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1.0 Objective: 1.1 To lay down the procedure for the Operation and Calibration of Analytical Balance (ISHIDA).2.0 Scope: 2.1 This SOP is applicable for the operation and calibration of Analytical Balance in Analytical Development labs.3.0 References: 3.1 In-house.4.0 Responsibility:4.1 Executive/Officer Analytical Development Shall be responsible for the operation and lay down of the analytical balance.5.0 Accountability:5.1 AD Manager: For effective implementation of the SOP. 6.0 Procedure:6.1 Operating Instructions:6.1.1 Check the Spirit level of the balance given on the front side of the balance. It should be in the middle position.6.1.2 Balance warm-up time is 5 minutes for the stabilizing purpose after Power supply is ON.6.1.3 For Switching On, press the On/Off key, and for switching off press the On/Off key again from the front panel.6.1.4 After switching On the system will initialize and a normal weight display appears.6.1.5 The weight of any container/butter can be tared by the zero/Tare key and the display set to zero. The tarring range encompasses the entire weighing range of the balance. If you wish to tare a container, place this on the weighing pan. Close shield doors. Then press the zero/Tare key to start the tarring process. After completion of the process, the normal weight is displayed on the screen.6.1.6 If a container/butter paper is tarred on the balance when it is unstable, the tarring operation will be shown in the blinked display.6.1.7 After completion of tarring, the zero display appears and balance is ready for operation.6.1.8 Before Operating the Balance check for proper cleaning, Spirit level, and Daily verification as per the procedure. The above steps shall be performed at the beginning of the day or after any power failure, which leads to the shutdown of the balance for a longer time. Keep the balance always in condition for all the working shifts.6.1.9 Place the material and record the weight.6.1.10 After recording the weight, remove the material from pan and tare the weighing balance with the help of zero/Tare key.6.1.11 Care should be taken not to weigh above the given operating range.6.1.12 To change the weighing mg to gram Press and hold the Function key till 1 Set 1 icon displays repeatedly press the Function key till displays Then change 1 to 2 by using zero/Tare key.6.1.13 For any change then press zero/Tare key and For setting save press Function key and quit from this icon press Print key. 6.2 Cleaning:6.2.1 Disconnect the balance from power supply.6.2.2 Clean the external surface of the instrument using a clean lint-free cloth or soft brush.6.2.3 Only AD analysts shall clean the internal area of the instrument with 70% IPA.6.3 Handling of Weights:6.3.1 Ensure that the weights used are calibrated and certified.6.3.2 Always use forceps to place the weight on the balance pan.6.3.3 Do not drop the weight with force on the pan of the balance, to avoid any variation in the results.6.3.4 Weights used for calibration should be always cleaned with a soft brush and wiped with a clean dry mop before & after each use. 6.4 Daily verification of balance:6.4.1 Weighing Note:6.4.1.1 During operation all the sliding doors of balance shall be properly closed.6.4.1.2 Balance pan and surrounding shall be cleaned on pre and post weighing.6.4.2 For Solid:6.4.2.1 Take the Square pan size butter paper and keep it in the middle of the balance pan and tare the paper.6.4.2.2 Take the required amount of sample to be weighed and close all the sliding doors of balance and take print as gross weight.6.4.2.3 Carefully transfer the material to glassware/pots without striking the paper and put the butter paper on pan and take weight.6.4.2.4 Subtract the tare weight from the gross weight and get the net weight of the material.6.4.3 For Liquid:6.4.3.1 Put the container with having dry and clean bottom pan and tare the container. (Ensure that container weight is not more than 50% of the maximum weighing capacity of balance).6.4.3.2 Take the required amount of sample in a container to be weighed and close all the sliding doors of balance and take print as net weight and remove the container. Related: Daily Verification of Balance 6.5 Verification:6.5.1 Check the spirit level, if not leveled adjust the level with the help of spirit level indicator and use leveling screw situated at the base of the instrument.6.5.2 Perform internal calibration by pressing the relative key.6.5.3 Minimum weight for verification range shall be 2000 standard deviation of uncertainty measurement. Note: In the pharma industry, the general chapters (GC) and of the USP are widely recognized as standards for managing balances, and how a minimum weight is calculated is also stipulated in these chapters.According to the general chapters Balances, a balance used for samples that necessitate accurate