



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning & Operation of Checkweigher cum Metal Detector	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

1.1 To lay down a procedure for cleaning and operation of Checkweigher cum metal detector, Make: Technofour Electronic Pvt. Ltd.

2.0 SCOPE:

2.1 This procedure is applicable for cleaning and operation of Checkweigher cum metal detector, Make: Technofour Electronic Pvt. Ltd. in production department.

3.0 RESPONSIBILITY:

- 3.1 TA and TTA : Cleaning and operation.
- 3.2 Officer, Executive- Production : Supervision.
- 3.3 IPQA, Executive-Production : Verification and implementation of SOP.
- 3.4 Manager-Production : SOP compliance.

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 CLEANING

- 5.1.1 Ensure that all the materials of previous batch are removed from the packing cubicle.
- 5.1.2 Remove "UNDER PROCESS" label and affix "TO BE CLEANED" label on the machine with date and sign of the production officer.
- 5.1.3 Switch "OFF" the all-utility supply before cleaning.
- 5.1.4 Clean the control panel with clean and dry lint free cloth.
- 5.1.5 Clean SS surface of machine with the lint free cloth using 70% V/V IPA solution.
- 5.1.6 Clean inside surface of metal detector and Checkweigher, conveyer belts and its assembly by dry lint free cloth.
- 5.1.7 Clean the rejection tray with dry lint free cloth.
- 5.1.8 Replace "TO BE CLEANED" label and affix "CLEANED" label on the machine with date and sign of the production officer.
- 5.1.9 Record the cleaning activity in equipment usage log as per SOP (Making entries in equipment usage and cleaning log sheet.)



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5.1.10 Clean the surrounding area as per SOP (Cleaning of production area).

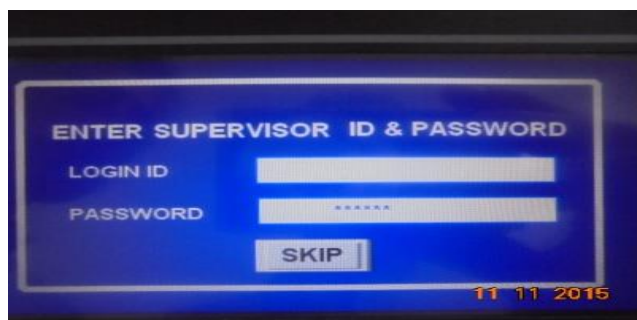
5.2 Metal Detector Setting Procedure:

5.2.1 Turn "ON" the ON/OFF knob given on Checkweigher, metal detector will turn "ON" and following screen will displayed:



5.2.2 If metal detector not applicable in batch a separate 'ON/OFF' knob given to turn 'ON or OFF' the metal detector at back side of machine.

5.2.3 Touch the sign given at top right side corner of window (5.2.1) to open the lock for window and screen will be displayed as:



5.2.4 Three different user ID and their password given with their right assignments as:

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

5.2.5 Enter the LOGIN ID & PASSWORD' and enter.



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5.2.6 Now start conveyor belt by selecting 'conv' key in window.

5.2.7 Pass five bottles containing product through the metal detector aperture and record the each bottle S_{max} value in BPR.

5.2.8 Pass a bottle containing product with Ferrous bid and record S_{max} value.

5.2.9 Pass a bottle containing product with Non Ferrous bid and record S_{max} value.

5.2.10 Pass a bottle containing product with SS bid and record S_{max} value.

5.2.11 Set the threshold value in between the maximum S_{max} value of product and minimum S_{max} value of bids and record it in BPR. Selecting field near the 'THR' key as:



5.2.12 Select 'MENU' key from given window and new window will be opened:



5.2.13 Select the 'PRODUCT LIBRARY' key from below given window as:



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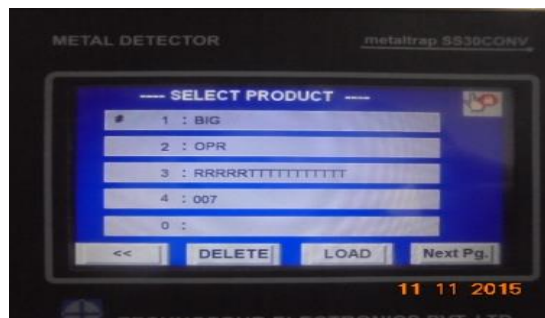
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5.2.14 Select the 'SELECT PRODUCT' option if product recipe already saved as displayed:



5.2.15 Select 'DELETE' option if previously saved recipe want to delete and select 'LOAD' option if already saved recipe required to load on machine as:



5.2.16 To formulate new recipe select the 'VIEW/EDIT PRODUCT' option from window (as 5.2.14) and new window displayed:



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5.2.17 Select the sr.no. and then 'EDIT' then provide all information required e.g. product name, B.no., THR value, RPH for respective product.



