



**STANDARD OPERATING PROCEDURE**

|   |                        |
|---|------------------------|
| <b>Department:</b> Production   | <b>SOP No.:</b>        |
| <b>Title:</b> Operation, Cleaning, Calibration and Verification of Checkweigher | <b>Effective Date:</b> |
| <b>Supersedes:</b> Nil  | <b>Review Date:</b>    |
| <b>Issue Date:</b>  | <b>Page No.:</b>       |

**1.0 OBJECTIVE:**

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

**2.0 SCOPE:**

This SOP is applicable for Operation and Cleaning of Checkweigher in Three Piece Line at .....

**3.0 RESPONSIBILITY:**

Officer/Executive - Production

**4.0 ACCOUNTABILITY:**

Head - Production

**5.0 DEFINITIONS:**

Not Applicable

**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 120 vials/min.

**6.1.3** Speed of infeed star wheel NMT 6.5 round/min.

**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 ‘LOGIN’ icon and make the entry of ‘LOGIN ID’ and ‘LOGGIN PASSWORD’ then click on ENTER.

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

**6.2.5** Touch the “PRODUCT SET UP” then touch the “PRODUCT DATA” for Edit icon to register the product and open the Product Setting Screen.

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



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**6.2.5.2** After the entry of name and code to save Re login the login ID and login password

**6.2.5.2.1** Select target to enter the mass of the product to be weighed.

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

**6.2.5.2.3** Select lower limit to enter the lower limit mass value of the product.

**6.2.5.2.4** Touch the “**NEXT PAGE**” key to return to the Product Display screen.

**6.2.5.2.5** Record the Operation details in Format Titled “**Equipment Log**” of SOP.

**6.3 CHALLENGE TEST OF CHECKWEIGHER:**

**6.3.1** Prepare the lower & higher weight vials for challenge test from the respective batch i.e. lower weight vial shall be prepared by removing the solution from vial upto below lower limit & higher weight vial shall be prepared by pouring the solution in another vial above from the higher limit.

**6.3.2** Pass these vials from the Checkweigher before start the batch, middle of batch & end of batch, record the observation in **Annexure-I**, Titled “**Challenge Test Record for Checkweigher**”.

**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** At the end of process challenge test vials to be discarded and record the details in **Annexure-I**.

**6.4 CLEANING OF CHECKWEIGHER:**

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

**6.4.2** Wipe the surface of Checkweigher with lint free mop.

**6.4.3** Clean the surface of Checkweigher with 70% IPA solution.

**6.4.4** Make the electrical connection and check its display.

**6.4.5** After cleaning verify the Checkweigher and used.

**6.4.6** Record the cleaning details in “**Equipment Log**” as per Format No.....



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**6.4.7 Frequency:** Carry out the cleaning process every day before startup of a shift and at the end of Shift.

**6.5 CALIBRATION OF CHECKWEIGHER:**

**6.5.1 Calibration Frequency:** First working day of every month before use.

**6.5.2** Check the cleanliness of the area.

**6.5.3** Switch 'ON' the main power supply of the Checkweigher.

**6.5.4** Turn the power switch 90 degrees clockwise to the "ON" the Checkweigher and check that zero is displayed on the screen.

**6.5.5** 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-II**, Titled "**Checkweigher Calibration Record**".

**6.6 VERIFICATION OF CHECKWEIGHER:**

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

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

**6.6.3** Place the Standard Weights one by one in the center of the Platform of the Weighing Conveyor and record the observations in **Annexure-III**, Titled "**Checkweigher Verification Record**".

**6.7 VERIFICATION OF DETECTED/REJECTED VIALS:**

**6.7.1** First time detected/rejected vials to be weighted again by pass through the same Checkweigher to detect the lower/higher weight.

**6.7.2** Second time detected/rejected vials to be verified by using the weighing balance (off line) to detect the lower/higher weight.

**6.7.3** Record the all above details in **Annexure-IV**, Titled "**Batch Reconciliation Record after Weight by Checkweigher**".

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



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**7.0 ABBREVIATIONS:**

|      |                              |
|------|------------------------------|
| SOP  | Standard Operating Procedure |
| Ltd. | Limited                      |
| QTY. | Quantity                     |
| QA   | Quality Assurance            |
| NMT  | Not More Than                |
| Min. | Minute                       |
| IPA  | Isopropyl Alcohol            |
| PD   | Production Department        |

**8.0 ANNEXURES:**

| ANNEXURE No. | TITLE OF ANNEXURE  | FORMAT No. |
|--------------|--|------------|
| Annexure-I   | Challenge Test Record For Checkweigher                   |            |
| Annexure-II  | Checkweigher Calibration Record                          |            |
| Annexure-III | Checkweigher Verification Record                         |            |
| Annexure-III | Batch Reconciliation Record After Weight By Checkweigher |            |

**9.0 DISTRIBUTION:**

- Controlled Copy No.1      Production Department
- Master Copy                      Quality Assurance Department

**10.0 REFERENCES:**

- SOP Titled “Equipment Log”.

**11.0 REVISION HISTORY:**

| Revision No. | Change Control No. | Details of Changes | Reason of Changes | Effective Date | Done By |
|--------------|--------------------|--------------------|-------------------|----------------|---------|
| 00           | Not Applicable     | Not Applicable     | New SOP           |                |         |





**PHARMA DEVILS**  
PRODUCTION DEPARTMENT

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**ANNEXURE-II**  
**CHECKWEIGHER CALIBRATION RECORD**

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

**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-III

#### CHECKWEIGHER VERIFICATION RECORD

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

| S.No. | Date | Spirit Level<br>Ok/Not Ok | Standard<br>Weight (A) |        | Displayed<br>Weight (B) | Difference<br>(A - B) | Done By<br>Sign & Date | Checked By<br>Sign & Date | Remarks |
|-------|------|---------------------------|------------------------|--------|-------------------------|-----------------------|------------------------|---------------------------|---------|
|       |      |                           | 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 |                         |                       |                        |                           |         |

