



## On Line Inspection of Washed Empty/Filled/Labeled Bottles

### **1.0 OBJECTIVE**

- 1.1 To lay down a procedure for on line inspection of washed empty / filled / labeled bottles during Liquid Orals filling and packing operation.

### **2.0 SCOPE**

- 2.1 This procedure is applicable for online inspection of washed empty / filled / labeled bottles of all the Liquid dosage forms.

### **3.0 RESPONSIBILITY**

- 3.1 Technical associate Production : for execution  
3.2 Officer / Executive Production : For checking  
3.3 Officer / Executive IPQA : For verification  
3.4 Head Production: shall ensure compliance and implementation of the SOP

### **4.0 DEFINITION(S)**

- 4.1 NA

### **5.0 PROCEDURE**

#### **5.1 Washed Empty Bottles**

- 5.1.1 Switch 'ON' the tube light of empty bottle inspection unit.  
5.1.2 Receive the washed empty bottles on empty bottle inspection unit from bottle washing machine through Turn table and attached conveyor.  
5.1.3 Check the bottles against the white tube light background for the following defects.  
5.1.3.1 Cracked bottles (If applicable)  
5.1.3.2 Deformed bottles  
5.1.3.3 Foreign particles (Any particle like fiber, dust, residue etc.)  
5.1.3.4 Air bubble  
5.1.3.5 Embedded particles  
5.1.4 Record the inspection time and rejection details in respective BPR.  
5.1.5 Destroy the rejected bottles (As per reference Disposal in production department)

**NOTE :** Randomly inspect the HDPE bottles from the conveyor belt after washing for effectiveness of cleanliness (for presence of any foreign particles).

#### **5.2 Washed Empty Bottles( Bulk line)**

- 5.2.1 Washed empty bottles are received through conveyor at air jet cleaning machine.  
5.2.2 Checker inspects the bottles at conveyor belt.



### **On Line Inspection of Washed Empty/Filled/Labeled Bottles**

- 5.2.3 Check the bottles for the following defects :-
  - 5.2.3.1 Deformed bottles.
  - 5.2.3.2 Cracked bottle.
  - 5.2.3.3 Black spot, color spot.
  - 5.2.3.4 Foreign particles (Any particles like fibre, dust, residue etc.)
  - 5.2.3.5 Embedded particles
- 5.2.4 Record the inspection time and rejection details in respective BPR.
- 5.2.5 Destroy the rejected bottles (As per reference – Disposal in production department)

**NOTE:** Randomly check the HDPE bottles from the conveyor belt for effectiveness of cleanliness.

#### **5.3 Labeled bottles (Liquid orals and Bulk lines)**

- 5.3.1 Receive the labeled bottles from sticker labeling machine on attached conveyor.
- 5.3.2 Check the following details, during on line inspection of labeled bottles -
  - 5.3.2.1 Correct and legible coding.
  - 5.3.2.2 Cross labeling i.e. improper alignment of two corner of label.
  - 5.3.2.3 Coding details on bottle label i.e. Mfg. Lic. No. or Code No., Batch No., Mfg. Date, Exp. Date, Maximum Retail Price (whichever is applicable).
  - 5.3.2.4 Problem in printed matter (such as shrinking / enlargement of printing matter etc.)
  - 5.3.2.5 Colour or shade variation of the label.
- 5.3.3 Record the observation and accountability in BPR
- 5.3.4 Put the rejected bottles after inspection into rejection box.

#### **5.4 Filled and sealed Bottles.**

- 5.4.1 Operate the filled bottle inspection unit as per reference SOP (Cleaning and operation of inspection unit for empty and filled bottles).
- 5.4.2 Receive the filled bottles on visual inspection unit from bottle filling & sealing machine through attached conveyor after checking all in process during filling process.
- 5.4.3 Check the bottles for the following defects under white background.
  - 5.4.3.1 Full filled or empty bottles (For clear and amber colour bottle in which product is visible on inspection belt)
  - 5.4.3.2 Defective cap sealing of filled bottles/improper screw capping in HDPE bottles (improper cap shall be corrected by inspector during inspection, if any bottle or cap found damaged then both cap and bottle shall be rejected)
  - 5.4.3.3 Foreign particles in filled volume (For clear and amber colour bottle in which product is visible on inspection belt).



### On Line Inspection of Washed Empty/Filled/Labeled Bottles

- 5.4.3.4 Less volume in filled bottles (For clear and amber colour bottle in which product is visible on inspection belt)
- 5.4.4 Record the inspection time and rejection details in respective BPR.
- 5.4.5 Destroy all the rejected bottles by Transferring the rejected bottles to the wash area and open the bottles and collect the liquid in a container, pour sufficient amount of water in to the liquid and destroy the liquid in drain of wash area and scrap the opened bottles and caps. (As per reference SOP – Disposal in production department)

**NOTE:** 1.) Collect all the rejected labeled bottles from the rejection container before completion of batch/day end (where the batch discontinued till next day i.e. in “A/B/C” shift where batch shall be restarted on next working day). Count the rejected bottles & remove the measuring cup from the bottles. Record all rejected bottles into the BPR. Deface the rejected bottles, collect in double polybag and transfer to respective Bulk storage area through dynamic pass box. Open bottles and pour the filled liquid into a container. After collection of liquid in container, transfer the liquid in holding tank for Filling & sealing process. Collect all the opened bottles and ROPP cap in a poly bag and scrap the rejection (As per reference SOP - Disposal in production department).

After completion of batch, count and reconcile all measuring cup and rejected labeled bottles into the BPR, remove measuring cup from bottles and Deface the rejected bottles. Collect the bottles in double polybag and transfer to wash area. Open the rejected bottles and discard the liquid in wash area. Collect all the opened bottles and ROPP cap in a poly bag and scrap the rejection (As per reference SOP - Disposal in production department).

2.) Rotate the inspectors at the frequency of four hours.

#### 6.0 ABBREVIATION(S):

- 6.1 SOP : Standard operating procedure
- 6.2 No. : Number
- 6.3 BPR : Batch packing Record
- 6.4 Mfg. Date : Manufacturing date
- 6.5 Exp. Date : Expiry Date
- 6.6 Mfg. Lic No.: Manufacturing License Number
- 6.7 B.No. : Batch number
- 6.8 HDPE : High density poly ethylene

#### 7.0 REFERENCE(S):

- 7.1 SOP: Disposal in production department.
- 7.2 SOP: Cleaning and operation of inspection unit for empty and filled bottles.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## On Line Inspection of Washed Empty/Filled/Labeled Bottles

### 8.0 ANNEXURE(S):

8.1 Nil

### 9.0 DISTRIBUTION

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy ( s )** : Production department (02), Quality Assurance (01)

9.3 **Reference copy (s)** : Production department (3)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date
1.					