Dissolution testing for novel drug delivery systems

Disso India 2015 Conference

Goa – August 31th & September 1st 2015

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SPS: Who we are?

- Created in 2005
- Located in Orleans (France)
- Clients in Europe, America, Asia
- CRO specialized in *in vitro* dissolution and release testing
- Creation of a knowledge network for the benefit of disso users
- "Developing dissolution": Academia collaborations…

SPS: Who we are?

- cGMP compliant facility
- All analytical techniques: HPLC, UPLC, UV-Vis
- All compendial dissolution techniques
- Experts for automation (dissolution, sample preparation…)
- Experience on fast dissolving as well as long-acting products
- Consulting for manufacturing troubleshooting, failed BE, IVIVC

Outline

– Introduction

– Semi-solids topical forms

– Parenteral forms

– Lipophilic dosage forms

– Medical devices

– References and conclusion

Abstract (1)

New types of formulations and drug delivery technologies call for a new approach to in-vitro drug release testing.
Indeed, characterizing drug release rate is of outmost importance and traditional dissolution methods such as paddle and basket are not tailored to these novel dosage forms.

Products such as medical devices, combination products, injectable suspensions, nanoparticles and other parenteral formulations can be challenging when it comes to the development of a dissolution method:

- the physiological conditions are different than the GI tract
- the release timeframe can range from hours to months
- drug concentration is not always related to therapeutic effect
- etc…

Abstract (2)

Moreover, different dissolution methods may be developed throughout the lifecycle of the product.
These method developments should be driven by the final purpose of the method:

- Formulation screening / comparison (including generic vs RLD)
- IVIVC (In Vitro- In Vivo Correlation)
- Quality Control

The flow through cell technique is able to fulfill the requirements of such complex formulations. Its flexibility and ability to characterize the release properties of a wide variety of formulations make it a powerful tool for pharmaceutical development as well as for QC often ensuring a better discrimination thus better safety for the patient.
This presentation will present and discuss current and new applications related to the USP Apparatus 4.

Any question…

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