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Evaluation on Stability of Plant-Based Softgels (SeaGel® Technology) versus Gelatine Softgels

Jin Zhao[a], Becca Putans [a], Thomas Watson [a], Michael Evangelista[b], Ian Gillespie [a], Jeremy Barnes[b], Mohammad Qadir[c] *

[a]The International Flavors and Fragrances (IFF), Midland, MI 48674, USA, addresses, Country, [b] IFF, Wilmington, DE 19803 USA, [c] IFF, Pharma Solutions, 1st Floor, Reigate Place,43 London Road, Reigate, RH2 9PW, UK

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*Corresponding author.
Tel.: +447792371103
E-mail:
Mohammad.Qadir@iff.com

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SUMMARY

In this study, a simple model fill formulation of Ibuprofen was encapsulated using either gelatine as the shell-forming material or a plant-based material based on IFF's SeaGel® technology (noted as SeaGel® softgels). The result indicates a similar performance at time zero between animal-sourced material (gelatine) and plant-based material (SeaGel®). Importantly, at accelerated conditions, SeaGel® showed no change in performance in disintegration and dissolution over 6 months of stability compared to gelatine which showed significantly slower disintegration and dissolution behaviour than freshly produced gelatine softgels. This work indicates the superior performance of gelatine alternative SeaGel® softgels during stability and long-term performance.

INTRODUCTION

Softgels continuously serve as a preferred dosage form for oral drug delivery in pharma and dietary supplements. As softgels can easily encapsulate a variety of liquid and semi-solid formulations especially for poorly soluble active pharmaceutical ingredients (API), also they can be used to enhance the bioavailability of active ingredients. Additionally, they are easy to swallow, help in masking unpleasant odours and tastes, and allow a high amount of active ingredients in one dose[1]. Gelatine softgels currently dominate the pharmaceutical industry, but there are numerous challenges with the material. For instance, gelatine has the potential to crosslink with active ingredients leading to the reduced solubility of the capsule shell. Gelatine is sensitive to high temperature and high/low humidity conditions, presenting challenges with the storage and shipment of gelatine softgels. There is also a growing consumer preference for non-animal products to suit different dietary needs (vegan, halal, kosher, etc). In this study, a simple model fill formulation was used to encapsulate a poorly soluble API, Ibuprofen (IB), using either gelatine as the shell-forming material or a plant-based material based on IFF's SeaGel® technology (noted as SeaGel® soft gels).

Comparative data was generated using both USP I method and the modified USPI/HPLC method was used to study the dissolution behaviour of Ibuprofen from gelatine and SeaGel® soft capsules stored at both accelerated conditions (40 ºC, 75% RH) and long-term conditions (30 ºC, 65% RH) for more than 6 months.

MATERIALS AND METHODS

Gel masses of gelatine or SeaGel® (carrageenan and modified starch) were prepared on a Ross CDA-4 mixer. The prepared gel masses were then transferred to a rotary die process using a Farmateck FTK55

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encapsulator. Capsules were made using size 7.5 oval dies and filled with 400 mg of a 7.3 wt % IB in medium chain triglycerides (MCT).

Capsule disintegration was tested using a disintegration tester (model QC-21, Henson) as described in USP <701>. A modified USP I method was used for in vitro dissolution experiments with Agilent 708-DS and spectrophotometer Carey 60. HPLC analyses of IB were also conducted using an Agilent chromatograph consisting of G1311B pump, G1329B autosampler, G1316A oven, and G1314F UV detector. Capsule burst strength, elasticity, and hardness was measured using a texture analyser with TA-4 probe and 1 mm/s compression speed for burst, and 0.1 mm/s compression speed for hardness.

RESULTS AND DISCUSSION

For freshly produced SeaGel® and gelatine softgels, it was observed that the plant-based SeaGel® softgels have slightly slower disintegration and delivery at a dissolution time of less than 80 minutes. However, the f2 similarity factor of SeaGel® to gelatine softgels was greater than 52 at all time points, which indicates an average difference of less than 10% between SeaGel® softgels and gelatine softgels. Additionally, when stored at accelerated storage conditions for up to six months, SeaGel® softgels showed no change in disintegration or dissolution performance while gelatine softgels showed significantly slower disintegration and dissolution behaviour than freshly produced gelatine softgels. As an example, Figure 1 shows a comparison of disintegration time as a function of storage time. Furthermore, the mechanical properties of gelatine softgels indicated possible cross-linking and migration of fill components and have higher variability than SeaGel® softgels as a function of aging time and aging conditions. This is consistent with similar findings of other scientists[2].

CONCLUSIONS

Dissolution of an active in the dosage form is critical for absorption and bioavailability and for product quality and consistency assessments during the drug product life cycle. SeaGel® softgels showed approximately equivalent API dissolution behaviour as that of gelatine capsules at the time of capsule production, but better stability than that of gelatine softgels.

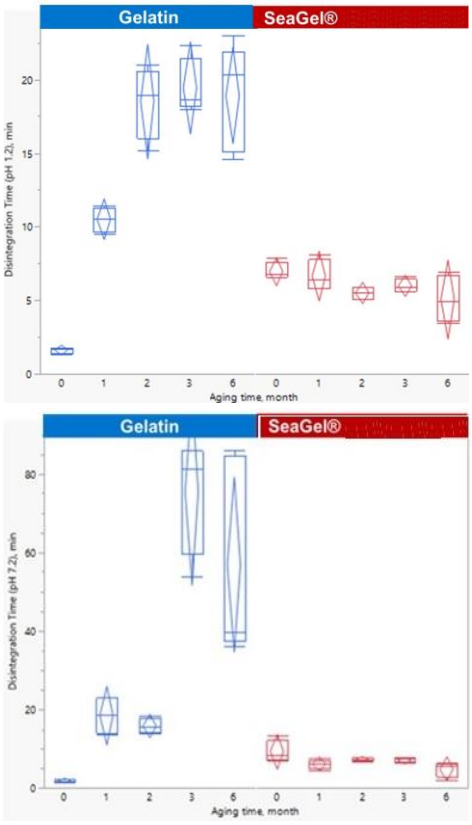

Fig. 1. *Comparison of disintegration time for gelatine softgels and SeaGel® softgels in buffer dissolution medium (a) pH 1.2 and (b) pH 7.2 under accelerated storage conditions 40 °C and 75% RH.*

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REFERENCES

Rampurna Prasad Gullapalli, 2010, Soft Gelatin Capsules (Softgels), JPS, V 99, Issue 10, P 4107-4148

Murthy KS, Ender NA, Fawzi MB, 1989, "Dissolution Stability of Hard-shell Products. Part I. The Effect of Exaggerated Storage Conditions". Pharm Technol; 13: 72-84