Chapter 9

Summary
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The disintegration of hard gelatin capsule was influenced by pH of the test medium. Acidic pH (1.2) favored disintegration of gelatin capsules as compared to alkaline pH (7.6).

The hard gelatin capsules filled with different excipients showed faster disintegration as compared to the empty hard gelatin capsules.

The disintegration time of hard gelatin capsules was strongly influenced by the temperature of the dissolution medium. The increase in temperature of dissolution medium from 25°C to 37°C showed drastic decrease in disintegration time.

The disintegration time of hard gelatin capsules was found to be dependent on the type of capsule content. The superdisintegrants retarded the disintegration of capsule especially when the capsules were stored at high humidity.

The combined effect of storage at high humidity (68% RH) and at high temperature (45°C) was more pronounced on hard gelatin capsule disintegration.

The results of photostability study demonstrated negligible increase in disintegration time of hard gelatin capsule.

Coated pin-holed hard gelatin capsules showed faster disintegration. Faster penetration of dissolution medium through the hole seems to be a crucial factor in controlling disintegration time.

Low viscosity grade (5 cPs) HPMC proved to be a better film-former and glycerol proved to be a better plasticizer for coating of capsules.

Pin-holed capsules and coated pin-holed capsules showed insignificant increase in disintegration time on storage at room temperature for a period of 90 days at 20 and 40% relative humidity.

Hard gelatin capsules or combination capsules or modified gelatin capsules did not pick up substantial amount of moisture when stored at 25°C at 20% RH for 28 days.
These capsules showed different water uptake when filled with different excipient. Cab-O-Sil containing capsules, except HPMC capsules (Hc+Hb), showed higher water uptake.

Gelatin (Gc+Gb) capsules showed substantial longer disintegration time and pellicle formation where exposed to formalin, Ultraviolet light or microwave energy.

The combination capsules showed faster disintegration (< 5 min). Similar results were observed in modified hard gelatin capsules where a hole was drilled and a coat of HPMC was applied on the inside surface of capsule.

The use of modified capsules is suggested when cost reduction is one of the objectives.

The results of long-term storage, i.e. 18 months, are in agreement with the results of short-term study.

All the types of capsules deformed when exposed to microwave energy for a period of 2 hr.

Cross-linked combination and modified capsules disintegrated in less than 5 min when stored at 25°C at 20% RH for 60 days.

Increase in disintegration time was not observed in HPMC and combination capsules, since hydroxypropyl methylcellulose is resistant to formalin treatment.

Cost reduction, as compared to HPMC capsules can be achieved by using combination capsules.

Further cost reduction in case of modified capsules was unsuitable for certain excipients like betacyclodextrin and lysine, although it was successful in case of polyvinylpyrrolidone solid dispersion.

The complexes of poorly soluble drugs could be used to get the maximum advantage of drug dissolution from combination capsules without hindrance of cross-linking.
Finally, it is concluded that the problem of poor drug dissolution should not be solved only by preparation of drug-excipient complex but the characteristics (disintegration and dissolution) of the dosage form should also be simultaneously considered.

The blend of gelatin and HPMC can be used for the preparation of films or hard capsule shells.

The hard capsules wherein a part of gelatin is replaced with HPMC showed quick release of tartazine, a model excipient, even after severe cross-linking treatment.

The idea of incorporating HPMC in gelatin dispersion can also be explored in preparation of soft gelatin capsules, which also shows cross-linking tendency.

The original characteristics of gelatin i.e. gloss and transparency remained unchanged on incorporation of small amount of HPMC in hard gelatin capsules.