Q.C of Capsule

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Outline

- Definition
-Types of capsule
-In process quality control test
-Finish product quality control test
-Stability testing of capsule

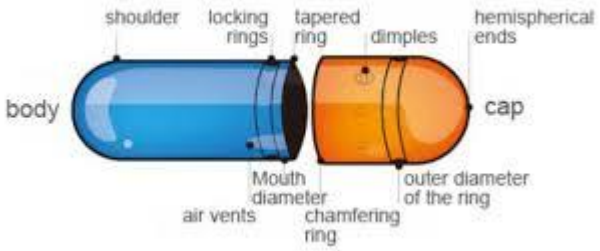
Definition

Capsule : is 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 gelatin shell ,the capsules can be hard or soft gelatin capsules

Hard gelatin capsules: typically used for powder or solid fills

Soft gelatin capsule: used for semisolid or liquid fills



In process quality control tests

- This test carried out by manufacturing personnel during the product manufacturing

- Adverse finding used as a guide to alter manufacturing – process parameters

- What is in process test for hard and soft gelatin capsule?

Finished product quality control tests

These tests help to identify whether the batch is acceptable for marketing or its intended usage

a- Permeability and sealing

b- potency and impurity content

C- weight variation test

- 20 capsule are selected and weighed individually, take average and compare each capsule weight with average
- Then test pass if none of the individual weight are less

Than 90% and not more than 110% of average weight

- If test requirements are not met we have to remove the powder , net content of powder can be weighed individually and compared with average net weight
- The requirements are met if not more than 2 of the individual`s difference is not greater than ± 10% of average . In any case difference should not be more than or equal to ± 25%

- if more than 2 and less than 6 net weights determined , they deviate ±10%. Then we go for additional 40 capsules.

- Net weight of 40 more capsules should be determined.

- In a total of 60 capsules not more than six should deviate from average by more than ±10% and none by more than ±25%

D- content uniformity test

- This test is performed when the capsule content specified in individual monograph and the capsule fail the weight variation test.

- If the weight of capsule is completely filled, no need for this test.

- In this test, 30 capsules are selected and 10 of them are assayed, so that by proper analysis, amount of drug can be determined

-If 9 10 in the specified potency range of 85 to 115% 10^{th} is in not outside 75 to 125%

- If more than 1 but less than 3 deviate, we have to go for remaining 20 and assayed

- Test requirements are met if none of capsules is outside 75-125% range (±25%) and not less than 27 of 30 are within 85-115% range (±15%) then particular batch passes this test

E- disintegration time test

-disintegration test for hard and soft gelatin capsules follows the same procedure and uses the same apparatus that used for tablet.

- Place one capsule in each of the six tube in the basket-rack, operate the apparatus for the specified period of time and the examine the state of capsules, all six capsules should disintegrate to pass the test

- Media : water

-temp.: 37±2 C°

F- Dissolution test

- This test is performed to ensuring that different batches of the drug product have similar drug release characteristics.

- Dissolution test of capsules uses the same apparatus and dissolution medium that used for Tablet

- Sampling after 45 min to be analysed spectrophotometrically, it should be not less than 75% of the labeled potency

G- microbial content test

- 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 period of time

Shelf – life test

- This tests are carried out after a period of storage at predetermined conditions to verify the shelf life of the drug product.

- Stability testing of capsules is performed to determine the physicochemical stability of the drug under specified package and recommended storage conditions