



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Checkweigher (CW 3000)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down the procedure for the Cleaning and Operation of Checkweigher.

### 2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of Checkweigher in Production Department.

### 3.0 RESPONSIBILITY:

3.1 Technical Associate: Operation

3.2 Officer/ Executive Production: Verification

3.3 Head Production: SOP Compliance

3.4 IPQA: SOP Compliance

### 4.0 DEFINITION (S):

4.1 Done By- The activity performed by the Person

4.2 Verified By- Evidence that establish or confirm the accuracy or truth of activity

### 5.0 PROCEDURE:

#### 5.1 CLEANING:

5.1.1 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer as per SOP (Status labeling).

5.1.2 Enter the cleaning starting time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.3 Ensure that the main power supply is switched "OFF".

5.1.4 Ensure that no previous batch/product are lying in and around the checkweigher.

5.1.5 Clean the conveyer belts of checkweigher by using dry lint free cloth.

5.1.6 Clean the rejection box with the dry lint free cloth.

5.1.7 Clean the entire surface of the machine with clean and dry lint free cloth.

5.1.8 Open the guards of the machine.

5.1.9 Clean the guards with clean and dry lint free cloth.

5.1.10 Clean the area inside the guard with clean and dry lint free cloth.

5.1.11 Open the control panel of checkweigher, clean the area with the dry cloth.

5.1.12 Clean the entire surface of the machine with clean and dry lint free cloth.



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- 5.1.13 Wipe the machine surface with 70% v/v IPA solution.
- 5.1.14 Affix label on checkweigher as “CLEANED” with date and signature of the production officer.
- 5.1.15 Record the cleaning activity of checkweigher in equipment usage log as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.1.16 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous “CLEANED” label by production & QA officer with date as per SOP (Status labeling).
- 5.1.17 Record the cleaning activity of checkweigher in equipment usage log as per SOP (Making entries in equipment usage and cleaning log sheet).

### 5.2 OPERATING PROCEDURE:

#### 5.2.1 Setting:

- 5.2.1.1 Ensure that the checkweigher is calibrated.
- 5.2.1.2 Open the compressed air valve and ensure that the compressed air pressure should not be less than 4 Kg/ cm<sup>2</sup>.
- 5.2.1.3 Switch “ON” the mains of the machine.
- 5.2.1.4 Switch “ON” the control panel of checkweigher.
- 5.2.1.5 And wait till it shows 0000.0 g.
- 5.2.1.6 Switch “ON” the control panel of checkweigher and wait till it shows MAIN SCREEN will appear as:



- 5.2.1.7 Press ‘DISPLAY’ key and screen will open with following details:



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5.2.1.8 Now select 'MENU' key following window will be displayed on screen



5.2.1.9 Three different users are given rights assignment to access above listed 'menu' as given below:

S.No.	Type of Functions	User Rights (Y/N)		
		User 1	User 2	User 3
1.	To create new 'user' & 'pass word'	N	N	Y
2.	To prepare Recipe	N	Y	Y
3.	Delete recipe	N	Y	Y

5.2.1.10 In above given window touch 'PRODUCT SET UP' key and window will be displayed with following detail:



5.2.1.11 In the 'PRODUCT LIBRARY' all the previously saved recipes with product name, B.no. and parameters details will be opened as:



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5.2.1.12 To create new job file go to 'PRODUCT DATA' key and new window will be open:



5.2.1.13 Touch the 'EDIT DATA' option and then edit new recipe into required field as displayed in window:



5.2.1.14 To set the new product edit the following:

PRODUCT NAME	#
BATCH NO.	#
TARGET WEIGHT	#
PRODUCT LENGTH (Product diameter)	#
UPPER LIMIT	#
LOWER LIMIT	#
SPEED	#
OPERATE DELAY (MD)	#
OPERATE DELAY (CW)	#



