



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation, Cleaning, Calibration and Verification of Checkweigher

SOP No.:		Department:	Production
		Effective Date:	
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1.0 OBJECTIVE:

To lay down a procedure for Operation, Cleaning, Calibration and Verification of Checkweigher.

2.0 SCOPE:

This SOP is applicable for Operation, Cleaning, Calibration and Verification of Check weigher in production.

3.0 RESPONSIBILITY:

Officer / Executive-Production

4.0 ACCOUNTABILITY:

Head - Production

5.0 ABBREVIATIONS:

IPA	Isopropyl Alcohol
Ltd.	Limited
Pvt.	Private
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 INSTRUCTIONS:

6.1.1 Check the cleanliness of the Checkweigher and ensure that is free from remains of the previous product.

6.1.2 Speed of Checkweigher NMT 80 vials / min in first time.

6.1.3 Speed of Checkweigher NMT 60 vials / min in second time.

6.2 OPERATION:

6.2.1 Switch “ON” the Main Switch.

6.2.2 Turn the power switch 90 degrees clockwise to the “ON” position.

6.2.3 Touch the ‘USER’ icon and make the entry of ‘USER NAME’ and ‘PASSWORD’ then click on LOGIN.

6.2.4 After the successful login, Touch to ‘PRODUCT’ icon to open the Product Selection screen.

6.2.5 Touch to unregistered icon and make sure the entry of Product Name and Product Code.

6.2.6 Touch the Edit icon to register the product and open the Product Setting Screen.



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6.2.7 After the entry of name and code touch on “**DETECT FUNCTION**” tab to display the setting menu to select the setting to be changed.

6.2.7.1 Touch on “**DETECT BASIS**” button of the setting menu to open the screen below:

6.2.7.1.1 Select target to enter the mass of the product to be weighed.

6.2.7.1.2 Select high limit to enter the upper limit mass value of the product.

6.2.7.1.3 Select lower limit to enter the lower limit mass value of the product.

6.2.7.1.4 Touch the “**RETURN**” key to return to the Product Setting screen.

6.2.7.2 SETTING OF WEIGHT RANGE:

6.2.7.2.1 With the reference of Batch Manufacturing Record (BMR) higher limit given in BMR set as target weight.

6.2.7.2.2 Set 0.2 gm as lower limit.

6.2.7.2.3 Set 0.8 gm as higher limit for every product.

6.2.7.3 Touch on “**PROCESSING PERFORMANCE**” button of the setting menu to open the screen below:

6.2.7.3.1 Select Product Length to enter the length of the product.

6.2.7.3.2 Select speed to enter the belt speed of the conveyor.

6.2.7.3.3 Touch the “**RETURN**” key to return to the Product Setting screen.

6.2.7.4 Touch on “**REVISION**” Button of the Setting Menu to Open the Screen below:

6.2.7.4.1 Place a tare on the weighing conveyor and touch the Get button.

6.2.7.4.2 Touch the “**RETURN**” key to return to the Product Setting screen.

6.2.7.5 Touch on “**DO MAP**” Button of the Setting Menu to Open the Screen below:

6.2.7.5.1 For each judgment item, touch the check box of the DO number to be output.

6.2.7.5.2 When the product is weighed and the judgment item is judged, a signal will be output from the specified DO according to the delay time and hold time.

6.2.7.5.3 When the Stop column is checked, the conveyor will stop according to the result of the



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specified judgment item.

6.2.7.5.4 Touch the “**RETURN**” key to return to the Product Setting screen.

6.2.7.6 Touch on “**DO Behavior**” Button of the Setting Menu to Open the Screen below:

6.2.7.6.1 Select Delay Time to enter a delay time for each DO.

6.2.7.6.2 Select Hold Time to enter a hold time for each DO.

6.2.8 CHANGING THE PRODUCT TO BE WEIGHED:

6.2.8.1 In the weighing screen, touch the Product Key to open the Product Selection screen.

6.2.8.2 Enter the group no. (1 to 10).

6.2.8.3 Touch the Read key to read the settings of the selected product.

6.2.8.3.1 Changing the product setting with the START button is available only when the selected product is different from the product to be weighed.

