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International Association for Pharmaceutical Technology
Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein

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APV NEWS

2024

14th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology

Vienna, Austria

18 - 21 March 2024

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Lokale Gruppen

Donnerstag, 20. Juli 2023

Lokale APV-Gruppe Rhein-Neckar ab 19:00 Uhr. Der Veranstaltungsort wird noch bekanntgegeben.
Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Dr. Viktoria Riedel (viktoria.riedel@schwabe.de).

Dienstag, 25. Juli 2023

Lokale APV-Gruppe Rhein-Main ab 19:30 Uhr. Der Veranstaltungsort wird noch bekanntgegeben.
Weitere Informationen und Angaben zu dem Veranstaltungsort sowie den nächsten Terminen erhalten Sie bei Cathrin Pauly (pauly@aspiras.de).

Dienstag, 19. September 2023

Lokale APV-Gruppe Berlin ab 19:00 Uhr bei der PDA Europe (Am Borsigturm 60, 13507 Berlin).
Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Dr. Andreas Sachse (andreas.sachse@cpl-sachse.de).

Lokale APV-Gruppe Ulm/Biberach/Ravensburg/Bodensee
Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Dr. Martin Müller (martin.mueller@vetter-pharma.com).

Lokale APV-Gruppe Basel
Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Dr. Lars Restetzki (lars.restetzki@roche.com).

Lokale APV-Gruppe Westfalen
Weitere Informationen und Angaben zu den nächten Terminen erhalten Sie bei Dr. Johanna Anlahr (johanna.anlahr@bayer.com).

Lokale APV-Gruppe Nordrhein
Weitere Informationen und Angaben zu den nächten Terminen erhalten Sie bei Klaus Wening (klaus.wening@grunenthal.com).

Lokale APV-Gruppe Mecklenburg-Vorpommern
Weitere Informationen und Angaben zu den nächten Terminen erhalten Sie bei Katharina Tietz (katharina.tietz@uni-greifswald.de).

Lokale APV-Gruppe Oberbayern
Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Dr. (USA) Julia Schulze-Nahrup (jsn@pharmoveo.de).

What´s hot in European Journal of Pharmaceutics and Biopharmaceutics?

Elena Richert, Ludwig-Maximilians-Universität, D-München

Air-liquid interface (ALI) impact on different respiratory cell cultures

Soraia Silva, Joana Bicker, Amílcar Falcão, Ana Fortuna

The intranasal route has been receiving greater attention from the scientific community not only for systemic drug delivery but also for the treatment of pulmonary and neurological diseases. Along with it, drug transport and permeability studies across the nasal mucosa have exponentially increased. Nevertheless, the translation of data from in vitro cell lines to in vivo studies is not always reliable, due to the difficulty in generating an in vitro model that resembles respiratory human physiology. Among all currently available methodologies, the air–liquid interface (ALI) method is advantageous to promote cell differentiation and optimize the morphological and histological characteristics of airway epithelium cells. Cells grown under ALI conditions, in alternative to submerged conditions, appear to provide relevant input for inhalation and pulmonary toxicology and complement in vivo experiments. Different methodologies and a variety of materials have been used to induce ALI conditions in primary cells and numerous cell lines. Until this day, with only exploratory results, no consensus has been reached regarding the validation of the ALI method, hampering data comparison. The present review describes the most adequate cell models of airway epithelium and how these models are differently affected by ALI conditions. It includes the evaluation of cellular features before and after ALI, and the application of the method in primary cell cultures, commercial 3D primary cells, cell lines and stem-cell derived models. A variety of these models have been recently applied for pharmacological studies against severe acute respiratory syndrome–coronavirus(-2) SARS-CoV(-2), namely primary cultures with alveolar type II epithelium cells and organotypic 3D models. The herein compiled data suggest that ALI conditions must be optimized bearing in mind the type of cells (nasal, bronchial, alveolar), their origin and the objective of the study.