weighing must be recalibrated over the operating range and meet requirements defined for repeatability and accuracy 6.5.4 In case of working range, maximum range shall be about 80% of the balance capacity.6.5.5 Place the standard weight one by one in the center of the platform of the balance and record the observation in Balance Verification Record refer to Annexure-II.6.5.6 If balance is moved from one place to another place, calibration shall be performed & verify the balance prior to use.6.5.7 If observations are out of tolerance limit, affix the Under maintenance label along with sign, and date and discontinue the use of the balance.6.5.8 Inform engineering department or service engineer of corrective action.6.5.9 Acceptance Criteria: Should be not more than 0.1% of reported standard value of respective standard weight or least of the balance whichever is higher. 6.6 Calibration (Monthly): Frequency 3 days.6.6.1 Following parameters shall be performed while performing calibration Accuracy Linearity Test Uncertainty Measurement Eccentricity Test 6.6.2 Accuracy:6.6.2.1 Check the accuracy of the balance using standard weight mentioned against the capacity of the balance.6.6.2.2 Place the standard weights one by one in the center of the platform of the balance and record the observation in the balance calibration record as per Annexure III.6.6.2.3 Acceptance Criteria: Should be not more than 0.1% of repeated standard value of respective standard weight or least of the balance whichever is higher.6.6.3 Linearity test:6.6.3.1 Linearity refers to the ability to deliver identical sensitivity throughout the weighing capacity of a balance.6.6.3.2 Put the following weight in the center of the weighing pan of balance as 100 mg, 500 mg, 1g, 5g, 50g, and 200g, and record the observation of each weight.6.6.3.3 Plot a graph of actual weight against observed weight.6.6.3.4 Acceptance Criteria: The correlation coefficient should not be less than 0.999. 6.6.4 Uncertainty measurement:6.6.4.1 Perform uncertainty measurement on 5.0g.6.6.4.2 Weigh selected standard weight 10 times and record the observation in annexure- II.6.4.3 Calculate mean and standard deviation from the above data.6.6.4.4 Calculate uncertainty for all the selected weights by using the following formula: 6.6.4.5 Acceptance criteria: Uncertainty is satisfaction if 2 standard deviation divided by the actual mass value, does not exceed 0.10%.6.6.4.6 If the standard deviation obtained is less than 0.41d, where d is the scale interval, replace this standard deviation with 0.41d. In this case, uncertainty is satisfaction if 2 0.41d, divided by the actual mass value, does not exceed 0.10%.6.6.5 Eccentricity test: 6.6.5.1 Eccentricity usually is expressed as the largest magnitude of any of the deviations between off centers reading for the least load.6.6.5.2 Place standard selected weight (50.0g) centrally on the pan and note down the result =R(1)Place standard at points 2, 3, 4, 5 and note down the result = R (2) .R (5) 6.6.5.3 Calculation: Subtract value R (1) from following R (2) .R (5)The maximum deviation of calculated difference is maximum differential eccentricity error.Example of eccentricity error differential calculation.Formula E = R (i) R (1) with E = eccentricity differential errorR (i) = following point indicationR (1) = central location indication. R (1) = 50.0003 g R (2) = 50.0001 g R (3) = 50.0004 g R (4) = 50.0007 g R (5) = 50.0003 g E (2) = 50.0001-50.0003 = -0.0002E (3) = 50.0004-50.0003 = 0.0001E (4) = 50.0007 -50.0003 = 0.0004E (5) = 50.0002-50.0003 = -0.0001 In this case, maximum differential eccentricity error is equal to approx. 0.0008 g. 6.6.5.4 Acceptance criteria: NMT 0.05 %6.6.5.5 Place the weight (30% of balance capacity or possible integer up to 30% of balance capacity as mentioned in the balance calibration record).6.6.5.6 If all the parameters fall within acceptance limit, affix the calibration status label.6.6.5.7 If any observation is out of limit, affix the under maintenance tag and discontinue use of balance.6.6.5.8 Inform service engineer or maintenance department of corrective action.6.6.5.9 After corrective action if balance is in working condition, recalibrate the balance prior to starting the activity.6.6.5.10 No repairs shall be done by another person except a qualified maintenance person or service engineer. 