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Nachrichten und Mitteilungen

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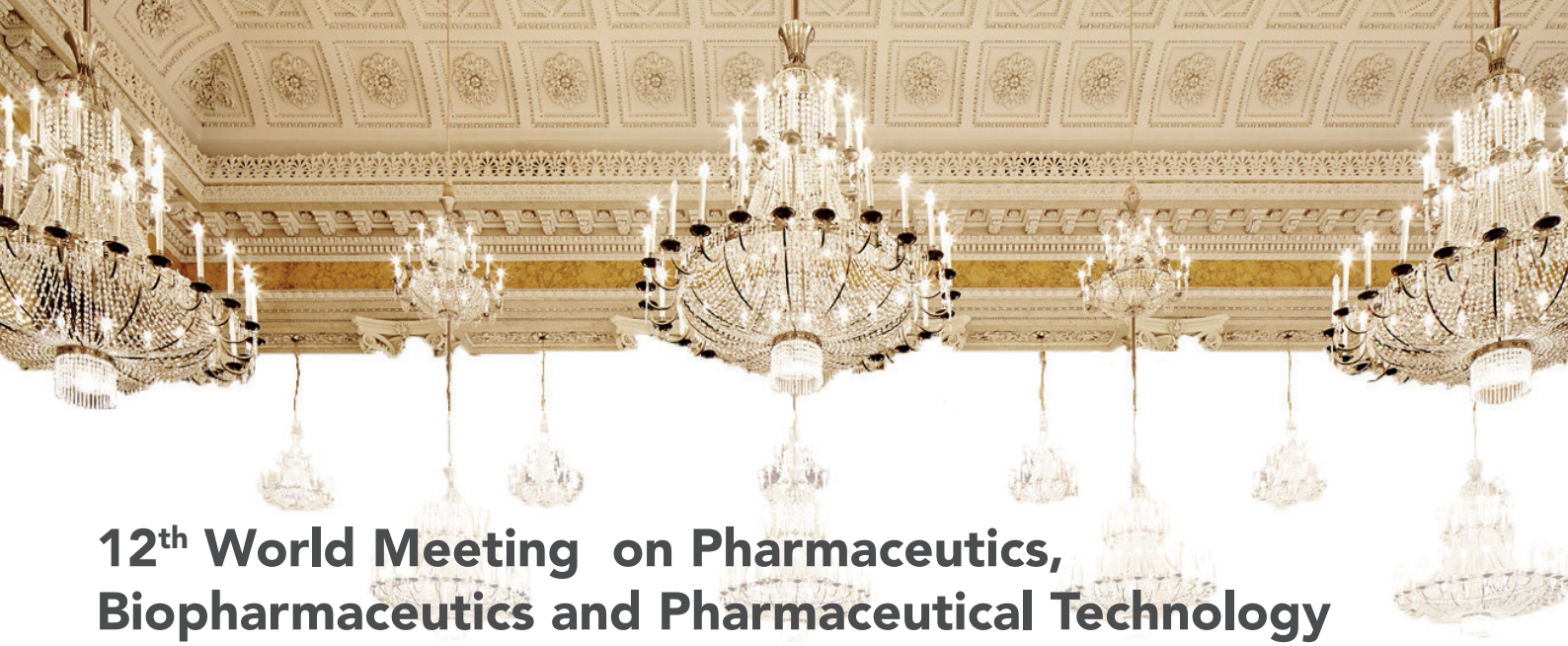
APV NEWS

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



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Lokale Gruppen

Lokale APV-Gruppe Rhein-Neckar demnächst als virtuelles Event!

Weitere Informationen und Angaben zu den nächten Terminen erhalten Sie bei Dr. Viktoria Riedel (viktoria.riedel@schwabe.de).

Mittwoch,26. Mai 2021

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).

Lokale APV-Gruppe Basel

Weitere Informationen und Angaben zu den nächten Terminen erhalten Sie bei Dr. Lars Restetzki (lars.restetzki@roche.com).

Lokale APV-Gruppe Berlin

Weitere Informationen und Angaben zu den nächten Terminen erhalten Sie bei Dr. Andreas Sachse (andreas.sachse@cpl-sachse.de).

