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APV NEWS

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Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein

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Lokale Gruppen

Montag, 18. März 2019
Lokale APV-Gruppe Westfalen um 19:30 Uhr in der Hövelsbrauerei in Dortmund (Hoher Wall 5-7, 44137 Dortmund).
Anmeldung erforderlich bis zum 18. Februar 2019 bei Dr. Johanna Anlahr (johanna.anlahr@bayer.com).

Dienstag, 19. März 2019
Lokale APV-Gruppe Nordrhein um 19:00 Uhr, Düsseldorfer Altstadt.
Weitere Informationen und Angaben zu dem Treffpunkt erhalten Sie bei Klaus Wening (klaus.wening@grunenthal.com).

Dienstag, 19. März 2019
Lokale APV-Gruppe Mecklenburg-Vorpommern um 19:00 Uhr in dem Restaurant Goldmarie (Fischstraße 11) in Greifswald.
Anmeldung erforderlich bis zum 19. Februar 2019 bei Katharina Tietz (katharina.tietz@uni-greifswald.de).

Mittwoch, 27. März 2019
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).

Mittwoch, 08. Mai 2019
Lokale APV-Gruppe Basel um 18:30 Uhr im Restaurant „Gifthüttli“, Schneidergasse 11, 4051 Basel (www.gifthuettli.ch).
Anmeldung erforderlich bis zum 03. Mai 2019 bei Dr. Lars Restetzki (lars.restetzki@roche.com).

Dienstag, 10. September 2019
Lokale APV-Gruppe Berlin um 19:00 Uhr in den Firmenräumen der Bayer Pharma AG (Standort Berlin Wedding) statt.
Anmeldung erforderlich bis zum 05. August 2019 bei Dr. Andreas Sachse (andreas.sachse@cpl-sachse.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?

Eduard Trenkenschuh, Ludwig-Maximilians-Universität, D-München

Jasmine Tomar et al./European Journal of Pharmaceutics and Biopharmaceutics 133 (2018) 85-95

Passive inhalation of dry powder influenza vaccine formulations completely protects chickens against H5N1 lethal viral challenge

Jasmine Tomar, Carin Biel, Cornelis A.M. de Haan, Peter J.M. Rottier, Nikolai Petrovsky, Henderik W. Frijlink, Anke Huckriede, Wouter L.J. Hinrichs, Ben Peeters

Bird to human transmission of high pathogenicity avian influenza virus (HPAIV) poses a significant risk of triggering a flu pandemic in the human population. Therefore, vaccination of susceptible poultry during an HPAIV outbreak might be the best remedy to prevent such transmissions. To this end, suitable formulations and an effective mass vaccination method that can be translated to field settings needs to be developed. Our previous study in chickens has shown that inhalation of a non-adjuvanted dry powder influenza vaccine formulation during normal breathing results in partial protection against lethal influenza challenge. The aim of the present study was to improve the effectiveness of pulmonary vaccination by increasing the vaccine dose deposited in the lungs and by the use of suitable adjuvants. Two adjuvants, namely, Bacterium-like Particles (BLP) and Advax, were spray freeze dried with influenza vaccine into dry powder formulations. Delivery of dry formulations directly at the syrinx revealed that BLP and Advax had the potential to boost either systemic or mucosal immune responses or both. Upon passive inhalation of dry influenza vaccine formulations in an optimized set-up, BLP and Advax/BLP adjuvanted formulations induced significantly higher systemic immune responses than the non-adjuvanted formulation. Remarkably, all vaccinated animals not only survived a lethal influenza challenge, but also did not show any shedding of challenge virus except for two out of six animals in the Advax group. Overall, our results indicate that passive inhalation is feasible, effective and suitable for mass vaccination of chickens if it can be adapted to field settings.

