Evaluation of soft gelatin capsules pdf

Drug product testing is generally divided into three stages: 1. In-process testing 2. Finished product testing 3. Shelf-life testingEvaluation of capsule drug products Drug product testing is generally divided into three stages: 1. In-process testing, during the manufacture of the drug product. These batteries of tests are carried out at predefined intervals during the product manufacturing, by the manufacturing personnel, and their results recorded on the batch record. Adverse findings in these tests can be used as a guide to alter the manufacturing-process parameters. 2. Finished product testing, after the whole batch has been manufac-tured. These tests help identify whether the batch is acceptable for marketing or its intended usage. 3. Shelf-life testing, after the whole batch has been packaged. These tests are frequently carried out after defined periods of storage at prede-termined conditions. They help to assign and verify the shelf life and usability of the drug product. In-process tests Visual inspection of soft gelatin capsules is done to ensure absence of clearly malformed, damaged, or improperly filled capsules. During the encapsula-tion of soft gelatin capsules, the following parameters are usually closely monitored and controlled: · Gel ribbon thickness and uniformity across the ribbon · Seal thickness · Weight of the capsule fill and its variation from capsule-to-capsule · Weight of the capsule shell and its variation from capsule-to-capsule · Moisture level of the capsule shell before and after drying Visual inspection, fill weight, and fill-weight uniformity are the key in-process tests used for hard gelatin capsules. Finished product quality control tests Permeability and sealing Soft gelatin capsules are tested for physical integrity (absence of leakage) by visual inspection. Similarly, hard gelatin capsules are tested for any breach of physical integrity (breakage or opened cap and body). Potency and impurity content All capsules are tested for drug content (potency, as a percent of label claim). In addition, most drug products are tested for the related substances or impuri-ties. These must meet predefined specifications for a batch to be acceptable. Average weight and weight variation Ten hard gelatin capsules are usually weighed individually and the con-tents are removed. The emptied shells are individually weighed and the net weight of the contents is calculated by subtraction. The content of active ingredient in each capsule may be determined by calculation based on the percent drug content in the formulation for high drug load formulations. For soft gelatin capsules, the gross weight of 10 gelatin capsules is deter-mined individually. Then each capsule is cut open, and the contents are removed by washing with a suitable solvent (that dissolves the fill but not the shell). The solvent is allowed to evaporate at room temperature, fol-lowed by weighing of the individual washed shells. The net contents are calculated by subtraction and the content of active ingredient in each of the capsules can be determined by calculation based on the percent drug content in the formulation. Fill-weight variation of capsules is often a function of equipment setup and filling operation. An automated capsule sizing machine and/or weight checker is frequently used to discard over- or underfilled capsules. Uniformity of content Uniformity of content of the active ingredient can be determined by weight variation of the fill of hard or soft gelatin capsules for high drug load (API ≥25% w/w of the total fill weight), high fill-weight (250 mg/capsule) formu-lations. For low drug load and low fill-weight formulations, each capsule must be analyzed individually by the potency method for the content of the active ingredient. The uniformity of content is assured if predetermined criteria for the range and variation in the content of the active ingredient are met. Disintegration Disintegration of hard and soft gelatin capsules is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the GI tract. The disintegration media varies depending on the type of capsules to be tested. Dissolution Drug absorption and physiological availability depend on the drug sub-stance being in the dissolved state at the site of drug absorption, viz. the GI fluids. The rate and extent of dissolution of the drug from the capsule dosage form is tested by a dissolution test. Dissolution test provides means of quality control in ensuring that (a) different batches of the drug prod-uct have similar drug release characteristics and (b) that a given batch has similar dissolution as the batch of capsules that was shown initially to be clinically effective. Moisture content Water content of the entire capsule or the capsule contents are determined by Karl Fisher titrimetry to enable the correlation of water content with the degradation profile or drug-release characteristics of capsules. Microbial content The capsules are tested to ensure lack of growth of bacteria and mold by microbiological