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

The effect of residual moisture on a monoclonal antibody stability in L-arginine based lyophilisates

Ivonne Seifert, Wolfgang Friess

Amino acids are not only used as buffering agents in lyophilisation, but also exhibit cryo- and lyoprotecting characteristics. L-Arginine based lyophilisates were tested regarding their ability to stabilise a monoclonal antibody (mAb) at different residual moisture (RM) levels. Arginine base was formulated with citric, hydrochloric, lactobionic, phosphoric, and succinic acid for pH adjustment. Lyophilisates with less than 0.5% and approx. 2.5% RM were stored for up to 6 months at 40 °C. The mAb aggregation in arginine in combination with hydrochloric acid and succinic acid was similar or even less compared to a sucrose reference formulation. Arginine in combination with citric acid, lactobionic acid, and phosphoric acid resulted in lower protein stability. Overall, arginine formulations with high RM levels resulted in better protein stabilisation despite decreased glass transition temperatures (Tg). Whereas we detected mAb glycation in the sucrose-based formulations, this chemical reaction did not occur in arginine-based formulations. Arginine hydrochloride and succinate, especially at high RM levels, could be promising alternatives to sucrose for stabilisation of mAb in lyophilisates.

Temperature/end point monitoring and modelling of a batch freeze-drying process using an infrared camera

Maitê Harguindeguy, Davide Fissore

Temperature monitoring and accurate drying end time determination are crucial for final product quality in vacuum freeze-drying of pharmaceuticals. Whether crystalline or amorphous solutes are used in the formulation, product temperature during ice sublimation should be kept below a threshold limit to avoid damage to the product structure. Hence, there is a need to continuously monitor product temperature throughout this process. Current monitoring tools, such as thermocouples and Pirani gauge pressure sensors, have several limitations such as affecting product dynamics or imprecise end point determination. In this work, a monitoring tool based on infrared (IR) thermography is used for batch freeze-drying processes. Batches using three different vial sizes, with up to 157 vials, were studied, allowing to extend and better describe the representativeness of IR thermography for this application. The detailed axial temperature profiles obtained through IR imaging allowed not only a comprehensive non-invasive temperature monitoring of the product, but also tracking of the sublimation interface. IR temperature measurements and primary drying end point determination were compared to standard methods and thus verified. Parameters important for freeze drying design space calculation, namely the global heat coefficient (KV) and cake resistance to vapor flow (Rp), were also accurately estimated with the proposed method.

Versatility of hydrogel-forming microneedles in in vitro transdermal delivery of tuberculosis drugs

Qonita Kurnia Anjani, Andi Dian Permana, Álvaro Cárcamo-Martínez, Juan Domínguez-Robles, Ismaiel A. Tekko, Eneko Larrañeta, Lalit K.Vora, Delly Ramadon, Ryan F.Donnelly

Current therapy of tuberculosis (TB) has several limitations, such as risk of liver injury and intestinal dysbiosis due to frequent oral administration of antibiotics. Transdermal administration could be used to improve antibiotic delivery for treatment of Mycobacterium tuberculosis infection. Therefore, we developed a novel approach, using hydrogel-forming microneedle (MN) arrays to transdermally deliver TB drugs, namely rifampicin, isoniazid, pyrazinamide and ethambutol, which have different physicochemical properties. These drugs were individually prepared into three types of drug reservoirs, including lyophilised tablets, directly compressed tablets and poly(ethylene glycol) tablets. Formulations of each drug reservoir type were optimised to achieve a rapidly dissolving tablet, and further integrated with hydrogel-forming MN arrays for in vitro permeation studies. Three types of hydrogel formulation were manufactured using different type of polymers and crosslinking processes. These MN arrays were then evaluated in terms of swelling ability, morphology and physical properties. Results of solute diffusion studies showed that drug permeation across the swollen hydrogel membrane was affected mostly by physiochemical properties and functional groups of each drug. In the in vitro studies, the amount of permeated drug through the hydrogel-forming MN arrays across the dermatomed neonatal porcine skin was affected by the drug solubility and reservoir design. The highest permeation of rifampicin (3.64 mg) and ethambutol (46.99 mg) were achieved using MN arrays combined with the poly(ethylene glycol) tablets and directly compressed tablet, respectively. For isoniazid and pyrazinamide, the highest drug permeation was attained using lyophilised reservoir with the amount of drug delivered approximately 58.45 mg and 20.08 mg, respectively. These equate to transdermal delivery of approximately 75% (rifampicin), 79% (isoniazid), 20% (pyrazinamide) and 47% (ethambutol) of the drugs loaded into the reservoirs on average. Importantly, the results of this work have demonstrated the versatility of hydrogel formulations to deliver a TB drug regime using MN arrays. Accordingly, this is a promising approach to deliver high dose of TB drugs.

