IMPACT OF MASKING ON METHYLPHENIDATE DISSOLUTION FOR OVER ENCAPSULATED CAPSULES OF RITALIN LA 10 MG

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Background

- Drug development for a double-blind clinical trial
- Over-encapsulated capsules + backfilled excipient for masking
- Ritalin LA (Extended release) containing 10 mg Methylphenidate (MH) - Bimodal release of RITALIN (SODAS® technology)

Objective

➢ To study the potential impact of masking in over-encapsulated capsules on MH dissolution compared with bare capsules, thanks to in vitro biopharmaceutical parameters.

Methods

- MH dissolution study : - bare capsules (n=6) - over-encapsulated (n=6)
  Backfilled excipient = microcrystalline cellulose (MC)
- 2 release phases : 1 unique dissolution medium = a Britton-Robinson buffer at 37°C → pH 2 for 2h → pH 6.8 for 3h
- Basket dissolution apparatus (EurPh 2.9.3) at 50 rpm
- 15 samples/capsule

- Desintegration test (EurPh 2.9.1)

Conclusions

➢ A similarity between over-encapsulated and bare capsules is demonstrated by using MC.