DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

INTEGRATED 3 PIECE VIAL

FILLING MACHINE

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

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PROTOCOL CONTENTS

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1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, 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 **Integrated 3 Piece Vial Filling Line with Model No. CFL-120)**.
- 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.

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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 and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	• Review of the 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. ➢ 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 Process Description. ➢ Safety Features and Alarms. • Review of Qualification Protocol after Execution.

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5.0 BRIEF EQUIPMENT DESCRIPTION:

The Line consists of four parts / machines

1. Bottle Orienting & Feeding Machine
2. 6 Head Filling Machine
3. Dropper Fixing
4. Screw Capping Machine

Bottle Orienting & Feeding Machine:

Orientator is a simple mechanical feeding system for plastic vials. The machine is equipped with multi-pocket Pick-up Star wheel. This star wheel picks up and feeds vials one by one into the feeder star wheel through a chute. A mechanical inverter is used to invert the vials which are coming upside down. And a feeder star wheel transfers vials from the Orientator to the Turn table. Another star wheel is used to transfer vials from Turn table to Filling station. Two IR sensors are used in between Orientator and Filling station to maintain trouble free running of the machine.

Head Filling Machine:

Filling machine consists of syringe less “Pressure and Time Setting” Filling System with the Pre and Post Nitrogen Flushing attachment. This machine consists of 18 head filling station in which 6 heads re used for filling and remaining 12 heads are used for pre and post Nitrogen flushing. An indexing mechanism is used for transferring vials from Orientator to filling station with the help of a intermediate turn table. Filling volumes can be adjusted independently on PLC screen while the machine is running.

Dropper Fixing & Screw Capping Machine:

It is a eight head rotary screw capping machine. It works on rotary basis in which screw capping is done in a continuous running system. The whole machine is driven on a single motor. A vibrator is used for feeding caps and cap dispenser is used for placing caps. Screwing cap is done by most advanced Bush type capping head. This machine is provided with 8 heads to achieve required output. Vial transfer from inlet conveyor to outlet conveyor is achieved by means of star wheel. Enough height adjustment is given on the capping head to suit different size of vials.

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6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for …….

The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Integrated 3 Piece Vial Filling Machine is designed to fill sterile Liquid Eye solution with different Volume in different sizes of vials & Dropper Fixing, the same as well Screw Capping.	Should be able to filled volume accurately with minimal spillage.	Process Requirement
Working: The machine works on vacuum filling principle.	Filling of material should be highly accurate.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 440 V Phase : 1 Phase Frequency : 50 HZ	GMP Requirement
Room Condition	Temperature : 23 ± 2 ºC RH : NMT 55 %	Process Requirement
Air supply(Nitrogen gas for dosing)	0.5 Kg/cm^2	Process Requirement
Vacuum supply	25 Hg.	Process Requirement

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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Model	**CFL-120**
Dimensions	2700 mm L x 1800mm H x 1400 mm W
Orientator Pockets	36 Nos.
Storage Capacity of Orientator Hopper	200 to 300 vials (for 5 ml)
Diameter of Orientator Bowl	700 mm.
Filling Heads	6 Nos.
Nitrogen Pre Gassing	6 Nos.
Nitrogen Post Gassing	6 Nos.
Turntables	5 Nos.
Turntable size	Φ225- Qty.1no, Φ325- Qty. 1no, Φ400- Qty 3 nos.
Dropper Feeder Bowl size	Φ350mm
Storage Capacity	500 Droppers.
Cap Feeder Bowl Size	Φ450mm
Storage Capacity	300 Caps
DESIGN OF DRIVE TRANSMISSION	
ORIENTATOR	
Motor:	Make :Siemens RPM: 1400 Power : 1 HP,AC, 3 Phase
Gear Box	Make : greaves Size : A200 Ratio :60:1, worm reduction
Gear Box To Feeder Wheel	19T x ½''-28T x ½'' sprocket
Feeder wheel to Main star wheel shaft	19T x 3/8'' -68 x 3/8'' sprocket
FILLING	
Motor:	Make :Siemens RPM: 1400 Power : 1/2 HP,AC, 3 Phase