Part II: Matrix based scaffold lyophilization facilitates processing as a prerequisite for an innovative packaging system

Daniel Kullmann, Carmen Lema Martinez, Jörg Lümkemann, Jörg Huwyler

On large manufacturing lines, the fill finish process of drugs is generally accomplished by filling vials and syringes with their respective deliverable doses. Glass as a final container provides excellent protection of the drug product because of its chemical inertia, gas impermeability and relative robustness. However, due to potential needle stitch issues, diluent mix ups, or the required use of complex closed system transfer devices, lyophilizate vials present a significant challenge for healthcare professionals during the correct preparation of intravenous (IV) infusions. A more suitable container could potentially minimize such shortfalls during the preparation of IV infusions. Our investigations aimed at assessing if a novel medication system, consisting of an infusion bag separated into individual dry product and liquid diluent chambers, could facilitate the storage of a lyophilized product equivalently to the current standard, a vial. By incorporating an intermediate process container into two different dual chamber bags (DCB), the stability of a model monoclonal antibody formulation (mAb) was studied. The DCBs were evaluated over a 24-week period against their liquid and lyophilized dosage form equivalents in glass vials. Their stability was assessed through investigations into protein stability, residual moisture uptake of the dry products and permeability of the foil and film materials. It could be demonstrated that the stability of the incorporated drug is highly dependent on the container configuration. Ultimately it could be shown that the storage of lyophilizates is equally possible in DCBs as it is in vials, while being stored next to the diluent within the administration device.

Application of biorelevant in vitro assays for the assessment and optimization of ASD-based formulations for pediatric patients

Janis Niessen, Álvaro López Mármol, Ruba Ismail, Julia T. Schiele, Karola Rau, Andrea Wahl, Kerstin Sauer, Oliver Heinzerling, Jörg Breitkreutz, Mirko Koziolek

Amorphous solid dispersions (ASD) have been a successful formulation strategy to overcome the poor aqueous solubility of many novel drugs, but the development of pediatric formulations presents a special challenge due to variable gastrointestinal conditions in children. It was the aim of this work to design and apply a staged biopharmaceutical test protocol for the in vitro assessment of ASD-based pediatric formulations. Ritonavir was used as a model drug with poor aqueous solubility. Based on the commercial ASD powder formulation, a mini-tablet and a conventional tablet formulation were prepared. Drug release from the three formulations was studied in different biorelevant in vitro assays (i.e. MicroDiss, two-stage, transfer model, tiny-TIM) to consider different aspects of human GI physiology. Data from the two-stage and transfer model tests indicated that by controlled disintegration and dissolution excessive primary precipitation can be prevented. However, this advantage

of the mini-tablet and tablet formulation did not translate into better performance in tiny-TIM. Here, the in vitro bioaccessibility was comparable for all three formulations. In the future, the staged biopharmaceutical action plan established herein will support the development of ASD-based pediatric formulations by improving the mechanistic understanding so that formulations are developed for which drug release is robust against variable physiological conditions.

Therapeutic deep eutectic solvents: A comprehensive review of their thermodynamics, microstructure and drug delivery applications

Magdy M. Abdelquader a b, Shu Li a, Gavin P. Andrews a, David S. Jones

Deep eutectic solvents (DES) are multicomponent liquids that are usually formed by coupling a hydrogen bond donor and acceptor leading to strong non-covalent (NC) intermolecular networking and profound depression in the melting point of the system. Pharmaceutically, this phenomenon has been exploited to improve drugs' physicochemical properties, with an established DES therapeutic subcategory, therapeutic deep eutectic solvents (THEDES). THEDES preparation is usually via straightforward synthetic processes with little involvement of sophisticated techniques, which, in addition to its thermodynamic stability, make these multi-component molecular adducts a very attractive alternative for drug enabling purposes. Other NC bonded binary systems (e.g., co-crystals and ionic liquids) are utilized in the pharmaceutical field for enhancing drug's behaviours. However, a clear distinction between these systems and THEDES is scarcely discussed in the current literature. Accordingly, this review provides a structure-based categorization for DES formers, a discussion of its thermodynamic properties and phase behaviour, and it clarifies the physicochemical and microstructure boundaries between DES and other NC systems. Additionally, a summary of its preparation techniques and their experimental conditions preparation is supplied. Instrumental analysis techniques can be used to characterize and differentiate DES from other NC mixtures, hence this review draws a road map to for this purpose. Since this work mainly focuses on pharmaceutical applications of DES, all types of THEDES including the highly discussed types (conventional, drugs dissolved in DES and polymer based) in addition to the less discussed categories are covered. Finally, the regulatory status of THEDES was investigated despite the current unclear situation.

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