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HOLD DELAY #

- 5.2.1.15 Touch the field near “PRODUCT NAME” and a key pad will open then feed the required product name and press ‘enter’.
- 5.2.1.16 Touch the field near “BATCH NO” and a key pad will open then feed the required batch no. and press ‘enter’.
- 5.2.1.17 Touch the field near “TARGET WEIGHT” and a key pad will open and take the average gross weight of the 20 good filled Bottles/cartons and feed the value by using numeric key and press “Enter”.
- 5.2.1.18 Touch the field near “PRODUCT LENGTH” and a key pad will open.
- 5.2.1.19 Touch the field near “UPPER LIMIT” and a key pad will open then feed the required value by the numeric key.
- 5.2.1.20 **Tolerance Limit Setting:**
- 5.2.1.20.1 **For filled and sealed bottle:**
- 5.2.1.20.1.1 **Weight Data:** Take 20 filled Bottle weighing data in static condition on checkweigher. Calculate the average weight and put it in the nominal weight.
- 5.2.1.20.1.2 Up to 100 Counts Pack (or along with silica gel/cotton) shall be  $\pm 1.0$  gm of nominal weight.
- 5.2.1.20.1.3 More than 100 Counts Pack (or along with silica gel/cotton) shall be  $\pm 3.0$  gm of Nominal weight.
- 5.2.1.21 **For filled carton:**
- 5.2.1.21.1 **Weight Data:** Take 20 filled carton weighing data in static condition on checkweigher. calculate the average weight and put it in the nominal weight.
- 5.2.1.21.2 For carton with bottle upto 100 count (or along with silica gel/cotton) / upto 10 blister/strip/pouch with or without leaflet set tolerance limit  $\pm 1.0$  gm of nominal weight.
- 5.2.1.21.3 For bigger weight carton with bottle more then 100 count (or along with silica gel/cotton) with or without leaflet in one carton. Tolerance limit shall be  $\pm 3.0$  gm of nominal weight.
- 5.2.1.21.4 For bigger weight carton more then 10 blister / Strip / Pouch with or without leaflet in one carton. Tolerance limit shall be define by considering the half of the strip/ blister / Pouch weight. (Limit shall be 50%  $\pm$  of strip/blister/ Pouch weight).
- 5.2.1.22 **For Pouch:**
- 5.2.1.22.1 Tolerance limit shall be assign as per BPR.
- 5.2.1.23 Touch the field near “SPEED” and a key pad will open. Feed the required speed by using the numeric keys.



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5.2.1.24 Touch the field near “CW DELAY” and a key pad will open. Feed the required value by using the numeric keys. It is delay for reject mechanism to remain in “ON” condition.

5.2.1.25 Select the ‘machine setup’ from window (as 5.2.1.8) and new window will be displayed as:



5.2.1.26 Select the “DY COMP.” and it turn “ON” Dynamic compensation is used to compensate the weight difference of the pack when it is in motion and in static condition.

5.2.1.27 Select the “NEW DY. COMP.” and then pass a normally field bottle 20 times. The conveyor will stop automatically after 20<sup>th</sup> time and display will shows the compensation checkweigher is ready with dynamic compensation.

5.2.1.28 Select the the ‘ZERO’ key and after small delay it will show 0000.0g.

5.2.1.29 Now machine is ready for operation.

5.2.1.30 **NOTE:**

5.2.1.30.1 Dynamic compensation depends on speed of the conveyor target weight and product length so if either of these are changed or in case of power failure dynamic compensation has to be done again.

5.3 **OPERATION:**

5.3.1 Remove the “CLEANED” status label and affix “UNDER PROCESS” label on the machine.

5.3.2 Switch “ON” the control panel of checkweigher and wait till it shows MAIN SCREEN.

5.3.3 Press ‘DISPLAY’ key and screen will open as per window shown 5.2.1.6.

5.3.4 Then press “SET ZERO” and 0000.0g will be appeared after some delay.

5.3.5 Ensure that the tower lamp indications and its rejection mechanism is functioning by passing the Bottles with less weight and higher weight as per the frequency given in the BPR.

5.3.6 In case of correct fill value tower lamp glows green lamp.

5.3.7 At the end of activity, select further ‘CONV.ON’ key to stop the conveyor. Switch “OFF” the mains of the checkweigher and close the compressed air valve.



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5.3.8 Check the rejection of the checkweigher and check the Bottles for correct fill value. If any discrepancy is observed take corrective action.

### 5.4 CHALLENGE TEST:

#### 5.4.1 Challenge test for filled and sealed bottle:

5.4.1.1 Pass normally filled and sealed bottle through the checkweigher i.e. as per pack size mentioned in BPR.

5.4.1.2 It must be pass through checkweigher and record the observation in Annexure-II.

5.4.1.3 Take normal filled bottle and paste on it 'challenge test sticker' for identification.

5.4.1.4 Now remove and add some tablets/capsule from container for challenge test that gross weight of challenge test sample should be less or more then given tolerance imit.

