

PHARMA DEVILS GUALITY ASSURANCE DEPARTMENT

Management of Change Parts for Oral Liquids

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1.1. To lay down a Procedure for Usage, Control and Storage of Change Parts for liquid orals.

2.0 SCOPE

2.1. This procedure is applicable for the proper usage and control of change parts of Bottle washing machine, Mono block bottle filling & sealing machine and Automatic dosing cup pressing machine in liquid department.

3.0 RESPONSIBILITY

- 3.1. Technical associate Production For Execution
- 3.2. Officer/ Executive Production Department For verification and implementation of SOP
- 3.3. Head Production Department- To ensure compliance of the SOP

4.0 **DEFINITION (S)**

4.1. NA

5.0 PROCEDURE

- 5.1. Change Parts Usage
- 5.2. In case of Product change over using of different change parts depends upon the bottle size (PET, HDPE, and Glass Bottles).
- 5.2.1. Change parts for Bottle Washing Machine:
- 5.2.1.1. Bottle Feeding Warm Shaft
- 5.2.1.2. Star Plate (Inlet & Outlet)
- 5.2.1.3. Star Plate Guide (Inlet & Outlet)
- 5.2.2. Change parts for Mono block bottle filling and cap sealing machine:
- 5.2.2.1. Piston
- 5.2.2.2. Nozzle
- 5.2.2.3. Inlet, Intermediate and Discharge Plate
- 5.2.2.4. Bottle Guide
- 5.2.2.5. Sealing star plate
- 5.2.2.6. Bottle feeding Warm
- 5.2.2.7. HDPE cap plunger / Screw head jaw
- 5.2.2.8. Cap Chute, Cap Die, Cap bridge, Cap head
- 5.2.2.9. Nozzle centering cup



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- 5.2.2.10. Sealing head / Sealing Head Spring
- 5.2.3. Change parts for Automatic cup dosing pressing machine:
- 5.2.3.1. In feed star wheel
- 5.2.3.2. Center star wheel
- 5.2.3.3. Outer star wheel
- 5.2.3.4. Bottle guide
- 5.2.3.5. Bottle feeding Warm
- 5.2.4. Ensure that all the change parts shall be marked as per respective bottle size.
- 5.2.5. The bottles which are not suitable for capping on dosing cup pressing machine or bottles which does not consist dosing cup can be run without using of any change part on dosing cup pressing machine. In such case, change parts will be removed and only conveyor belt is used for movement of bottles from inspection belt to turn table (Secondary packing hall) on dosing cup pressing machine.

5.3 Control and Storage of Change Parts

- 5.3.1. After completion of the batch dismantle the change parts which are not required for the next product. Clean the change parts as per procedure mentioned on respective SOP's i.e. ("Cleaning and operation of Rotary bottle washing machine"), ("Cleaning and operation of Filling and sealing machine"), ("Cleaning and operation of Automatic dosing cup pressing machine").
- 5.3.2. Check all the cleaned change parts for any damage. If any damage is found inform the concerned Executive/ Manager.
- 5.3.3. Clean the change parts and pack them in clean poly bag or shrink wrap the change part.

 Record the usage and damage with reason (if any) in the Annexure I {"Usage Record for Change Parts of Rotary bottle washing machine"} and Annexure III {"Usage Record for Change Parts (Automatic Dosing Cup Machine)"} & Annexure-IV {"Usage Record for Change Parts of Liquid filling & sealing machine").
- 5.3.4. Physically check all the change parts at month end or starting of the month and Fill the Change Parts Accountability Report as per Annexure II {"Change Parts Accountability Report"}.

6.0 ABBREVIATION (S)

- 6.1. SOP: Standard Operating Procedure.
- 6.2. No.: Number

7.0 REFERENCE (S)

7.1. NA



PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

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8.0 ANNEXURE (S)

Annexure no.	Tittle of Annexure	Format no.	Mode of Execution
Annexure I	Usage Record for Change Parts of Rotary bottle washing machine		Log Book
Annexure II	Change Parts Accountability Report		Log Book
Annexure III	Usage Record for Change Parts (Automatic Dosing Cup Machine)		Log Book
Annexure-IV	Usage Record for Change Parts of Liquid filling & sealing machine		Log Book

9.0 **DISTRIBUTION**

9.1. **Master Copy**: Quality Assurance

9.2. **Controlled copy (S):** Production department(01), Quality Assurance (01)

9.3. **Reference copy (S):** Production department (02)

10.0 REVISION HISTORY

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date





ANNEXURE I

USAGE RECORD FOR CHANGE PARTS OF ROTARY BOTTLE WASHING MACHINE

Department: Production (Liquid Oral)

S.No.	Date	Change parts used for product	Pack		Name of Change part Bottle Washing M/C		Damaged (If any)	Reason for damage	Cleaned & Packed by	Checked By
				Bottle feeding Worm shaft	Star Plate (Inlet & Outlet)	Star Plate guide (Inlet & Outlet)				





ANNEXURE II CHANGE PARTS ACCOUNTABILITY REPORT

Department: Production (Liquid)	Oral)		
DATE: From	To		

S.No.	CHANGE PARTS	OPENING QTY. [A]	QTY. RECEIVED [B]	DAMAGED (IF ANY) [C]	CLOSING QTY. {[A+B]-C}	CHECKED BY





ANNEXURE III Usage Record for Change Parts (AUTOMATIC DOSING CUP MACHINE)

Department: Production (Liquid Oral)

S.No.	Date	Change parts used	Pack		Autor		Damaged (If any)	Reason for	Cleaned &	Checked by		
		for product		In feed Star wheel	Center star wheel	Outer star wheel	Bottle guide	Bottle guide In feed Worm		damage	Packed by	





ANNEXURE IV

USAGE RECORD FOR CHANGE PARTS OF FILLING & SEALING MACHINE

Department: Production (Liquid Oral)

S. No	Date	Change Parts used for product	Pack	Name of Change parts Filling & Sealing Machine										Damaged (If any)	Reason for damage	Cleaned	Checked by
				Piston Nozzle, Inlet, Intermediate discharge plate, Guide, Sealing star plate Sealing worm	Cap chute	Cap Head	Cap Bridge	Nozzle centering cup	Sealing Head			ed & Packed by	ed by				