7.0 Abbreviations:SOP: Standard Operating ProcedureNo. : NumberDept. : DepartmentAD: Analytical Development% : PercentSD: Standard Deviationg: GramLCD: Liquid Crystal Displaymg: MilligramMin. : MinimumMax. : MaximumIHS: In-house specification 8.0 Annexures:8.1 Annexure I: Analytical Balance Logbook.8.2 Annexure II: Daily Verification Record of Analytical Balance.8.3 Annexure III: Calibration Record of Analytical Balance. Annexure Will be provided shortly Annexure I: Analytical Balance Logbook. Annexure II: Daily Verification Record of Analytical Balance. Annexure III: Calibration Record of Analytical Balance. Panks Pamyal is a Author and Editor at Pharmaguddu.com. He Worked in Top Pharmaceuticals MNCs in India had a more than 10 years experience in Quality control department. He Delivering most valuable insights and knowledge through this website. Analytical Balance SOP covers below points:General instruction for operation of analytical balance Calibration parameters for calibration of analytical balances.Daily calibration of Analytical balance: Monthly calibration of Analytical balance:Accuracy check Repeatability (Measurement of Uncertainty) Eccentricity check Off-Center Load Test Calibration format for Daily calibration of Analytical balance: Calibration format for Monthly calibration of Analytical balance.To define procedure for calibration of Analytical Balances.This procedure is applicable for following balances used in Quality Control Department. MakeModelNo.CapacityLeast countOperational rangeShimadzuAUW120D42 gm.01 mg1 mg to 10 gmCitizenCV220220 gm.01 mg50 mg to 200 gm Quality Control Chemist and above 5.1 OPERATION : General instruction for operation of analytical balances.The initial step to assemble the proper equipment, such as container for weighing, receiving vessels, forceps, spatula of proper size and so forth. Use containers of size such that the loading capacity of the balance is not exceeded. Ensure that the containers selected to receive the weighing material are clean and dry. The balance and the surrounding work area have to be kept neat and tidy. Balance door should be closed to stabilize the scale. Ensure that balance should be kept on vibration free platform. Ensure that air currents are not present on the location where the balance is installed. 5.2 CLEANING Clean the balance platform and display board with dry lint free clean cloth. Wipe the balance with wet lint free clean cloth. Wipe the balance platform with dry free clean cloth. In case of sensitive balance, clean the balance and the pan as per the procedure given below.Remove the dust from pan with smooth nylon brush. Remove the pan from the balance and clean it with wet lint free cloth. Fix the weighing pan properly on the balance. 5.3 CALIBRATION General instruction for calibration of analytical balances.If necessary, turn on the power, and allow the balance to equilibrate for at least 1 hour before proceeding with the calibration. Check the spirit level of the balance; adjust the level with help of mounting screws, if required. Before starting the calibration, standard weight should be kept on balance platform at room temperature for at least 15 minutes to reach thermal equilibrium. Required standard weight shall be kept one by one at the center of the weighing pan. Balance shall be verified daily for minimum, middle and maximum operational range of balance. Do not use any solvents or compressed air for cleaning of the weighing balance. Ensure the cleanliness of the instrument area. Ensure the balance is clean and free from dust. Balance shall be calibrated for the entire operational range of balances. Ensure all the standard weights should be clean. Ensure the balances are calibrated and verified before use. (All the standard weights should be calibrated once in year 30 days) Ensure the stamping by the Weight and Measure controlling authority once in year 30 days. In case of power failure, once the power is resumed, re-verify the balance and then start the further activity as per procedure. If it is required to use the balance for weight which is out of operational range, the balance shall be verified for that particular weight. The weight displayed should be within limit of tolerance. Use the balance only after rectification/ recalibration. If weight displayed is not within tolerance limit then stop weighing on the balance and label as Out of Order and inform to Engineering and QA departments. Out of Order label Daily calibration of Analytical balances.Analytical balances shall be verified daily by using standard weights mentioned as follows: MakeModelStandard weights usedShimadzuAUW120D1 mg, 500 mg, 5 gm & 10 gmCitizenCV22050 mg, 1 gm, 100 gm & 200 gm Acceptance criteria: Observed weight of corners should not exceed 0.10% of center position.Off-Center Load Test Place the standard weight on the center of the pan (Location A) and record the observed weight in calibration protocol (Figure-1) Without lifting move the standard weights between the center (Location A) and rear edge of the platform (Location B) & record the reading. Without lifting move the standard weight halfway between the center (Location A) and front edge of the platform (Location C) & record the reading. Without lifting move the standard weight halfway between the center (Location A) and left edge of the platform (Location D) & record the reading. 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