

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

**E. Groshens, X. He, D. Cade<sup>1</sup>**

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

<sup>1</sup>Dominique.Cade@pfizer.com

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E. Groshens, X. He, D. Cade<sup>1</sup>

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.

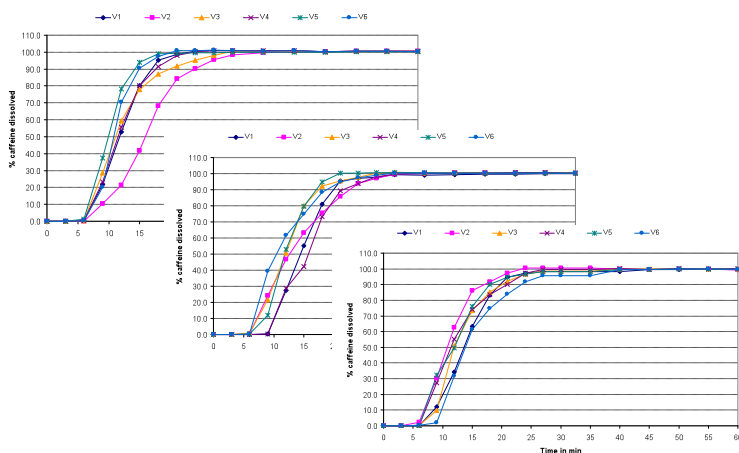
Method: USP dissolution apparatus 2 (paddle) 50 rpm 37 °C ; 900 ml USP SGF(1) fluid without enzyme, Sotax dissolution sinker. Sampling times: 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 35, 40, 45, 50, 55, 60 minutes. Caffeine assay UV wavelength 293 nm.

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



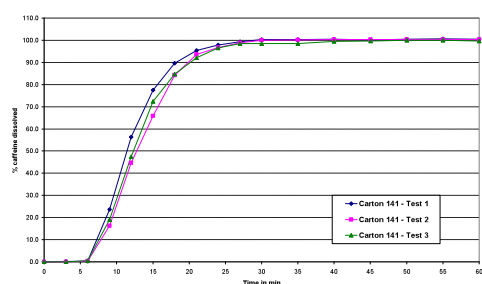
## RESULTS

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

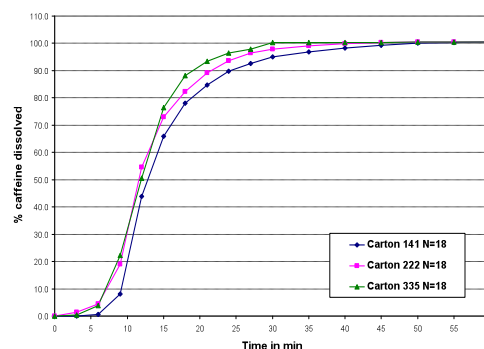


- Reproducibility within batch: three *in vitro* dissolution tests (n=6) performed with capsules from the same box.

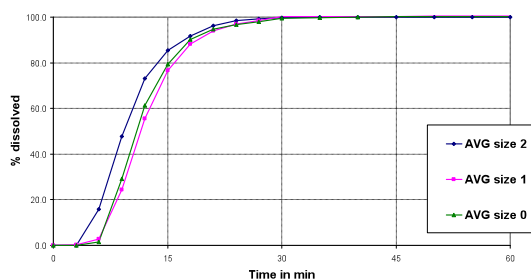
Comparison of the averages:



- 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

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