6.2.8.4 Touch the “**RETURN**” key to return to the Product Setting screen.

6.2.9 SUMMARY OF WEIGHING RESULTS:

6.2.9.1 In the Weighing screen, touch the Summary key to open the Weighing History screen.

6.2.9.2 Touch the Update key to update the displaying contents to display the newest history.

6.2.9.3 Touch the Right arrow key to go to the All Summary.

6.2.9.4 Touch the “**RETURN**” key to return to the Weighing screen.

6.2.9.5 Record the Operation details in “**Machine Utilization Record**”.

6.2.9.6 Record the Rejection in BMR.

6.2.9.7 Additional check point shall be taken during filling of lower pack size having fill Volume 3.0 ml or lower mentioned as below-

6.2.9.7.1 Arrange the filled crates of vials after end of checkweigher process.

6.2.9.7.2 Collect 50 vials randomly from each tray / crates and offline recheck the weight of these vials through checkweigher after completion of filling and online checkweigher to find any vial having less volume / weight.



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6.2.9.7.3 Record the details in **Annexure No.-V “Offline weight verification record through checkweigher”**

6.2.9.7.4 Take the printout of these vials and attach with the BMR.

6.3 CHALLENGE TEST OF CHECKWEIGHER:

6.3.1 Prepare the lower & higher weight Vials / Tubes for challenge test from the respective batch i.e. lower weight vial shall be prepared by removing the solution from vial up to below lower limit & higher weight vial shall be prepared by pouring the solution in another vial above from the higher limit. Perform challenge test of Vials / Tubes for higher, lower & normal limit and mark with cross (X) marking.

6.3.2 Pass these Vials / Tubes from the Checkweigher before start the batch, middle of batch & end of batch, record the observation in **Annexure-II**, Titled **“Challenge Test Record for Checkweigher”**. Mention the frequency in remark column as Initial, Middle and End.

6.3.3 If challenge test passed start the weighing of filled vials by Checkweigher and if challenge test failed inform to the Engineering department for the rectification of Checkweigher.

6.3.4 After rectification of Checkweigher again perform the challenge test as per section no. **6.3.1 & 6.3.2**.

6.3.5 Product specific challenge test with respect to higher, lower & normal set weight range.

6.3.6 At the end of process challenge test Vials / Tubes to be discarded and record the details in **Annexure-II**, Titled **“Challenge Test Record for Checkweigher”**.

6.4 VERIFICATION OF DETECTED / REJECTED VIALS / TUBES:

6.4.1 First time detected / rejected Vials / Tubes to be weighted again by pass through the same Checkweigher at speed of 60 vials / Min. to detect the lower / higher weight.

6.4.2 Record the all above details in **Annexure-III**, Titled **“Batch Reconciliation Record after Weight by Checkweigher”**.

6.4.3 Final rejection should be recorded in the Batch Manufacturing Record (BMR).

6.5 VERIFICATION OF CHECKWEIGHER:

6.5.1 Verification Frequency: Daily before use / immediately after maintenance work / Power Failure / Relocation of Checkweigher.



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6.5.2 Verify the Checkweigher using two Standard Weights certified by Weights and Measures Department.

6.5.3 Place the Standard Weights one by one in the center of the Platform of the **Weighing Conveyor** and record the observations in **Annexure-IV**, Titled “**Checkweigher Verification Record**”.

6.6 CALIBRATION OF CHECKWEIGHER:

6.6.1 Calibration Frequency: Monthly \pm 3days before use.

6.6.2 Check the cleanliness of the area.

6.6.3 Switch ‘ON’ the main power supply of the Checkweigher.

6.6.4 Turn the power switch 90 degrees clockwise to the “ON” the Checkweigher and check that zero is displayed on the screen.

