder.

The model SHPF-1 can handle a bottle size range from 22 mm diameter to 85 mm diameter with the appropriate change parts. Bottle height adjustable from 50 mm to 200 mm. filling range starts from 01 gms. To 1000 gms. Can be accommodated with the appropriate change parts.

“DMEC” Automatic Powder Filling is designed for accurate volumetric filling of dry syrup powder, granule substances in quantities from 01 gm to 1000 gm per fills. Any type of container like tin, jar, bottles, bags, pouches, cardboard drums can be utilized for filling the powder. General accuracy of filling ranging between 1.5 % to 2.5 % depending upon the density of powder and quality of powder with control humidity and temperature of the room.

7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to Manufacturer for Engineering Equipment as per the specifications mentioned in User Requirement Specification

PARTS DESCRIPTION:

- Top Cover
- Servo Motor
- Coupling
- Chain Cover
- Hopper
- Agitator Assembly (Clock Wise Direction)



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

- Main Shaft(Anti Clock wish)
- C.I Slide for bottle Centering
- Funnel & Augur
- Bottle Sensor
- Star Wheel & Guide Plate
- Conveyor
- PNP Sensor for Servo Filling
- Conveyor Gearbox with Motor
- Powder Head Up & Down Screw with Handle
- Electric Panel (Inside)
- Safety Clutch for Star Wheel along with Gear Box and Motor
- Agitator Gearbox with Motor

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Single head automatic powder filling machine is designed to fill powder different weights in different sizes of bottles.	Should be able to filled weight accurately.	Process Requirement
Working	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	415 Volts, 3 phase, 50 Hz for main supply with neutral.	Design Requirement
Room Condition	Should be able to meet the requirement of Clean Environment.	cGMP Requirement

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S. No	CRITICAL VARIABLES	DESCRIPTIONS	REFERENCE
01.	Machine Frame Structure	Machine frame is made of SS 304duly welded & grinded surface and fully covered with S S 304 Sheet. Suitable SS covers cover the entire body from sides. Main Motor, Servo Motors, Worm-worm Wheel, Gear Box which are assembled inside.	Design Requirement
02.	Machine Drive Mechanism	Main Drive Servo Motor mounted on top plate with C.I Coupling to main delivery shaft for Augur Drive to get desire quantity of powder as per controller setting.	Design Requirement
03.	Worm-Worm Wheel assembly	Worm-Worm Wheel Gear Box Assembly transmit power to chain drive to Agitate Agitator Assembly in Hopper to agitate & Mix Powder.	Design Requirement
04.	Star Wheel Drive Assembly	Star wheel Drive through Gear box with A.C Drive system for bottle Transit on conveyor with clutch system for safety.	Design Requirement
05.	Conveyor Drive Assembly	Conveyor Drive through Gear Box with two Speed ratio by chain by wheel drive.	Design Requirement
06.	Turn Table Drive	N.A	Design Requirement



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
01	Make	D.M. Engineering Co.	Design Requirement
02	Model	Single Head Automatic Powder Filling Machine	Design Requirement
03	Dimension	Length:1500 mm Width:950 mm Height:1700 mm	Design Requirement
04	Bottle Diameter	22 mm to 85 mm	Design Requirement
05	Conveyor Length	5 ft.	Design Requirement
06	Filling Range	1 Gms. To 1000 Gms.	Design Requirement
07	Height	50 mm to 200 mm	Design Requirement
08	Filling Accuracy	1 % to 2.5 %	Design Requirement
09	Hopper Capacity	15-20 Kgs. Approx.	Design Requirement
10	PLC A.C Drive	Touch Pad (HMI)	Design Requirement
11	Net Weight	270 Kgs.	Design Requirement
12	Gross Weight	550 Kgs.	Design Requirement
13	Machine Support	4 Nos.	Design Requirement
14	Machine Support Setting Screw	4 Nos.	Design Requirement
15	Machine Cover	Available	Design Requirement
16	Servo Motor Drive for Augur	1 No.	Design Requirement
17	Star Wheel	1 Set	Design Requirement
18	Star Wheel with A.C Drive System	Available	Design Requirement
19	Bottle Conveying Belt S.S Belt	Available	Design Requirement
20	Bottle Guide on Conveyor Belt	Available	Design Requirement
21	Bottle Conveying Gear Drive	Available	Design Requirement
24	Bottle Sensor	1 No.	Design Requirement
25	Star Wheel Sensor Valve	1 No.(Proximity)	Design Requirement




PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
26	Machine controller	Available	Design Requirement
27	Panel Box with PLC, HMI & Servo Drive	1 No.	Design Requirement
ELECTRIC PANNEL			
28	PLC for servo motor housing	1 Unit	Design Requirement
29	A.C frequency Drive shaft	2 Unit	Design Requirement
30	Main ON-OFF Selector Switch	1 Unit	Design Requirement
31	Emergency Stop button	1 No.	Design Requirement
32	HMI with touch Screen Control	1 Unit	Design Requirement
SERVICES			
33	Power Requirement	415 V 3 Phase, 50 Hz for Main Supply with neutral.	Design Requirement

 PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD AUTOMATIC POWDER FILLING MACHINE	PROTOCOL No.:
--	--	----------------------

8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine frame Structure	SS 304
2.	Machine Covers	SS 304
3.	Servo motors	Panasonic
4.	Hopper	SS316 L
5.	Agitator Assembly	SS316 L
6.	funnel	SS316 L
7.	Augur	SS316 L
8.	Delivery Shaft	SS316 L
9.	Delivery Shaft Housing	C.I
10.	Worm Wheel Shaft Housing	Aluminum
11.	Worm	NA
12.	Worm Wheel	NA
13.	Chain Sprocket	M.S
14.	Cross Slide	C.I with Powder Coating
15.	Motor	3000 RPM 1.3 Nm/750 W Servo Motor, 1 No. 0.25 HP 1440 RPM Star/Delta motor for Star Wheel 0.50 HP 1440 RPM Star/Delta motor for Conveyor 0.50 HP 1440 RPM Star/Delta motor for Agitator

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided	Safety Requirement
Variable Frequency Drive	Motor safety from overload	Safety Requirement
Main Supply	Main power supply should be always switched off when not in use.	Safety Requirement
Emergency Button	Protection against abnormal condition	Safety Requirement

 PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD AUTOMATIC POWDER FILLING MACHINE	PROTOCOL No.:
--	--	----------------------

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Single Head Automatic Powder Filling machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know-how, Quality Standards, Inspection of Site, Costing, feedback from Market.	cGMP Requirement

Reference: (1) User Requirement Specifications (URS).
 (2) Design & Functional Specifications provided by Vendor.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant Documents(Certificates)

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

11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

12.0 RECOMMENDATION:

13.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
GA	:	General Arrangement
HMI	:	Human Machine Interface
HP	:	Horse Power
Hz	:	Hertz
Kg	:	Kilograms
mm	:	Millimeter
MOC	:	Material of Construction
RPM	:	Revolution per Minute
SS	:	Stainless Steel
MS	:	Mattel Steel



PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY SSURANCE)			