

Gelatin Capsule Shell Cross-Linking

Tier II Dissolution Method Development in the Presence of Sodium Lauryl Sulfate

Xiling Song, Yong Cui, Minti Xie

Cross-linking in hard gelatin capsule shells is a common cause of slowdown in Tier I dissolution testing; however, direct addition of purified pepsin to the medium, as described in USP <711>, may not always be a solution if the medium contains sodium lauryl sulfate (SLS). The author develops a practical approach to avoid unwanted interaction between pepsin and SLS in dissolution Tier II tests.

Hard gelatin capsules are a common solid oral dosage form, but exposure to accelerated conditions, e.g. 40 °C and 75% relative humidity (RH), can cause capsule shell cross-linking. Capsule shell cross-linking arises from gelatin polymerization, a process facilitated by high temperature, high humidity, ultraviolet (UV) and visible irradiation, dyes, and aldehydes (1–4). The main impact of gelatin cross-linking is prolonged capsule disintegration time, and a subsequent slow-down of drug product dissolution rate. In the event that hindered dissolution arises from gelatin cross-linking and the product fails specification, USP <711> recommends the addition of enzymes (e.g., pepsin) to the dissolution medium to serve as the Tier II dissolution test (5). It is important, though, to confirm that dissolution failure is a direct outcome of cross-linked gelatin shells rather than degradation of drug product performance.

Sodium lauryl sulfate (SLS) is a surfactant commonly used in dissolution medium to improve the solubility of poorly water-soluble drugs. The presence of SLS in dissolution medium deactivates pepsin, which complicates the Tier II method described above (6). One option would be to redevelop the dissolution method and abandon SLS. But this option could be costly in time and resources, and may discourage the use of SLS in capsule formulations in general, despite its excellent solubilizing capability, low cost and ease of use. Performing Tier II dissolution tests in the presence of SLS is considered beneficial to the development and quality control of capsule formulations.

This article will detail the experimental procedures and the study results of a case where the above issues were encountered and tackled in the development of a capsule formulation. A slowdown in dissolution rate was discovered for the gelatin capsule formulation when it was stored at accelerated conditions of 40 °C and 75% RH for three months.

Materials

Size one opaque hard gelatin capsule shells were purchased from Capsugel. Dissolution was performed using USP Apparatus II (paddles), Model VK 7000 (Varian). Stand-alone UV-Vis spectrometer with diode array capacity, Model 8453, was from Agilent. Capsule sinkers (size 8/23) were from Sotax. SLS (reagent

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