|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.0** | **PURPOSE:** | | | | | | | | | | | | |
|  | To Lay down the procedure for operation, calibration and cleaning of electronic weighing balance (5 Kg Balance). | | | | | | | | | | | | |
| **2.0** | **SCOPE:** | | | | | | | | | | | | |
|  | This SOP is applicable for operation, calibration and cleaning of electronic weighing balance having maximum weighing capacity 5kg (IP/PRD/BAL/061) in Store Department. | | | | | | | | | | | | |
| **3.0** | **RESPONSIBILITY:** | | | | | | | | | | | | |
|  | **3.1** | | Store Designees are responsible for preparation and following the SOP. | | | | | | | | | | |
|  | **3.2** | | QCD Designees are responsible for Monthly calibration. | | | | | | | | | | |
|  | **3.3** | | Store In charge is responsible for review and implementation of SOP. | | | | | | | | | | |
|  | **3.3** | | QA Manager / designee is responsible for the approval, distribution and  Archival of the SOP. | | | | | | | | | | |
| **4.0** | **DEFINITION:**NA | | | | | | | | | | | | |
| **5.0** | **PROCEDURE:** | | | | | | | | | | | | |
|  | **5.1** | **Operational Procedure:** | | | | | | | | | | | |
|  |  | **5.1.1** | | | Switch on the on/off switch. | | | | | | | | |
|  |  | **5.1.2** | | | To turn the balance on, Press the On/Off button located on the balance key board. | | | | | | | | |
|  |  | **5.1.3** | | | The balance performs display test and initialisation process with 8.8.8.8.8.8. | | | | | | | | |
|  |  | **5.1.4** | | | After few seconds balance display will show 0. | | | | | | | | |
|  |  | **5.1.5** | | | In case balance is switched off due to power failure, restart the balance. Allow 5 minutes warm up time to get balance stabilised to show 0. | | | | | | | | |
|  |  | **5.1.6** | | | **Key indications on display:**   * Re-zero indication ON when the net weight on the platter is zero. * Tare indication ON when the balance has a weight tarred. | | | | | | | | |
|  |  | **5.1.7** | | | Store designee will perform Verification of balance on daily basis for its accuracy and record the activity in equipment usage logbook. | | | | | | | | |
|  |  | **5.1.8** | | | After verification, balance will ready to use for weighing activity. | | | | | | | | |
|  |  | **5.1.9** | | | If the balance shows other than 0, press re-zero key, now display shows 0 and balance is ready for weighing activity. | | | | | | | | |
|  |  | **5.1.10** | | | The performed activity / usages of balance will recorded in equipment usages | | | | | | | | |
|  |  |  | | logbook of weighing balance as per current version of SOP for equipment usages recording (IP/PRD/SOP/063). | | | | | | | | | |
|  | **5.2** | Calibration and Verification Procedure : | | | | | | | | | | | |
|  |  | 5.2.1 | | | | Before starting Calibration / Verification following Instructions will followed : | | | | | | | |
|  |  |  | | | | 5.2.1.1 | | | | Ensure that the warm up process is completed. | | | |
|  |  |  | | | | 5.2.1.2 | | | | Ensure the standard weights used are within the validity period of its calibration. | | | |
|  |  |  | | | | 5.2.1.3 | | | | Ensure leveling of balance before starting calibration / Verification. | | | |
|  |  |  | | | | 5.2.1.4 | | | | The balance must be calibrated as per the calibration schedule. | | | |
|  |  |  | | | | 5.2.1.5 | | | | Never touch the Calibrated weights with bare hands, Always use gloves. | | | |
|  |  |  | | | | 5.2.1.6 | | | | De-dust loose dust from calibrated weights by soft brush prior to calibration if appears. | | | |
|  |  |  | | | | 5.2.1.7 | | | | Store all calibrated weights in the box after use. | | | |
|  |  | **5.2.2** | | | | **Balance Verification procedure :** | | | | | | | |
|  |  |  | | | | **5.2.2.1** | | | | Operate the balance by follow the procedure given in Section **5.1.1** to **5.1.6.** | | | |
|  |  |  | | | | **5.2.2.2** | | | | Verification of balance will perform by verifying three standard certified calibratedweights daily before starting activity. | | | |
|  |  |  | | | | **5.2.2.3** | | | | The selected weights shall covers minimum, maximum and middle operating range of the balance. | | | |