5.4.1.5 It must be rejected by checkweigher and fall into rejection box.

5.4.1.6 Record the observation in Annexure-II.

#### 5.4.2 Challenge test for filled carton:

5.4.2.1 Pass good filled carton through the checkweigher.

5.4.2.2 It must be pass by checkweigher.

5.4.2.3 Record the observation in Annexure-II.

5.4.2.4 Take normal filled carton as challenge test sample & defaced the carton.

5.4.2.5 Then make up gross weight of challenge test sample less or more then the given tolerance limit by add and remove of packing component (s).

5.4.2.6 Pass this carton through the checkweigher.

5.4.2.7 Carton must be rejected and fall into rejection box by checkweigher.

5.4.2.8 Record the observation in Annexure-II.

#### 5.4.2.9 FREQUENCY:

5.4.2.9.1 At start, after every 4 hour of operation and at end of operation done by production and verified by production.

#### 5.4.3 Challenge test for rejection confirmation sensor

5.4.3.1 Pass entity with less or high weight then set limit through checkweigher.

5.4.3.2 Disturb the "OPERATE DELAY" by increasing or decreasing its value so that rejected entity could pass through conveyor belt and not fall into rejection box by rejection mechanism.

5.4.3.3 Conveyor belt must be stop when rejected entity passing through rejection confirmation sensor.

5.4.3.4 Further set the "OPERATE DELAY" as per point no.5.2.1.24 that it reject the low or higher weight



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entity and fall into rejection box.

5.4.3.5 Enter observation in Annexure-II.

### 5.4.3.6 Frequency:

5.4.3.6.1 At start, after every 4 hour of operation and at end of operation done by production and verified Production.

## 6.0 ABBREVIATION (S):

6.1 SOP : Standard operating procedure

6.2 SS : Stainless Steel

6.3 IPA : Iso Propyl Alcohol

6.4 Q.A. : Quality Assurance

6.5 V/V : Volume/ Volume

6.6 LED : Light emitting diode

## 7.0 REFERENCE (S):

7.1 SOP: Making entries in equipment usage and cleaning log sheet

7.2 SOP: Status labelling

## 8.0 ANNEXURE(S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure- I	CHECKWEIGHER (CW 3000) DAILY VERIFICATION RECORD		Log Book
Annexure -II	CHECKWEIGHER CHALLENGE TEST FOR WEIGHT VARIFICATION & REJECTION CONFIRMATION SENSOR(CW-3000) Technofour Pvt Ltd.		Control copy

## 9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled Copy (S):** Production Department (2)

9.3 **Reference Copy (S) :** Production Department (2)





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### 10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details of Revision	Effective Date
1.	00		New SOP	NA	





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### ANNEXURE II

#### CHECKWEIGHER CHALLENGE TEST FOR WEIGHT VERIFICATION & REJECTION CONFIRMATION SENSOR(CW-3000) Technofour Pvt Ltd.

**Frequency:** At start, after every 4 hour of operation and at end of operation done by production and verified by production.

#### For Carton

**Note:** Nominal weight is to be given from batch packing record for avg. of 20 Cartons

#### Calculation for set the tolerance limit:

Nominal Weight of carton	Nominal weight $\pm 1.0$ gm*/ $\pm 3.0$ gm**/ $\pm 50\%$ of blister/strip/pouch #	Tolerance limit of nominal weight of carton

\* Set tolerance limit for carton with bottle upto 100 count (or along with silica gel/cotton) / upto 10 blister/strip/ pouch with or without leaflet and tick mark ( $\checkmark$ ) which is applicable.

\*\* Set tolerance limit for bigger weight carton with bottle more than 100 count (or along with silica gel/cotton) with or without leaflet in one carton.

# Set tolerance limit for bigger weight carton with bottle more than 100 count (or along with silica gel/cotton)/more than 10 blister/strip/pouch with or without leaflet in one carton and tick mark ( $\checkmark$ ) which is applicable.

#### For Container

#### Calculation for set the tolerance limit:

**Note:** Nominal weight is to be given from batch packing record for avg. of 20 containers

Nominal weight of container	Nominal weight of container $\pm 1.0$ gm@ / $\pm 3.0$ gm \$	Tolerance limit of nominal weight of container

@ Up to 100 counts + silica gel / cotton pack/leaflet shall be  $\pm 1.0$  gm of nominal weight and tick mark ( $\checkmark$ ) which is applicable

\$ More than 100 count + silica gel / cotton/leaflet  $\pm 3.0$  gm of nominal weight and tick mark ( $\checkmark$ ) which is applicable.

