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What is friability test of tablet

Hardness refers to the breaking force of a tablet, measuring its mechanical integrity. It's essential to calibrate the equipment and ensure consistent testing conditions. The relationship between kiloponds and newtons is 1:1, but it's crucial to consider the orientation and shape of the tablet during testing. For accurate comparisons, tablets should have the same dimensions, weight, geometry, and orientation. However, unique shapes may require specific orientations for breaking force determination. Friability measures how easily a tablet loses its mass when tumbled in air or water. For smaller tablets (less than 650 mg), take a 6.5g sample of whole tablets. Larger tablets require a 10-tablet sample. Rotate the drum 100 times, remove loose dust, and accurately weigh the remaining tablets. The maximum acceptable mean weight loss is 1.0%. Effervescent and chewable tablets may have different friability specifications, while hygroscopic tablets need an humidity-controlled environment. Use a drum with a specific internal diameter and depth, rotating at 25 ±1 rpm. The drum should be polished to prevent tablet binding during tumbling. Hardness and Friability Testing in Pharmaceuticals: A Guide for Tablets Friability Test Procedure: Weigh tablets accurately, then place them in a drum called a friabilater and rotate them. Check tablet mass loss due to chipping as well as broken tablets. The test is performed to determine how much weight is lost due to mechanical shock during manufacturing, transportation, and delivery. It also checks the durability of tablets and the mass loss of tablet powder through chipping. 10 tablets are used for the test. Tablets weighing 6.5 grams or less are suitable if the unit weight is equal to or less than 650 milligrams. If a unit weight exceeds 650 mg, collect 10 tablets as a whole sample. Uncoated and compressed tablets are typically used in friability testing. The friability value is expressed in % and calculated using the formula: Friability = W1 - W2 / W1 X 100. W1 is the weight of the tablet before the test, and W2 is the weight of the tablet after the test. The test is usually run once, but may be repeated twice if necessary. The result is then returned as the mean of the three trials. The acceptance criteria for friability testing according to USP is that the test should not exceed 1% of the tablet's weight after 4 minutes or 100 rounds in the apparatus. Several factors can affect the friability test, including tablet design, hardness, punch condition, binder used, and moisture content of tablet granules. The procedure involves weighing tablets accurately, checking the calibration status of the apparatus, setting the test parameters, starting the testing, removing and re-weighing samples, and calculating the loss using the formula. If the result is outside the acceptable limits, repeat the test three times and determine the mean. The apparatus rotates the tablets at a specific speed for a set period, after which they are weighed again to calculate the friability using the formula: Friability (%) = [(Initial tablet weight – Final tablet weight) / Initial tablet weight] × 100. The test typically involves 6 to 10 tablets, randomly selected from different parts of the batch. Friability testing is essential in tablet manufacturing to ensure compliance with regulations and provide critical information about tablet quality. Maintaining low friability values is crucial for patient safety, regulatory compliance, and pharmaceutical product effectiveness. The test measures the weight loss of powder from the surface of tablets due to mechanical action, providing insights into tablet strength and robustness. By analyzing friability, manufacturers can identify potential issues with packaging integrity, patient satisfaction, and overall quality. The apparatus used for testing friability must have multiple drums, allowing for simultaneous testing of various samples. The test procedure for Friability Test is as follows: for tablets weighing less than or equal to 650 mg, a sample size of approximately 6.5 g is required; for heavier tablets, 10 whole units are sufficient. Prior to and after the test, tablets must be carefully de-dusted. The calculation for determining friability is given by: Friability (%) = (W1 - W2) / W1 * 100, where W1 represents the initial weight of the tablets, and W2 denotes the weight after tumbling. The acceptable limit for friability is not more than 1.0%. In cases where cracked or broken tablets are present in the sample after testing, the test fails. If the results are difficult to interpret or if the weight loss exceeds the targeted value (not more than 1.0%), the test may be repeated twice, and the mean of the three tests is calculated. A maximum mass loss of not more than 1.0% is generally considered acceptable for most products. In cases where tablets bind together during tumbling, it is essential to adjust the drum base to form an angle of approximately 10° with the horizontal surface. For hygroscopic tablets, a humidity-controlled environment is necessary for accurate testing. The calibration parameters for the friability test apparatus include a revolution per minute range of 24 to 26 RPM (25 ± 1 RPM), a time limit of 3 minutes and 50 seconds to 4 minutes and 10 seconds (4 minutes ± 10 seconds), and a frequency of quarterly tests. The friability test is crucial for determining the durability of tablets, granules, and spheroids before coating, packaging, and transportation in the pharmaceutical industry. The Friability Test Apparatus is used to evaluate the ability of tablets to withstand mechanical stress. The apparatus consists of a drum attached to a horizontal axis that rotates at 25 ± 1 rpm. The drum is equipped with dual scooping projections for running multiple samples simultaneously. During the test, tablets are tumbled in the drum and then dedusted and weighed before and after operation. The formula W = (W1 - W2) / W1 × 100 is used to calculate the friability, where W1 is the initial weight of tablets and W2 is the final weight after operation. A maximum weight loss of not more than 1.0% is considered acceptable for most products, but chewable tablets and effervescent tablets may have different specifications. Hygroscopic tablets require an appropriate humidity-controlled environment for testing. The test can be run once, or if defects are present, the sample fails the test. For granules and spheroids, two methods are available: fluidized-bed apparatus and oscillating apparatus. The friability test formula is F = m1 (100−T1) − m2 (100 − T2) m1 × 100, where F is the friability, T1 is the percentage loss on drying before the test, and T2 is the percentage loss on drying after the test. Inadequate binder or over-drying of granules can affect the results. The use of certain excipients, such as microcrystalline cellulose, can also impact the friability at lower compression pressures. The tablet design is influenced by several factors that affect its friability. To improve friability, it's essential to adjust binder levels, change weaker excipients, ensure proper drying of granules, and select the right tablet shape. Improving friability also involves optimizing hardness levels and using sufficient lubricants with the correct blending times. Additionally, adjusting pressure settings can enhance friability. The Friability Test of tablets is a crucial measure of their resistance to compression, packaging, and shipping. This test helps determine the strength of compressed tablets and is used in various pharmacopeias worldwide, including the USP, BP, Ph. Eur., IP, and JP. Friability refers to the weight loss of powder from the surface of tablets due to mechanical stress. The test measures weight loss during transportation or handling of tablets and is performed throughout production to ensure tablet integrity. The Friability Test Apparatus has specific standards for materials, dimensions, and specifications, including the drum's internal diameter, depth, outer diameter of the central ring, curved projection radius, and revolution per minute. References: 1. Lachman, Lieberman, H.A., & Kanig, J.L. (1986). The Theory and Practice of Industrial Pharmacy. 2. United States Pharmacopeia and National Formulary (USP 43–NF 38). 3. British Pharmacopoeia Commission. (2021). British Pharmacopoeia 2021. To determine the friability of a tablet, follow these steps: Collect an equal number of tablets from both sides of the chute and label them with their weight (if ≤ 650mg, use a 6.5g or less tablet). If the unit weight exceeds 650mg, collect 10 tablets as a whole sample. Always check calibration status before performing the test and ensure proper dedusting of tablets. Set parameters (rpm, time) & start the test. After completion, dedust the entire tablet and weigh it on the calibrated balance. Calculate friability using the formula: Friability (%) = ((W1 - W2) / W1) * 100, where W1 is the initial weight and W2 is the final weight after tumbling. Reperform the test three times if results fall outside limits. The acceptance limit for friability is not more than 1.0%. Weak tablets may be caused by poor design, low moisture content, insufficient binder, or over-lubrication.