|  |  |  | | | | **5.2.2.4** | | | | The weights to be used for the 5 Kg balance verification are 500 g, 2000 g and 3000 g. | | | |
|  |  |  | | | | **5.2.2.5** | | | | Place the 500g, 2000g and 3000g weights individually on centre of balance platform and record the details as per annexure II of this SOP. | | | |
|  |  |  | | | | **5.2.2.6** | | | | Frequency of verification: Verification of balance will perform daily before starting any activity by store personnel for its accuracy. | | | |
|  |  |  | | | | **5.2.2.7** | | | | **Acceptance Criteria:** Observed weight must be well within the ± 0.5 % of the standard weight or least count.  The tolerance limits of acceptance will 0.5 % of the standard weight | | | |
|  |  |  | | | |  | | | | or least count.  E.g. For 5 kg max. weighing capacity balance, 0.5 g is the least count. For 500g test load tolerance limit is + 2.5 g display shows 497.5 – 502.5 g. For the Acceptance criteria / Tolerance range Refer Daily Verification record for 5 kg balance i.e. Annexure II of this SOP. | | | |
|  |  | **5.2.3** | | | | **Procedure for Balance Calibration /Performance Check:** | | | | | | | |
|  |  |  | | | | **5.2.3.1** | | | | Operate the balance by follow the procedure given in Section 5.1.1 to 5.1.6. | | | |
|  |  |  | | | | **5.2.3.2** | | | | Calibration of balance will performed by verifying five standards certified calibrated weights. | | | |
|  |  |  | | | | **5.2.3.3** | | | | Place 200 g, 300 g, 500 g, 1000 g and 4000 g weights individually on centre of balance platform and record the details as per annexure I of this SOP. | | | |
|  |  |  | | | | **5.2.3.4** | | | | Frequency of Calibration /Performance Check: It will performed monthly and after any maintenance work and / or after relocation of weighing Balance. | | | |
|  |  |  | | | | **5.2.3.5** | | | | Acceptance Criteria: Observed weight will within the ± 0.5 % of the standard weight or least count.  The measurement of weights within acceptable range of individual weight as per Calibration Record of 5 kg balance i.e. annexure I of this SOP. | | | |
|  |  |  | | | | **5.2.3.6** | | | | Repeatability / Uncertainty Measurement: | | | |
|  |  |  | | | |  | | | | **5.2.3.6.1** | Load 2500 g the standard certified calibrated weight on the centre of the pan and then record the display value in annexure I of this SOP. | | |
|  |  |  | | | |  | | | | **5.2.3.6.2** | Remove the weight and repeat the steps for 10 times. | | |
|  |  |  | | | |  | | | | **5.2.3.6.3** | Calculate the uncertainty “U” at each measurement point in 10 readings by use the following formula ; | | |
|  |  |  | | | |  | | | |  | Repeatability = | 3 XStandard deviation | X 100 |
| Smallest net weight (g) |
|  |  |  | | | |  | | | | **5.2.3.6.4** | Acceptance criteria: The Repeatability / Uncertainty Measurment will not more than 0.1% | | |
|  |  |  | | | | **5.2.3.7** | | | | Eccentricity Measurement: | | | |
|  |  |  | | | |  | | | | **5.2.3.7.1** | Load 2500 g of standard certified calibrated weight on the centre of the pan and then record the display value in annexure I of this SOP. | | |
|  |  |  | | | |  | | | | **5.2.3.7.2** | Remove the weight and repeat the steps 5 times by placing weight at different position one by one as suggested in diagram. | | |
|  |  |  | | | |  | | | |  | **1**  **2**  **5**  **3**  **4** | | |
|  |  |  | | | |  | | | | **5.2.3.7.3** | Acceptance criteria : RSD for Eccentricity Measurment will not more than 0.05 %. | | |
|  | **5.3** | **Frequency :** | | | | | | | | | | | |
|  |  | **5.3.1** | | | | Balance verification : Daily | | | | | | | |
|  |  | **5.3.2** | | | | Internal Balance Calibration : Monthly | | | | | | | |
|  |  | **5.3.3** | | | | External Balance Calibration : Annually | | | | | | | |
|  | **5.4** | After completion of calibration affix **‘CALIBRATED’** label as per the current version of SOP for Calibration and Validation of Equipment, Instrument and devices (IP/QAD/SOP/017). | | | | | | | | | | | |
|  | **5.5** | After each maintenance job, relocation and / or if it is not in continuous use calibrate the system before using. | | | | | | | | | | | |