6.6.5 Place the Standard Weights one by one in the center of the **Weighing Conveyor** of the Checkweigher and note down the reading in the **Annexure-I**, Titled “**Checkweigher Calibration Record**”.

6.7 CLEANING OF CHECKWEIGHER:

6.7.1 Switch off the Checkweigher and disconnect the main switch before cleaning activity.

6.7.2 Wipe the surface of Checkweigher with cotton cloth or brush.

6.7.3 Clean the surface of Checkweigher with 70% IPA solution.

6.7.4 Make the electrical connection and check its display.

6.7.5 After cleaning verify the Checkweigher and used.

6.7.6 Record the cleaning details in “**Machine Utilization Record**”.

6.7.7 Frequency: Cleaning of the checkweigher shall performed at the end of the operation activity of the batch and whenever required.

6.8 REVISION OF FILLING WEIGHT RANGE:

6.8.1 Check the fill volume in calculated filling weight range vials.

6.8.2 If fill volume is greater/ less than standard fill volume limit then revise the calculated filling weight range.

6.8.3 For lower weight range-



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Revised Lower Weight Range = Lower standard limit of fill volume X Lower calculated weight range
Observed fill volume

6.8.4 For upper weight range-

Revised Upper Weight Range= Upper standard limit of fill volume X Upper calculated weight range
Observed fill volume

6.8.5 Change the weight range in tag and mention the term 'revised fill weight range' on the top of tag, dually signed by IPQA and Production. Attach both tag of weight range in BMR.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Checkweigher Calibration Record	
Annexure-II	Challenge Test Record for Checkweigher	
Annexure-III	Batch Reconciliation Record after Weight by Checkweigher	
Annexure-IV	Checkweigher Verification Record	
Annexure-V	Offline weight verification record through checkweigher	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production (Injection, I-Block)
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY: CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE-I CHECKWEIGHER CALIBRATION RECORD

Month		Year	
Department		Location	
Balance ID. No.		Checkweigher Capacity	2000 gm
Least Count	0.1 gm	Operating Range	02 gm - 100 gm
Calibration Date		Next Calibration Due Date	
Std. Wt. Certified On		Next Due Date	

1.0 Accuracy by Using Standard Weight:

Standard Weight	Observed Weight	Difference	Limit*
02 gm			
05 gm			
10 gm			
20 gm			
50 gm			
100 gm			

*Standard Weight $\pm 2 \times$ least count of the Balance

2.0 Precision:

Standard Weight	1	2	3	4	5	6	7	8	9	10	Mean	%RSD	Limit
02 gm													RSD NMT 0.5%
100 gm													

3.0 Corner Load Test:

Standard Weight	Left	Right	Front	Back	Middle	Mean	% RSD	Limit
02 gm								RSD NMT 0.5%
100 gm								

Done By
Sign & Date

Checked By
Sign & Date



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ANNEXURE-IV CHECKWEIGHER VERIFICATION RECORD

Month		Year	
Department		Least Count	0.1 gm
Location		Operating Range	02 gm to 100 gm
Checkweigher ID No.		Checkweigher Capacity	2000 gm
Min Standard Weight	02 gm	Acceptance Limit	1.9 gm to 2.1 gm
Max Standard Weight	100 gm		99.9 gm to 100.1 gm

Date	Standard Weight (A)		Displayed Weight (B)	Difference (A - B)	Done By Sign & Date	Checked By Sign & Date	Remarks*
	Min	Max					
	Min	02 gm					
	Max	100 gm					
	Min	02 gm					
	Max	100 gm					
	Min	02 gm					
	Max	100 gm					
	Min	02 gm					
	Max	100 gm					
	Min	02 gm					
	Max	100 gm					
	Min	02 gm					
	Max	100 gm					
	Min	02 gm					
	Max	100 gm					

*Put (√) for OK and (X) for Not OK