5.2.18 Collect the standard bids from the rejection box and clean them with lint free cloth and reconcile them in batch record.

Note: In case of sachet containing metal ingredient metal detector will not be functional and activity for that process should not be applicable.

5.3 Checkweigher Setting

5.3.1 Open the compressed air valve and ensure that the compressed air pressure should not be less than 5 Kg/cm².

5.3.2 Switch "ON" the control panel of checkweigher and wait till it shows MAIN SCREEN will appear as:



5.3.3 Press 'DISPLAY' key and screen will open with following details:



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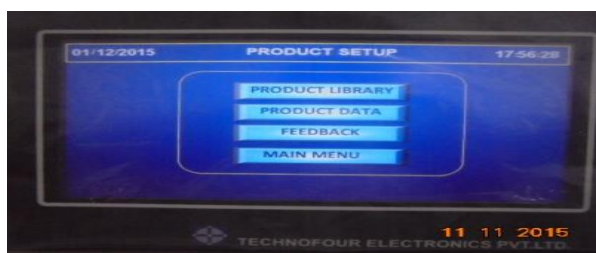
5.3.4 Now select 'MENU' key following window will be displayed on screen



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

S.no.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Manager
1.	Start and Stop of Machine	Y	Y	Y
2.	To create new 'user' & 'password'	N	N	Y
3.	To prepare Recipe	N	Y	Y
4.	Delete recipe	N	Y	Y

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



5.3.7 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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5.3.8 To create new job file go to 'PRODUCT DATA' key in (5.3.6) and new window displayed:



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



5.3.10 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)	#

5.3.11 Touch the field near "PRODUCT NAME" and a key pad will open then feed the required product name and press 'enter'.

5.3.12 Touch the field near "BATCH NO" and a key pad will open then feed the required batch no. and press 'enter'.



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5.3.13 Touch the field near “TARGET WEIGHT” and a key pad will open and take the average gross weight of the 20 good filled Bottles and feed the value by using numeric key and press “Enter”.

5.3.14 Touch the field near “PRODUCT LENGTH” and a key pad will open. Feed the diameter of Bottles by using the numeric key.

5.3.15 Touch the field near “UPPER LIMIT” and a key pad will open then feed the required value by the numeric key.(Upper limit is the maximum allowable weight from “TARGET WEIGHT” and will be as per Annexure-II.

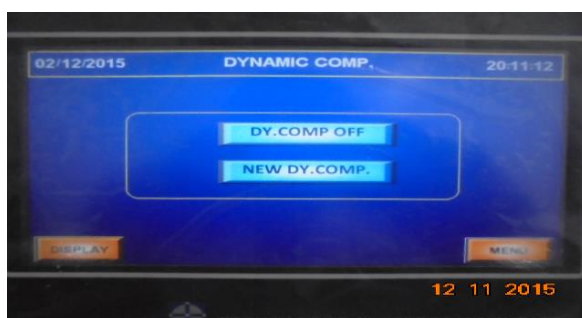
5.3.16 Touch the field near “LOWER LIMIT” and a key pad will open. Feed the required value by using the numeric keys.(Lower limit is the minimum allowable weight from “TARGET WEIGHT” and will be as per Annexure-II.

5.3.17 Touch the field near “SPEED” and a key pad will open Feed the required speed by using the numeric keys.

5.3.18 Touch the field near “MD DELAY” and a key pad will open. Feed the required value by using the numeric keys. “MT delay” is the delay for reject mechanism to be activated after the object leaves the weighing conveyer feed the required, MT delay in milliseconds by pressing numeric key and pressure key. Higher the speed Lower the “MT delay”.

5.3.19 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.

5.3.20 Select the ‘machine setup’ from window (as 5.3.4) and new window will be displayed as:



5.3.21 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.

5.3.22 Select the “NEW DY. COMP.” and then pass field bottle 20 times. The conveyor will stop automatically after 20th time and display will shows the compensation checkweigher is ready with dynamic compensation.

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

5.3.24 Now machine is ready for operation.

NOTE : 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.