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Critical Variables	Acceptance Criteria
Gear Box	Make : Greaves Size : A200 Ratio :30:1, worm reduction
OTHER DRIVE TRANSMISSION DETAILS	
From Clutch to Indexer inlet	19T - 32T (1/2″ P)
DROPPER FIXING:	
Motor:	Make :Siemens RPM: 1500 Power : 1 HP,AC, 3 Phase
Gear Box	Make : Greaves Size : A237 Ratio :60:1 ,worm reduction
From clutch to main shaft	19T - 22T (1/2” P)
From main shaft to Inlet star wheel shaft	92Tx2M Spur Gear
From Inlet star wheel to Outlet star wheel shaft	19T - 19T (1/2” P)
SCREW CAPPING	
Motor:	Make :Siemens RPM: 1500 Power : 1 HP,AC, 3 Phase
Gear Box	Make : Greaves Size : A237 Ratio :30:1 ,worm reduction
From clutch to main shaft	19T - 22T (1/2” P)
From main shaft to gear housing shaft	17T - 22T (1/2” P)
From gear housing shaft to outlet star wheel shaft	19T - 57T (3/8” P)
From infeed star wheel shaft to outlet star wheel shaft	19T - 19T (1/2” P)
TURN TABLE 1&2	
Motor:	RPM: 20 Power : 1/4 HP,AC, 3 Phase
SPROCKET DETAILS	
From motor to TT-1	15T - 22T (3/8” P) Sprocket
From TT-1 to Idler shaft	20T - 20T (3/8”P) Sprocket

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Critical Variables	Acceptance Criteria
Idler Shaft to TT-3	1:1 Gear (62Tx2M) Sprocket
TURN TABLE 3,4&5	
Motor:	RPM: 20 Power : 1/4 HP,AC, 3 Phase
From motor to TT-3	15T - 22T (3/8"P) Sprocket
From TT-3 to TT-4	20T - 20T (3/8"P) Sprocket
From TT-4 to TT-5	20T - 20T (3/8"P) Sprocket

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Bottom & Top frames	SS-304 Square pipe and angles.
2.	Main plate	M.S with SS304 Cladding
3.	Orientator Hopper	SS304
4.	Orientator Disc	SS304
5.	Orientator bridge plate	SS304
6.	Orientator Star wheel cavities	DELRIN
7.	Inverter Plate	SS304
8.	Timer mechanism	SS304
9.	Filling Nozzles	SS316L
10.	Other Liquid contact parts	SS316L
11.	All liquid contact hoses	SILICON
12.	Vertical Housings of DF and SC	S.S. 304
13.	Top and Bottom discs of DF & SC	S.S. 304
14.	Plunger Housings of DF & SC	Aluminium with Gunmetal

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S.No.	Parts Name	Material of construction
15.	Dropper Fixing Head and Feeder bowl	SS316
16.	Other Dropper contact Parts	SS316
17.	Cap Feeder bowl and Chute	SS304
18.	Capping head	SS-304 with PU bush
19.	Other Cap contact parts	SS304
20.	All turntable discs	SS304
21.	Star wheel Bridge Plates	SS304
22.	Main shaft	EN-8
23.	Main Housings	M.S With S.S-304 outer cover
24.	Other shafts	E.N-8.
25.	Other Bearing housings	M.S
26.	Taper roller & Ball bearings	KOYO/ SKF MAKE
27.	Feeder Star wheels	Delrin
28.	Cabin Door	Acrylic
29.	Main Panel	SS304
30.	Remote panels	SS304
31.	All covers & guards	SS304
32.	All guides	Delrin
33.	**CONTROL PANEL**	
34.	Main Panel	SS304
35.	Mounting plate	SS304

S.No.	Parts Name	Material of construction
36.	Remote panels	SS304
37.	All covers & guards	SS304

7.5 SAFETY:

Critical Variables	Specified Function	Reference
Hardware Emergency switch at Operator Console	For Operator Safety.	Safety Requirement
Vacuum pressure drop interlock	For safety of the batch	Safety Requirement
Motor overload Relay for Vacuum pressure and de dusting blower	For Motor & equipment protection.	Safety Requirement
Air pressure drop interlock	For safety of the batch & the process.	Safety Requirement
Dropper fixer low level – Machine stop	For safety of the batch & the process.	Safety Requirement
Motor overload Relay	For Motor & equipment protection.	Safety Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Integrated 3-piece vial Filling Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in PO and URS.

(2) Operating and service manual for integrated 3-piece vial Filling Machine.

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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
Hr	:	Hour
Kg	:	Kilogram
mm	:	Millimeter
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
SS	:	Stainless Steel
URS	:	User requirement specification
KG	:	Kilogram
TFM	:	Three piece filling machine
DQ	:	Design Qualification
No	:	Number
ID.	:	Identification
GA	:	General Arrangement
V	:	Volt
HZ	:	Hertz
°C	:	Centigrade
%	:	Percentage
L	:	Length
W	:	Width
H	:	Height
Ml	:	Mililiter
HP	:	Horse power
AC	:	Alternating Current
NLT	:	Not Less Than
NMT	:	Not More Than

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			