eurofins | BioPharma Product Testing

Release testing of semi-solid forms : expertise needed

- Do you need to evaluate the release of your active ingredient from a semi-solid form following a change of manufacturing process or of component/excipient?
- Do you want to compare the release of your active substance during a screening of formulas under development?

EUROFINS ASSISTS YOU

- To meet the requirements of USP 1724
- To choose your formulation

CASE STUDY :
USP<1724> SEMISOLID DRUG PRODUCTS - PERFORMANCE TESTS

«...The product performance test can be used to assess sameness of the drug product after post-approval changes...»

«...Product performance tests do not directly measure bioavailability and relative bioavailability (bioequivalence), they can detect in vitro changes that may correspond to altered in vivo performance of the dosage form.»

USP<1724>

"Drug Release Rate Determination Using Immersion Cell Apparatus"
Comparison of cutaneous Gel containing the same API (5g%g)

DRUG RELEASE CONDITIONS

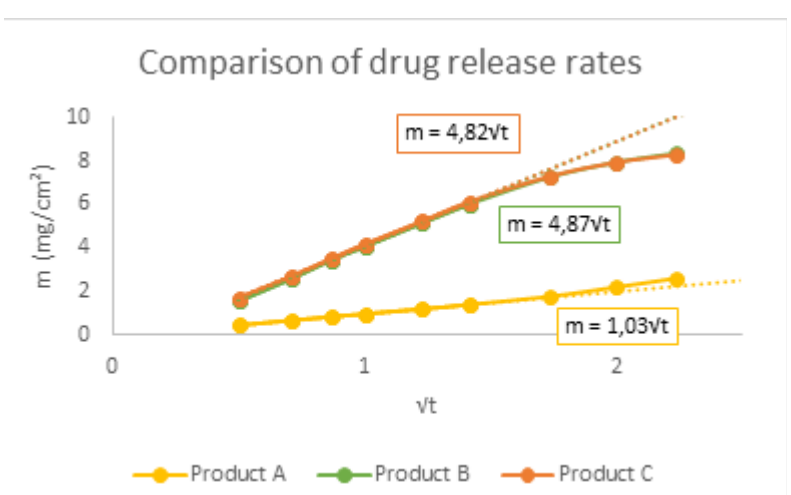
- Apparatus: Immersion cell Model A and B
- Membrane: Hydrophilic polypropylene
- Dissolution medium: Acetate buffer pH 5.5
- Volume in each vessel: 150mL
- Bath temperature: 37°C ± 0.5°C
- Rotation speed: 50rpm
- Sampling times: 15min, 30min, 45min, 1h, 1h30, 2h, 3h, 4h, 5h
- Sample volume: 3mL (replaced)
- Sample filtration before HPLC analysis: 0.45µm GHP

SAMPLES ANALYSIS

- Assay of released API by HPLC
- Column: Zorbax ODS C 18 250 x 4,6mm ; 5µm particle size
- Column Temperature: Room temperature
- Flow rate: 1.0mL/min
- Wavelength: 245nm
- Run time : 10min
- Volume of injection: 20µL
- Mobile phase (isocratic mode) : Acetic Acid 1% / Acetonitrile R (25/75)

PROFILES OVERLAY - RELEASE RATE COMPARISON

"...The individual amount (mg/cm²) of drug released is plotted versus the square root of time. The slope of the resulting line is the rate of drug release."



Impact of permeation enhancer/solvent : Product B (enhancer 1)/ Product C (enhancer 2)

Combining concentration and Enhancer type, no significant change observed on drug releasebetween Product B and product C

Impact of gelling agent: Product A (gelling agent 1) / Products B and C (gelling agent2)

Change of gelling agent type has a significant impact on drug release.

WHY CHOOSE EUROFINS BIOPHARMA PRODUCT TESTING ?

- A network of laboratories on a human scale
- Performing analyzes according to EP, USP, JP pharmacopoeia
- A fleet of advanced equipment with different types of dissolution equipment (1 to 6)
  - USP app. 1 and 2 (Basket / Paddle)
  - USP apparatus 3 and 4 (Reciprocating Cylinder/ReciFlow-through cell)
  - USP app. 5 and 6 (Paddle over disc - Ph.Eur. Celle method/Cylinder)
  - Franz cell (Vertical diffusion cell)
  - Moll-Bender cell/Enhancer cell
  - In-situ monitoring with fiber optic
  - USP/Ph. Eur. intrinsic and apparent dissolution testing apparatus
  - Chewing-gum tester

CONTACT US

Email : laurahoyez@eurofins.com

Phone: + 33 (0)5 34 47 05 65