5.4 OPERATION:



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- 5.4.1 Remove the "CLEANED" status label and affix "UNDER PROCESS" label on the machine.
- 5.4.2 Switch "ON" the control panel of Checkweigher and wait till it shows MAIN SCREEN.
- 5.4.3 Press 'DISPLAY' key and screen will open as per window shown 5.3.2
- 5.4.4 Then press "SET ZERO" and 0000.0g will be appeared after some delay.
- 5.4.5 For metal detector follow the procedure as per 5.2.5 to 5.2.17 point.
- 5.4.6 For checkweigher follow the procedure as per 5.3.2 to 5.3.10 points.
- 5.4.7 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.
- 5.4.8 In case of correct fill value tower lamp glows green lamp.
- 5.4.9 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.
- 5.4.10 Check the rejection of the checkweigher and check the Bottles for correct fill value. If any discrepancy is observed take corrective action.

5.5 Challenge Test:

5.5.1 Challenge test for filled bottle

- 5.5.1.1 Pass filled bottle through the checkweigher cum metal detector i.e. as per pack size mentioned in BPR.
- 5.5.1.2 It must be pass through checkweigher and record the observation in Annexure-II.
- 5.5.1.3 Took filled bottle and paste 'challenge test sticker label' on it for identification.
- 5.5.1.4 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 limit.
- 5.5.1.5 It must be rejected by checkweigher cum metal detector and fall into rejection box.
- 5.5.1.6 Record the observation in Annexure-II.

FREQUENCY:

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

5.5.2 Challenge test for rejection confirmation sensor

- 5.5.2.1 Pass entity with lesser or higher weight then the set limit through checkweigher cum metal detector.
- 5.5.2.2 Enter observation in Annexure-II.
- 5.5.2.3 Disturb the "OPERATE DELAY" by increasing or decreasing its value so that rejected bottle could pass through conveyor belt and not fall into rejection box by rejection mechanism.
- 5.5.2.4 Conveyor belt must be stop when rejected bottle passing through rejection confirmation sensor.
- 5.5.2.5 Further set the "OPERATE DELAY" so that it reject the low or higher weight entity and fall into



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rejection box.

5.5.2.6 Enter observation in Annexure-II.

FREQUENCY:

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

5.6 Verification of checkweigher:

5.6.1 Verify the checkweigher before start of operation by standard weight of 20gm, 400gm, 1000 gm, and 1600 gm record the observation in Annexure-I.

FREQUENCY: Daily before start of operation.

5.7 ABBREVIATION (S):

5.7.1 S_{max} : Signal Maximum

5.7.2 SOP : Standard Operating Procedure

5.7.3 MD : Metal Detector.

5.7.4 BPR : Batch Packing Record

5.7.5 RHS : Right Hand Side

5.7.6 CW : Checkweigher

5.7.7 S.S : Stainless Steel

5.7.8 V/V : volume/volume

5.7.9 IPA : Isopropyl alcohol

5.7.10 TTA : Training Technical Associate.

5.7.11 TA : Technical Associate.

6.0 ABBREVIATION (S):

6.1 SOP - Standard Operating Procedure

6.2 IPA – Isopropyl alcohol

6.3 v/v- Volume by Volume

7.0 REFERENCES (S):

7.1 SOP No.: Making entries in equipment usage and cleaning log sheet.

7.2 SOP No.: Cleaning of production area.

7.3 SOP No.: Status labeling

8.0 ANNEXURE (S):



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Annexure no.	Title of Annexure	Format No.	Mode of execution
Annexure I	Checkweigher daily verification		Log Book
Annexure II	Checkweigher cum metal detector, challenge test for weight verification & rejection confirmation sensor.		Controlled Copy

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 (01).

10.0 REVISION HISTORY:

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



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ANNEXURE I

Checkweigher Daily Verification

STANDARD WEIGHT	TOLERANCE	ACCURACY LIMIT
20 g	± 0000.2g	0019.8g to 0020.2g
400 g	± 0000.4g	0399.6 g to 0400.4g
1000 g	± 0001.0g	0999.0 g to 1001.0g
1600 g	± 0001.6g	1598.4 g to 1601.6g

Date	#Spirit level	#Zero Error	Reading shown on Checkweigher				#Remark	Checked by
			0020 g	0400 g	1000 g	1600 g		

Put 'OK' or 'NOT OK' in observation.



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ANNEXURE II

CHECKWEIGHER CUM METAL DETECTOR CHALLENGE TEST FOR WEIGHT VARIATION & REJECTION CONFIRMATION SENSOR

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

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

Note: @ Up to 100 counts pack (or along with silica gel/cotton) and tick mark (✓) which is applicable.

\$ More than 100 count (or along with silica gel/cotton) and tick mark (✓) which is applicable.

Calculation for set the tolerance limit:

Date		Set Tolerance Limit	
Equipment ID			
Product Name		Batch no.	
Tolerance Limit Set By		Tolerance Limit Verified By	

