Understanding capsule compatibility with lipid-based formulations: 2. Assessment of mechanical properties of gelatin and HPMC capsules after equilibration with formulations

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METHODS

In a second set of experiments, size 0 gelatin and HPMC capsule caps were immersed in different formulations for 2 weeks at 25°C, after which they were collected and carefully cleaned. The mechanical capsule properties, i.e., elastic stiffness, and elongation at break, were assessed using a texture analyzer (tensile rig: force in tension mode at a speed of 0.5 mm/s, Figure 2).

RESULTS AND DISCUSSION

The second set of experiments focused on the formulation-capsule shell interface. Mechanical results obtained for capsule caps immersed in formulations clearly showed that gelatin capsules were affected by the water content of the formulation, with considerable softening being observed for $\phi_w > 0.04$. These results were similar for formulations containing either Tween 80 or Kolliphor EL as surfactants and could be correlated with the thresholds determined in part 1 of this work for water channel formation [6]. Interestingly, HPMC capsules were found to be particularly robust and comparatively less affected by the presence of these continuous channels in the formulation.

CONCLUSIONS

It was shown that knowledge of the microstructural changes in lipid-based formulations (e.g., formation of water channels) is helpful for pharmaceutical scientists to overcome shell incompatibility and therefore to design quality into the final dosage form. Overall, HPMC capsules proved to be less sensitive to the presence of water in formulations than gelatin capsules. Furthermore, it was shown that the method of storage and analysis of the mechanical properties of capsules is of critical relevance for compatibility assessment.

REFERENCES