|  | **5.6** | Whenever balance shows weights out of the acceptance tolerance range, immediately withhold its use and handle it by referring current version of SOP for Calibration and Validation of Equipment, Instrument and devices (IP/QAD/SOP/017). | | | | | | | | | | | |
|  | **5.7** | External calibration (annual) of Balance will perform as per current version of SOP for calibration and validation of equipment, instrument and devices. | | | | | | | | | | | |
|  |  | (IP/QAD/SOP/017) | | | | | | | | | | | |
|  | **5.8** | Precautions and Cleaning : | | | | | | | | | | | |
|  |  | **5.8.1** | | | | Do not spill any solid or liquid material on balance. Do not use any aggressive cleaning agents (solvents or similar agents). | | | | | | | |
|  |  | **5.8.2** | | | | Make sure that no liquid enters the balance housing. | | | | | | | |
|  |  | **5.8.3** | | | | Wipe down the balance with a soft, dry piece of cloth. Clean the spillage after use to avoid cross contamination. | | | | | | | |
|  | **5.9** | Maintenance / Repairs: | | | | | | | | | | | |
|  |  | 5.9.1 | | | | If the weighing scale does not produce required calibration results and seem to be Out of calibration then withhold its use, immediately inform to QAD and proceed further as per current version of SOP Calibration and Validation of Equipment, Instrument and devices (IP/QAD/SOP/017). | | | | | | | |
|  |  | 5.9.2 | | | | If response of weighing balance is poor or if it requires any repair or maintenance then, it will labelled as “Under maintenance” and should be repaired or serviced. After completion of repair / maintenance work, it will be calibrated before use as per this SOP. | | | | | | | |
| **6.0** | **ABBREVIATION:** | | | | | | | | | | | | |
|  |  | | SOP | | | | : | Standard Operating Procedure. | | | | | |
|  |  | | QCD | | | | : | Quality control Department. | | | | | |
|  |  | | QAD | | | | : | Quality Assurance Department. | | | | | |
|  |  | | PRD | | | | : | Production department. | | | | | |
|  |  | | i.e. | | | | : | That is. | | | | | |
|  |  | | NA | | | | : | Not Applicable. | | | | | |
|  |  | | RSD | | | | : | Relative Standard Deviation. | | | | | |
| **7.0** | **REFERENCE:** OMCL and EDQM guideline for Qualification of equipment.  Eudralex Volume 4 Chapter 4 : Documentation (Sub Section :Others : 4.31) | | | | | | | | | | | | |
| **8.0** | **ANNEXURE:** | | | | | | | | | | | | |
|  |  | | Annexure I | | | | | | : | Calibration Record of 5 kg Electronic Weighingbalance | | | |
|  |  | |  | | | | | |  | (IP/STR/SOP/019/F01.02) | | | |
|  |  | | Annexure II | | | | | | : | Daily Verification record for 5kg Electronic Weighingbalance (IP/STR/SOP/019/F02.04) | | | |
| **9.0** | **REVISION HISTORY:** | | | | | | | | | | | | |
|  | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **SOP No.** | **Rev. No.** | **Effective**  **Date** | **Change**  **Control No.** | **Change History** | | IP/STR/SOP/019 | 00 | 14/04/2014 | - | New SOP | | IP/STR/SOP/019 | 01 | 01/11/2014 | IP/CCR/14/057 | Acceptance criteria, Procedural & Editorial Change | | IP/STR/SOP/019 | 02 | 20/12/2019 | IP/CCR/18/068 | 1. Company Logo Change. 2. SOP Format (Header) change. 3. Minor Procedural changes done in Section 5. | | IP/STR/SOP/019 | 03 | 23/08/2021 | IP/CCR/21/068 | 1. Change in SOP format as per SOP for SOP (IP/QAD/SOP/001). 2. Change in annexure format as per SOP for format numbering system (IP/QAD/SOP/059) 3. Minor editorial and procedural changes done in SOP. 4. Minor editing and formatting done in both annexure 5. Changes done in title of SOP as well as both   annexure. | | | | | | | | | | | | | |
|  | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **SOP No.** | **Rev. No.** | **Effective**  **Date** | **Change**  **Control No.** | **Change History** | | IP/STR/SOP/019 | 04 | 14/11/2022 | IP/CCR/22/065 | Incorporate reference of Eudralex volume 4 : Documentation reference and removed checked by sign in Annexure-II. | | IP/STR/SOP/019 | 05 |  | IP/CCR/24/005 | * Inline Warm-up time with equipment start-up time. * Warm-up time incorporated in annexure II of the SOP. | | | | | | | | | | | | | |