Nasal Biopharmaceutics: fit for current and future drug delivery needs?

Ben Forbes
(King's College London)

and

Claire Patterson (SEDA), Chris Roe (Quotient),
Alison Lansley (University of Brighton)

Nasal Biopharmaceutics:

fit for current and future drug delivery needs?

Wednesday 7th December 2022

09:00 – 11:40

Pentland Auditorium, EICC

A number of the scientific and regulatory hurdles that exist for developing and registering new nasally-delivered therapies provide common challenges across the pharmaceutical industry. This meeting represents an opportunity to bring together members of the scientific community across industry and academia to discuss specific biopharmaceutics challenges around the development of nasally administered therapies. Aims of the symposium include exploring the need for a network for regular meetings and collaboration, and the development of a consensus of the state-of-the–art in nasal biopharmaceutics.

The symposium will feature thought-provoking short talks summarising how we currently assess the biopharmaceutical properties and performance of nasal products with a focus on new developments and unmet needs. This will be followed by a facilitated panel discussion to explore current practices, opportunities and challenges in these areas. Any questions regarding the workshop programme may be directed to Ben Forbes, King's College London (ben.forbes@kcl.ac.uk).

Hosted by: DDL2022 DRUG DELIVERY TO THE LUNGS

NASAL BIOPHARMACEUTICS: fit for current and future drug delivery needs?

Time	Presentation	Presenter
09:00- 	**Introduction**	Ben Forbes, King's College London
09:05 	**Nasal biopharmaceutics: current and new methods for characterisation** • The T4N concept • Developments in in vitro testing of nasal products • Assessment of < 10 µm fraction	Regina Scherließ, Kiel University, Germany
09:20 	**Physiologically-based biopharmaceutics modelling for nasal delivery** • Applications of PBBM modelling in nasal drug delivery • Current status of nasal PBBM models • Future opportunities/call to action	Claire Patterson, SEDA, UK
09:40 	**Modelling deposition in the nasal cavity** • In silico models • In vitro methods • Realistic and idealised geometries	Andrew Martin, University of Alberta, Canada
10:00 	***In vitro* biopharmaceutical characterisation** • Cell models of the nasal cavity • Role of mucus • Role of mucociliary clearance	Alison Lansley, University of Brighton, UK
10:20	Refreshment Break	
11:00 	**Preclinical models and translation** • Nasal delivery study trends • Pre-clinical development for nasally administered medicines • Practicalities of nasal studies and future developments in study design and methods	Helen Palmer, Labcorp, UK
11:20 	**Clinical development** • Scintigraphic / MRI imaging and analysis of nasal delivery • Product and device performance evaluations • Nasal wick evaluations	Chris Roe, Quotient, UK
11:40 	**Panel discussion** • Gaps in biopharmaceutics for nasal delivery • Future directions and gap analysis: • Challenges and opportunities	All presenters
12:00 – 13:00	Networking Lunch in the Exhibition Hall for all DDL2022 Delegates	

STIMULI TO THE REVISION PROCESS

Stimuli articles do not necessarily reflect the policies of the USPC or the USP Council of Experts

Testing the In Vitro Product Performance of Inhalation and Nasal Drug Products: Views of the USP Expert Panel[a]

Masahiro Sakagami[b] and Nikoletta Fotaki[c]

Correspondence should be addressed to: Kahkashan Zaidi, Senior Principal Scientist, US Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852-1790; tel: +1 301-816-8269; email: kxz@usp.org.

ABSTRACT

While inhalation and nasal drug products are available as various different drug-device combination products for the treatments of local and systemic diseases, their compendial performance testing has concerned only delivered dose uniformity (DDU) and aerodynamic particle/droplet size distribution (APSD). This Stimuli article presents the views of the USP Expert Panel on New Advancements in Product Performance Testing (EP-NAPPT), providing the gap analysis and the recommendations for in vitro product performance testing for these local and systemic drug-device combination products. The gap analysis identified the following performance testing areas to be improved: 1) in vivo-predictive lung and nose delivery testing; 2) fast particle/droplet size testing; 3) spray pattern and plume geometry testing; 4) drug release/dissolution testing; and 5) in vitro product performance and physiologically-based pharmacokinetic (PBPK) modeling. Recommendations were then made to each area for identification of testing needs and improved in vivo prediction.

Workshop Aims

This morning:

- Enhance understanding of nasal biopharmaceutics
- Identify key challenges in development of nasal medicines
- Evaluate new/emerging methodologies for nasal biopharmaceutics
- Discuss best practices for developing and assessing nasal medicines
- Discuss translation of findings from pre-clinical to clinical settings

Post meeting:

- Nasal Drug Delivery posters at DDL
- Your feedback
- Meeting report
- Follow up activity

Please enjoy the meeting!