tests. These tests are usually carried out by incubation of the capsule contents in a growth medium and counting the colonies formed after a predefined period of time. Selection of the growth medium and duration of the test, as well as maintenance of aseptic conditions during the testing, are critical to successful assessment of microbial contamination by this method. SlideShare uses cookies to improve functionality and performance, and to provide you with relevant advertising. If you continue browsing the site, you agree to the use of cookies on this website. See our User Agreement and Privacy Policy. SlideShare uses cookies to improve functionality and performance, and to provide you with relevant advertising. If you continue browsing the site, you agree to the use of cookies on this website. See our Privacy Policy and User Agreement for details. Capsules are solid dosage forms in which the drug formulation in a powder, solution or suspension, a combination of miscible liquid, or a simple liquid formulation is enclosed in a shell. Depending on the composition of the gelatin shell, the capsules can be hard or soft gelatin capsules. Hard gelatin capsules are typically used for powder or solid fills, whereas soft gelatin capsules are used for semisolid or liquid fills. Lately, hard capsules have also been used for liquid or semisolid fills. In capsule formulation development and during filling of capsules, a number of quality control tests are performed to ensure that capsules produced meet the requirements as specified in official compendium and conventional requirements established by the industries over the years. These tests will be discussed in three stages: in-process testing, finished product testing and shelf-life testing. In-process quality control tests for capsule drug products In-process quality control tests for capsule drug products are carried out at predefined intervals during the product manufacturing, by the manufacturing personnel, and their results recorded on the batch record. Adverse findings in these tests can be used as a guide to altering the manufacturing-process parameters. During the encapsulation of soft gelatin capsules, the following parameters are usually closely monitored and controlled: Gel ribbon thickness and uniformity across the ribbon Softgels seal thickness at the time of encapsulation Weight of the capsule fill and its variation from capsule-to-capsule Weight of the capsule shell and its variation from capsule-to-capsule Moisture level of the capsule shell before and after drying Visual inspection, fill weight, and fill-weight uniformity are the key in-process tests used for hard gelatin capsules. Read Also: Manufacture of Hard Gelatin Capsules Finished product quality control tests for capsule drug products Finished capsules are subjected to a number of tests in accordance with compendial standards and regulatory requirements for unit dose capsule products. These batteries of tests help identify whether the batch is acceptable for marketing or its intended usage. Finished capsules are evaluated by the following tests: a. Permeability and sealing Soft gelatin capsules are tested for physical integrity (absence of leakage) by visual inspection. Similarly, hard gelatin capsules are tested for any breach of physical integrity (breakage or opened cap and body). All capsules are tested for drug content (potency, as a per cent of label claim). In addition, most drug products are tested for related substances or impurities. These must meet predefined specifications for a batch to be acceptable. c. Weight variation test The uniformity of dosage units may be demonstrated by determining weight variation or content uniformity. The weight variation method is as follows. d. Weight variation test for hard gelatin capsules Ten hard gelatin capsules are usually weighed individually and the contents are removed. The emptied shells are individually weighed and the net weight of the contents is calculated by subtracting the weight of the shell from the respective gross weight. The content of active ingredient in each capsule may be determined by calculation based on the per cent drug content in the formulation. e. Weight variation test for soft gelatin capsules For soft gelatin capsules, the gross weight of 10 gelatin capsules is determined individually. Then each capsule is cut open with a suitable clean, dry cutting instrument (e.g., scissors or a sharp open blade), and the contents are removed by washing with a suitable solvent (that dissolves the fill but not the shell). The solvent is allowed to evaporate at room temperature over a period of about 30 minutes, followed by weighing of the individual washed shells. The net contents are calculated by subtraction and the content of active ingredient in each of the capsules can be determined by calculation based on the per cent drug content in the formulation. Fill-weight variation of capsules is often a function of equipment setup and filling operation. An automated capsule sizing machine and/or weight checker is frequently used