INDUSTRIAL PHARMACY-I

UNIT III-CAPSULES

CLASS:22

TOPIC Packing, storage and stability testing of soft gelatin capsules and their applications.

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 and the influence of environmental factors.

Unprotected capsules rapidly reach equilibrium with atmospheric conditions under which they are stored.

Due to this property, effect of humidity and temperature, storage and packing conditions, effect of capsule content on the gelatin shell should be studied and the standards should be established.

Stability studies should be conducted by comparing test capsules and control capsule (capsule with just mineral oil).

The capsules must be set to an equilibrium conditions with 20 – 30% RH at 21 -24℃ before starting a stability study. The physical stability of soft gelatin capsules is associated primarily with the pick up or loss of water by the capsule shell.

the capsules should have satisfactory physical stability at temperatures ranging from the freezing point to as high as 60℃.

For unprotected capsules, stability test should be conducted as the following

Condition 1	Observation
RH lower than 20%, temperature lower than 2°C and greater than 38°C . Such a condition has only transient effects.	The transient effects are brittleness, susceptibility to mechanical shock. The capsule can return to normal when optimum storage conditions are provided. On returning to normal, capsule can become dull or may stick together.

Condition 2	Observation
RH greater than 45%, and temperature greater than 24°C	Capsule melts and fuse together
Condition 3	**Observation**
RH greater than 60%, and a reasonable temperature 21-24°C	Capsule shell picks up moisture. The capsule becomes softer, tackier, and bloated. The capsules do not leak unless any ingredient in the capsule attacks the gelatin under the influence of the moisture picked.

Manufacturer also conductsaccelerated physical stability study. The results of the study are then taken as a guide for reformulation of capsule content or capsule shell or for selection of retail package. The tests are done in the following conditions for two weeks

Tests conditions	Observation
Condition 1 :- 80% RH at room emperature in an open container	The results show a change in :- disintegration, leakage, unusual brittleness or softening of the capsule shell, loss of volatile ingredients from the capsule, widening of the corners of the capsule etc.
Condition 2 :- 40°C in an open container	
Condition 3 :- 40°C in a closed container (glass bottle with tight screw cap)	

Such defects observed in the results can be further corrected by changing the capsule content, gelatin content, colorants used, or the machine speed or machine dies.

• The control capsule should not undergo any changes other than Condition 1, as in such condition capsules have the effect of high humidity, and undergo picking up of moisture in the capsule shell.

• The stability studies and accelerated studies should be further conducted with capsules in its retail package.

Packaging of capsules

PACKAGING & STORAGEOF CAPSULES When bulk shipments of capsules are made by the manufacturer, they are temporarily protected from the normal changes in humidity by a suitable barrier such as 0.003 inch polyethylene bag within a standard fibre board carton. The bulk capsules should be stored in an air conditioned area in which the humidity does not exceed 45% RH at 21-24°C

Retail packaging of

capsules in the bulk shipment should be done in the similar conditions as soon as the shipments are opened, for the maximum physical and chemical stability of the product.

Capsules should be stored in glass or plastic containers or maybe strip or blister packaged, and stored at temperature not exceeding 30°C.

If the content in the capsules in glass or plastic container, are hygroscopic in nature, a packet of dessicant (eg. silica gel) is added to absorb any excess moisture present.

In strip packaging, capsules are tight sealed in aluminum or plastic film. In blister packaging, capsules are pushed out of the package, by a force given on any blister in the package

Applications of SoftGelatin Shell Capsules

• As an oral dosage form for human or veterinary use.

• As a suppository dosage form for rectal or vaginal use

• As a speciality package in the tube shape, for human or veterinary use of topical, ophthalmic, otic (ear) preparations.

• In the cosmetic industry, these can be formulated as a speciality package for breath fresheners, perfumes, bath oils, various skin creams etc