TABLE OF CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL FOR CAPSULE POLISHING MACHINE & UNFILLED CAPSULE SEPARATOR	PROTOCOL No.:

1.0 SYSTEM INFORMATION

Manufacturer	**Regd. Office:-**	**Works:-**
Customer		
Office		

Protocol Prepared By

Name of the Manufacturer	Signing Authority & Designation	Signature	Date

Protocol Approved By

Name of the Customer	Signing Authority & Designation	Signature	Date

2.0 OBJECTIVE

2.1 The Design Qualification Protocol (hereafter referred to as 'DQ') shall specify the Design Parameters of the Capsule Polishing Machine & Unfilled Capsule Separator (hereafter referred to as 'DPM & UCS') being manufactured by …….. for …….

2.2 This protocol shall confirm that the machine being manufactured shall comply with the specifications laid down in this protocol.

3.0 SCOPE

3.1 The scope of this DQ shall be confined to DPM & UCS.

3.2 The Qualification of any additional accessories apart from those specified in this DQ shall not be in the scope of this document.

3.3 The Qualification of the support utilities shall not be in the scope of this DQ.

3.4 The equipment shall be intended for polishing the capsules and separating the filled / unfilled capsules.

3.5 The equipment shall operate in a dust-free environment with humidity in the range 45 – 55 %RH and temperature in the range of 20 – 25° C.

4.0 RESPONSIBILITIES

4.1 Manufacturer

4.1.1 To provide the complete technical details of the equipment pertaining to its operational functions.

4.1.2 To prepare the DQ incorporating the following major parameters:

- Equipment Description
- Technical Specifications
- Material of Construction of different parts
- Utility Consumption

4.2 Customer)

4.2.1 To verify the DQ.

4.2.2 To approve the DQ

5.0 EQUIPMENT DESCRIPTION

The entire equipment comprises of the following units:

5.1 Capsule Polishing Unit

5.1.1 The capsule polishing machine consists of the polishing brush in the Teflon net assembly. The assembly is then enclosed inside the perforated SS cylindrical drum.

5.1.2 The perforated drum is placed on the tray like structure for the collecting the powder generated during the polishing of the capsules

5.1.3 The powder from the tray is sucked by means of the vacuum blower into the de-dusting tank

5.1.4 The polishing assembly is placed at an inclined position & has the spring that directs the capsules to the outlet. During this process, the capsules get rubbed against the brush thereby polishing the capsules.

5.1.5 The polishing assembly is driven by means of 0.5 HP electric motor through timing belt and pulley.

5.1.6 A variable frequency drive is provided to vary the RPM of the polishing brush

5.1.7 The electrical control panel for the polishing unit such as MCB, VFD etc. is placed in the common SS control panel.

5.2 Unfilled Capsule Separator Unit

5.2.1 The unfilled capsule separator unit consists of SS hopper assembly with outlet chutes at different heights.

5.2.2 The unfilled capsule separator unit works on the principle of the air flow that has the varying effects on the unfilled capsules and properly filled capsules.

5.2.3 The required airflow is developed by means of single phase blower and the airflow is directed in the circular fashion by means of a fixed impeller.

5.2.4 The capsules directed towards the periphery of the airflow by means of capsule guide pipe placed centrally on the impeller.

5.2.5 The circular direction of the airflow imparts clockwise motion on the capsules. The filled or unfilled capsule will rotate at a higher orbit and the properly filled capsules will rotate at the lower orbit.

5.2.6 The two outlet chutes are provided at different heights for collecting the capsule rotating at different orbits thus separating the unfilled capsules from the properly filled capsules

5.2.7 A dimmer is provided to vary the voltage of the blower thereby the airflow required for lifting the capsules. The airflow is adjusted depending on the filled weight of the capsules.

5.2.8 The electrical control for the separator unit is provided in the common SS electrical control panel.

6.0 TECHNICAL SPECIFICATION

S.No.	Parameter	Specification
1.	Capacity / Output	1,00,000 to 1,20,000 capsules / hr for powder & 80,000 to 1,00,000 Capsules / hr for pellets 60,000 to 70,000 capsules / hr for Tablet Depending up on the quality of filled capsules, Room condition
2.	Capsule size	Any size from '00' to '4'
3.	Adjustments	Variable Frequency Drive is provided for the polishing unit. A dimmer is provided to vary airflow of the blower for unfilled capsule sorter.
4.	Surface Finish	Internal Product Contact Parts - Mirror Finish i.e. < 0.4 Ra
		External Zone - Matt Finish i.e. < 0.8 Ra
5.	Mode of machine cleaning	Manually
6.	Room temperature	NLT 20 deg C and NMT 25 deg C
7.	Room humidity	NLT 45 % RH and NMT 55 %RH
8.	Polishing motor HP	0.5 HP
9.	Single phase blower	135watts
10.	De-dusting blower for polishing machine	135 mm Hg, 235 CFM
11.	De-dusting blower motor HP	3 HP
12.	**Packing Specifications**	
	Machine Dimensions (in mm) - Approx	As per the GA Drawing