to discard over- or underfilled capsules. f. Uniformity of content This test is performed only when the content is specified in the individual monographs and when capsules fail weight variation test. If the weight of capsules is completely filled no need of this test. Unless otherwise stated in the monograph for an individual capsule, the amount of drug substance, determined by assay, is within the range of 85.0 % to 115.0 % of the label claim for nine (9) of ten (10) dosage units assayed, with no unit outside the range of 75.0 % to 125.0 % of the labelled drug content. Additional tests are prescribed when two or three dosage units are outside of the desired range but within the stated extremes. Read Also: Manufacture of soft gelatin capsules g. Disintegration time test for capsules Disintegration of hard and soft gelatin capsules is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the gastrointestinal tract. The compendial disintegration test for hard and soft gelatin capsules follows the same procedure and uses the same apparatus described in the article “Quality Control Tests for Tablets”. The capsules are placed in the basket-rack assembly, which is repeatedly lowered 30 times per minute into a thermostatically controlled bath of fluid at 37 ± 2 ˚C and observed over the time described in the individual monograph. To fully satisfy the test, the capsules disintegrate completely into a soft mass with no firm core and only some fragments of the capsule shell. h. Dissolution test for capsules Drug absorption and physiological availability depend on the drug substance being in the dissolved state at the site of drug absorption. The rate and extent of dissolution of the drug from the capsule dosage form is tested by a dissolution test. This test provides means of quality control in ensuring that different batches of the drug product have similar drug release characteristics and that a given batch has similar dissolution as the batch of capsules that was shown initially to be clinically effective The compendial dissolution test for capsules uses the same apparatus, dissolution medium, and test as that for uncoated and plain coated tablets. However, in instances in which the capsule shells interfere with the analysis, the contents of a specified number of capsules can be removed and the empty capsule shells dissolved in the dissolution medium before proceeding with the sampling and chemical analysis. If the capsule floats on the surface of the dissolution fluid, a small, loose piece of nonreactive material, such as a few turns of a wire helix, may be attached to the dosage form to force it to sink to the bottom of the vessel. i. Moisture content Water content of the entire capsule or the capsule contents are determined by Karl Fisher titrimetry to enable the correlation of water content with the degradation profile or drug-release characteristics of capsules. j. Moisture permeation test The USP requires determination of the moisture-permeation characteristics of single-unit and unit dose containers to assure their suitability for packaging capsules. The degree and rate of moisture penetration is determined by packaging the dosage unit together with a colour-revealing desiccant pellet, exposing the packaged unit to known relative humidity over a specified time, observing the desiccant pellet for colour change (indicating absorption of moisture) and comparing the pre-test and post-test weight of the packaged unit. k. Microbial content The capsules are tested to ensure lack of growth of bacteria and mould by microbiological tests. These tests are usually carried out by incubation of the capsule contents in a growth medium and counting the colonies formed after a predefined period of time. Selection of the growth medium and duration of the test, as well as maintenance of aseptic conditions during the testing, are critical to successful assessment of microbial contamination by this method. Shelf-life test These tests are frequently carried out after defined periods of storage at predetermined conditions. They help to assign and verify the shelf life and usability of the drug product. Stability testing of capsules is performed to determine the physicochemical stability of the drug substance in the finished drug product under specified package and recommended storage conditions intrinsic stability of the active drug molecule and the influence of environmental factors (e.g., temperature, humidity, light), on formulation components, and the container and closure system. The battery of stress-testing, long-term stability and accelerated stability tests help determine the appropriate storage conditions and the product’s anticipated shelf life. References Allen L. and Ansel H. (2014). Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems. Philadelphia: Lipincott Williams and Wilkins. Aulton, M. and Taylor, K. (2013). Aulton’s Pharmaceutics: The Design and Manufacture of Medicines, (4th ed.). Edinburgh: Churchill Livingstone. Ghosh, T. and Jasti, B. (2005). 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