Spherical agglomerates of lactose as potential carriers for inhalation

Sarah Zellnitz, Dejan Lamešic, Sandra Stranzinger, Joana T. Pinto, Odon Planinšek, Amrit Paudel

We report here on spherical lactose agglomerates as potential carriers for inhalation applications. Micromeritic properties of three spherical lactose agglomerates (SA-A, SA-B, SA-C) and a standard lactose inhalation grade carrier

(Lactohale 100; LH100) were evaluated and compared. Ordered mixtures with micronized salbutamol sulfate as the model active pharmaceutical ingredient (API) and lactose carriers at two drug loadings (2 wt%, 5 wt%) were prepared, and in-vitro aerosolization performance was assessed. The spherical crystallization process led to particles with tailored micromeritic properties. These had larger specific surface area and greater fine fraction < 10 µm, compared to LH100, due to their coarse morphology. Their properties were reflected in the flowability parameters, where two types of spherical agglomerates of lactose showed more cohesive behavior compared to the other lactose grades. Blend uniformity showed improved homogeneous distribution of the API at higher drug load. In-vitro aerosolization tests showed that the spherical agglomerates of lactose enhanced the dose of API, compared to LH100. SA-B and SA-C showed significantly higher fine particle fractions at low drug load compared to the others, whereas overall, the largest fine particle fraction was for SA-B at high drug load. The carrier material attributes related to particle size, specific surface area, compressibility, flowability (cohesion, flow function), and air permeability were critical for aerosolization performance.

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Audi Q2 S 35 TFSI 110kW/150PS 6-Gang inkl. Navi Plus, Klimaautomatik, Infotainmentpaket, Sitzheizung vorn, Lederlenkrad mit Multifkt., Matrix-LED, 17" LMR mit Ganzjahresreifen etc.	27.630,25 €	269,00 €
Audi A5 Cabrio S line 40 TFSI 150kW/204PS S tronic inkl. Metallic, Polster Alcantara/Leder, Navigations- u. Infotainmentpaket, Klimaautomatik, Einparkhilfe plus/Kamera, Sitzheizung etc.	48.693,28 €	489,00 €
BMW X2 xDrive25e Advantage 162kW/220PS Autom. inkl. Metallic, Parkassist inkl. PDC/Kamera, Business Paket, Navi, Sitzheizung, Entertainment Paket, Lichtpaket, LED Scheinwerfer etc.	44.705,87 €	349,00 €
BMW 330e Limousine Advantage 215kW/292PS Automatic inkl. Business Paket Professional, Navi/ Live Cockpit, Klimaautomatik, Driving Assistant, LED-Scheinwerfer, Sportsitze vorn etc.	50.680,57 €	399,00 €
BMW 420d Coupé M Sport 140kW/190PS inkl. metallic, Business Paket, Live Cockpit Plus, Entertainment Paket, Driving Assistant, Active Protection, 18" LMR Doppelspeiche M Bicolor etc.	47.613,46 €	569,00 €
Jaguar E-Pace P300e AWD R-Dynamic S 227kW/309PS Autom. inkl. Yulong White, Lederpolster, Klimaautomatik, PDC v+h, LED-Scheinwerfer, Sitzheizung vorne, Winterpaket, 18" LMR etc.	51.114,30 €	569,00 €
LandRover Range Rover Evoque P300e S 227kW/309PS Automatic Panoramaschiebedach, Heck-klappe elektr., Winter Paket, Fahrassistenz Paket, Black Pack, Meridian Soundsystem, 20" LMR	56.449,60 €	469,00 €
Renault Twingo Limited Sce 75 54kW/75PS inkl. Pyrenées-Weiß, Klimaanlage, Einparkhilfe hinten, EASY-LINK Multimediasystem mit DAB+, Lederlenkrad, Smartphone-Integration etc.	10.899,16 €	99,00 €
Seat Ateca Style 1.0 TSI 81kW/110PS 6-Gang inkl. Businesspaket Infotain, Navigationssystem, Full Link, Climatronic, BeatsAudio Sound, PDC/Rückfahrkamera, Winterpaket, 17" LMR etc.	24.546,21 €	199,00 €
Seat Leon Sportstourer FR 1.4 e-Hybrid 150kW/204PS DSG inkl. Climatronic, Navigationssystem, Virtual Cockpit, Wireless Full Link, Winter-Paket, PDC/Rückfahrkamera, 17" LMR etc.	31.773,10 €	169,00 €
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VW Touran Highline 1,5 l TSI OPF 110kW/150PS DSG inkl. 3-Zonen Climatronic, Navi "Discover Media", PDC v+h/Rückfahrkamera, LED-Scheinwerfer, 17" LMR mit Ganzjahresreifen etc.	33.151,26 €	279,00 €
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Skoda Superb Combi Ambition 1,4 TSI iV 115kW/156PS 6-Gang automat. inkl. Climatronic, Navi, ACC, PDC v+h/Kamera, LED-Scheinwerfer, beheizbare Vordersitze, 18" LMR Antares etc.	39.547,90 €	229,00 €