Hypromellose Hard Capsules – Reproducibility of the
In Vitro Dissolution Performance in USP SGF Media

E. Groshens, X. He, D. Cade1
Chemical R&D Department, Capsugel, Division of Pfizer, 10, rue Timken F-68027 Colmar Cedex, France
1Dominique.Cade@pfizer.com

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Chemical R&D Department, Capsugel, Division of Pfizer, 10, rue Timken F-68027 Colmar Cedex, France

**Key words:** Hypromellose capsule, dissolution, reproducibility

**PURPOSE**

Hypromellose is a good alternative material for gelatin hard capsules. However the use of gelling agent impacts the *in vitro* dissolution profiles of HPMC capsules.

The present study confirms the high reproducibility of *in vitro* dissolution performance of Capsugel pure Hypromellose hard capsules Vcaps® Plus between lots, between manufacturing machines and between manufacturing locations when tested with caffeine 100 mg formulation and pH 1.2 media.

**METHODS**

Samples of Capsugel Vcaps® Plus: Industrial production from Capsugel Colmar (France), Capsugel Puebla (Mexico) and Capsugel Sagamihara (Japan) plants.

Dissolution testing: *in vitro* dissolution tests are performed with a blend: fill weight 400 mg. Composition: Caffeine / Lactose / Croscarmellose 25/65/10.

Method: USP dissolution apparatus 2 (paddle) 50 rpm 37 °C; 900 ml USP SGF(1) fluid without enzyme, Sotax dissolution sinker. Sampling times: 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 35, 40, 45, 50, 55, 60 minutes. Caffeine assay UV wavelength 293 nm.

Equipment: Dissolution test equipment Sotax AT70 or Vankel VK 7000 and Perkin Elmer Lambda 25.
RESULTS

• Reproducibility within batch: three in vitro dissolution tests (n=6) performed with capsules from the same box.

Comparison of the averages:

• Reproducibility between batches: three in vitro dissolution tests (n=6) performed with capsules from the different boxes.

• Reproducibility between manufacturing machines: three in vitro dissolution tests (n=6) performed with capsules from three different capsules production machines and different sizes.

CONCLUSION

We confirmed the high reproducibility of in vitro dissolution performance within sample, between lots, between manufacturing machines and between manufacturing locations for Capsugel pure Hypromellose Vcaps® Plus capsules.
REFERENCES

• (1) USP <711> Dissolution - Simulated Gastric Fluid TS without pepsin

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