INDUSTRIAL PHARMACY-I

UNIT III-CAPSULES

CLASS:20

TOPIC Manufacturing defects. In process and final product quality control tests for capsules

Some **Capsule Filling Problems and Remedies** are provided below.

Problems	Causes	Remedies
Loss of cap during transfer	• High vacuum • Misalignment of cap and body	• Reduce vacuum • Check the alignment of the cap and body

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Dents and pinholes 	• Excess closing/lock length • Over-filling of capsules, • Incorrect pin size or pin configuration	• Ensure the correct size disc is used • Ensure the correct amount of dose is filled in the capsule

Cracks in Capsules 	• The transfer of moisture from the capsule shell to encapsulated components • Misalignment of the upper and lower capsule segments • Incorrect setting of the cap hold-down pin	• Store the capsule properly • Make a Proper setting of pin

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Telescopic Capsules 	• Misalignment of cap and body • Closing pin not in the center of body • Damage the rubber sheet of the closing plate	• Align cap/body bush to bush gauge. • Check pin straightness using a gauge pin • Wear off capsule closing the rubber

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Dusty Capsules 	• Filling dusty fill.	• Use capsule polisher

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Empty Capsules 	• Malfunction in capsule filling machine	• Make the sure presence of safeguards in the capsule filling

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Damaged band 	• Badly tuned banding process, such as improper wheel height and speed, improper processing temperature, improper band thickness, and poor/bad band wheel.	• Set all the parameters accurately.

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Capsule getting damaged during loading	• Misalignment of rectifier block with bushes	• Verify visually the alignment of rectifier block with the cap/body bush

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Capsule non-separation	• Insufficient vacuum • Leakage through filters • Cap body bush misalignment • Worn out bushes	• Proper capacity pump. • Right alignment of cap and body bush • Replace these bushes with a new one.

Problems	Causes	Remedies
Weight variation	• Wrong selection of dosing disc thickness • Incorrect gap between dosing disc and supporting pad, tamping pin and body bush,dosing disc and wiper block, dosing disc and body bush	• Kindly select the proper dosing disc for filling of powder fully onto the capsule shell • Correct the all the Gaps.

Problems and Remedy of Capsule Manufacturing

Problems	Causes	Remedies
Capsule lock length variation	• Excess joined length • Improper setting of the closing plate • Damage the rubber sheet of the closing plate • Incorrect setting of the closing plate	• Check for the standard locking length • Check for the gap between the closing unit rubber sheet and capsules • Wear off of capsule closing unit rubber sheet

QUALITY CONTROL TESTS OF HARD GELATIN CAPSULE

• Weight variation test
Content uniformity test
• Disintegration test
• Dissolution test
• Moisture permeation test

Weight Variation Test

Weigh 20 capsules individually and find the average weight. Individual weights should be within 90% - 110% of the average weight. If this is requirement is not fulfilled, then the weight of contents of each individual capsule is determined and compared with the average weight of the contents. The difference between the individual content weight and average content weight are determined. The contents of the shell are removed with the help of a small brush. The requirements are met, :- if not more than 2 of the individual differences are greater than 10% of the average content weight, or, :- when no capsule content weight is greater than 25%

If more than 2 but less than 6 of the individual differences deviate from the requirements said before,

• Individual content weight, is determined for another 40 capsules.
• Average of 60 capsules content weight are taken.
• The difference of the individual content weight of the previous 20 capsules and the next 40 capsules are determined from the new average content weight of 60 capsules.

• For the test to pass :-
a) Difference should not exceed 10% of the new average content weight of 60 capsules for a minimum of 6 capsules.
b) when no capsule content weight is greater than 25%
• Rotoweigh and Vericap 1200 determines the weight of individual capsules automatically and also rejects the under filled or overfilled capsules.

Content Uniformity Test

•30 capsules are selected, 10 of which are assayed as per the procedure mentioned in the specific monograph. •
The requirements are met :-
a) If 9 out of 10 are in the range of 85 – 115% potency.
b) 10th capsule is not outside 75 – 125%.
• if more than 1 but less than 3 fall outside 85 – 115%, then the rest of the 20 capsules are assayed.
• In that case, the test passes, when all the 30 capsules, are within 75-125% potency, and not less than 27 of the 30 capsules are within 85-115% potency.

Disintegration Test

• Sameapparatus as used in the evaluation of disintegration in tablets.
• To test the disintegration time, one capsule is placed in each tube of the basket assembly, and the basket rack is position in a medium at 37°C. Perforated plastic discs are placed on top of the capsules.
• The capsules complies with the test, if all the capsules disintegrate, and all the particles pass through the mesh screen in the specified time. If any residue remains, it must have only a soft mass with no firm core.
• If 1 or 2 fails to disintegrate, the test is repeated with 12 additional tablets.
• According to the IP, hard shell capsules take only a maximum of 30 minutes to disintegrate.

Dissolution Test

• Sameapparatus as used in the evaluation of dissolution in tablets.

• To test the dissolution or drug release from the capsule, USP Apparatus II – the rotating paddle type is used mainly.

• As the capsule comes in contact with the aqueous media at 37°C, capsule shell absorb water and swell.

• The rate of water penetration is inversely proportional to the thickness of the capsule shell. The shell ruptures at the shoulder of the cap an the body part.

• Rate of gelatin solubility is dependent on the temperature of the solution. As the temperature decreases, the solubility of the gelatin decreases.

Moisture Penetration Test

•Degree and rate of moisture penetration is determined by packing the capsules together. Expose the packaged unit to a known relative humidity over a specified time.

• The change in initial and final weight is determined.