7.0 PRODUCT SURFACE CONTACT AREAS

Sr. No.	Component	Surface area
Capsule Polishing Machine		
1.	Powder tray	192325 sq. mm
2.	Sieve top cover	101410.61 sq. mm
3.	Capsule inlet chute	16425 sq. mm
4.	Capsule outlet chute	19025 sq mm
Unfilled Capsule Separator		
1.	Perforated hopper	92567.03 sq mm
2.	Capsule guide pipe	24347.35 sq mm
3.	Capsule hopper pipe	58496.45 sq mm
4.	Inlet & outlet chute	49500 sq mm

8.0 MATERIAL OF CONSTRUCTION OF VARIOUS PARTS

Sr. No.	Component	MOC
1.	Capsule Inlet chute	SS316
2.	Sieve Top Cover	SS316
3.	Sieve	SS316
4.	Capsule polishing Tray	SS316
5.	Capsule Outlet chute	SS316
6.	Separator hopper Top cover	SS316
7.	Hopper pipe unit	SS316
8.	Hopper	SS316
9.	Capsule Guide pipe	SS316

9.0 POWER AND UTILITY CONSUMPTION

Power Consumption:

Sr. No.	Parameter	Specification
1.	Voltage	415 V $\pm$ 10%
2.	Frequency	50 Hz $\pm$ 5%
3.	Connected Load	3.7 HP

Major Cabling details (In Client Scope)

Sr. No.	Parameter	Specification
1.	For Main supply	4 Sq.mm x 6 Core (Cu Armoured)
2.	For Blower Motor DPM	2.5 Sq.mm x 4 Core
3.	For Blower Motor UCS	2.5 Sq.mm x 1 Core

Utility Consumption:

Sr. No.	Parameter	Specification
1.	Compressed Air	NLT 5 kg/sq.cm, NL Moisture free, 200 LPM / 7 CFM

10.0 LIST OF BOUGHT-OUT ITEMS

Mechanical

Sr. No.	COMPONENT	MANUFACTURER
1.	Polishing motor	Siemens / equivalent
2.	Unfilled capsule separator blower	VBM enterprises/ equivalent
3.	Dedusting Blower DPM	Minivac / equivalent
4.	Blower Motor DPM	Hindustan Motor / equivalent
5.	Timing belt	Mitsubishi / equivalent

Electrical

Sr. No.	COMPONENT	MANUFACTURER
1.	Variable Frequency Drive	Mitsubishi / equivalent
2.	MCB	Schneider / equivalent
3.	Contactor & Overload relays	Siemens / equivalent
4.	Dimmer	ME Instruments / equivalent
5.	Main isolator switch	Salzer / equivalent
6.	Selector Switch	Teknic / equivalent
7.	Voltmeter	MECO / equivalent
8.	OEN Relay	OEN / equivalent
9.	Terminals	Connectwell / equivalent
10.	Cables	Polycab / Finolex / Spectra / equivalent

Pneumatic

Sr. No.	Component	Manufacturer
1.	Rotary connector	SMC Pneumatics / Equivalent
2.	Tubing	Festo / SMC Pneumatics / Equivalent

11.0 LIST OF CERTIFICATES

Sr. No.	Component	Type of Certificate
1.	**As mentioned in Point No. 8**	MOC Certificate
2.	Polishing motor	Test Certificate
3.	De dusting Blower DPM	Test Certificate
4.	De dusting Blower Motor DPM	Test Certificate
5.	Unfilled capsule sorter Blower	Test Certificate

12.0 SAFETY FEATURES AND INTERLOCKS

Sr. No.	Safety feature	Specified function
1.	Motor overload Relay	For Motor & equipment protection.
2.	VFD for Polishing motor	For Motor & equipment protection.

13.0 LIMITING CONDITION FOR MACHINE PERFORMANCE

13.1 Power Failure

In the event of power failure, the process shall halt and shall start only on restoration of power.

13.2 Control Panel Failure

Failure in the control panel shall result in the stoppage of process. The process will start only on rectifying by operator intervention.

14.0 LIST OF SUPPORTING DOCUMENTS

Sr. No.	Documents
1.	G.A. Drawing

15.0 VARIATIONS

Should there be any addition / modification in the DQ or the equipment after its supply, then, the same shall be duly incorporated on mutual agreement of the Customer and the Manufacturer, in writing, after verifying the technical feasibility of the same subjected to cost implications, if any.

16.0 REVIEW AND COMMENTS

17.0 ABBREVIATIONS

Sr. No.	Abbreviations	Expanded Definition
1.	Sq. mm.	Square Millimeter
2.	Mm	Millimeter
3.	L	Length
4.	W	Width
5.	H	Height
6.	MOC	Material of Construction
7.	V	Volt
8.	A	Ampere
9.	Hz.	Hertz
10.	kW	Kilowatt
11.	Cu	Copper
12.	CFM	Cubic feet / min
13.	NL	Non-Lubricating
14.	LPM	Litre per min
15.	MCB	Miniature Circuit Breaker
16.	HP	Horsepower
17.	RPM	Revolutions per Minute
18.	G.A.	General Assembly

18.0 APPROVAL SHEET FROM ……..

Department	Name	Designation	Sign	Date