Sarah H.M. Hedberg et al./European Journal of Pharmaceutics and Biopharmaceutics 133 (2018) 131-137

Cross-interaction chromatography as a rapid screening technique to identify the stability of new antibody therapeutics

Sarah H.M. Hedberg, Jonathan Rapley, Jonathan M. Haigh, Daryl R. Williams

Protein aggregation can be a major problem in the manufacturing of new biopharmaceuticals and there is a desirability for development of techniques that can predict the behaviour of new biopharmaceuticals early on in the development process. A technique that can be used to predict aggregation is self-interaction chromatography that is used to determine the second virial coefficient, B22, but one of the limitations includes the need to immobilise every protein of interest. In this study a related technique, cross interaction chromatography (CIC), is evaluated which overcomes this limitation. Three antibodies were studied across a range of NaCl concentrations with each antibody being studied as both a mobile phase and as the stationary phase - in total 6 different stationary-mobile phase combinations. The B22 values obtained for all three proteins correlated strongly with the B23 results obtained for the same protein in the mobile phase, and were significantly independent of the protein immobilised on the stationary phase. This observation allows the use of pre-prepared columns with known immobilised model proteins such as a polyclonal antibody or mAb, with other unknown monoclonal antibodies in the mobile phase. Preliminary experiments using a series of known immobilised mAbs columns with an unknown mAb in the mobile phase resulted in at least a 50 fold reduction in the amount of unknown protein needed and a rapid semi-quantitative assessment of aggregation propensity. CIC can speed up the screening process with minimum preparation time and therefore more rapidly be able to identify the aggregation stability of new antibody formulations.

Adrian Schmidt et al./European Journal of Pharmaceutics and Biopharmaceutics 133 (2018) 224-231

Simplified end-to-end continuous manufacturing by feeding API suspensions in twin-screw wet granulation

Adrian Schmidt, Hans de Waard, Klaus-Peter Moll, Peter Kleinebudde, Markus Krumme

This study focussed on investigating the coupling of continuous manufacturing of drug substance and continuous manufacture of drug product. An important step in such an integrated end-to-end continuous manufacturing was envisioned by dosing the API as suspension into a twin-screw wet granulation process. To achieve this goal, a model drug substance (ibuprofen) was fed as a concentrated aqueous suspension (50% w/w) into a twin-screw granulator and compared against traditional solid feeding of the model drug substance to meet a target ibuprofen load of 60% w/w in the formulation. Granulation and compaction behaviour were evaluated

to determine the impact of feeding API as suspension in twin-screw wet granulation on the critical quality attributes of the drug product. It was demonstrated that the ibuprofen suspension feed is comparable with the ibuprofen dry blend feed in twin-screw wet granulation. Next to enabling end-to-end continuous manufacturing, API suspension feed in twin-screw wet granulation could afford a number of additional advantages including manufacturing efficiency by removing the drying step for API, or overcoming processing issues linked to the bulk properties of the API powder (e.g. flowability).

Sien Dedroog et al./European Journal of Pharmaceutics and Biopharmaceutics 135 (2019) 1-12

Chemically identical but physically different: A comparison of spray drying, hot melt extrusion and cryo-milling for the formulation of high drug loaded amorphous solid dispersions of naproxen

Sien Dedroog, Christophe Huygens, Guy Van den Mooter

In spite of the large research efforts in the past two decades, it is still difficult, if possible at all, to predict what manufacturing technology will lead to the best amorphous solid dispersions (ASDs) in terms of drug to polymer ratio ("drug loading") and physical stability. In general, ASDs can be prepared by solvent based methods, heat based methods and mechanochemical activation. In the current study, one manufacturing technique per category was selected: spray drying, hot melt extrusion and cryo-milling, respectively. These processes were compared for their capability to formulate high drug loaded ASDs. High drug loadings may allow decreasing the pill burden and/or reducing dosage size, which both increase the therapeutic compliance. A fast crystallizer, naproxen, in combination with PVP K25, PVP-VA64, HPMC and HPMC-AS was used as a model system. Clear differences in the physical structure of the ASDs were observed. Our data indicate that not only the drug loading is dependent on the manufacturing process, but also the carrier that is able to incorporate the highest drug loading. This suggests that a carrier should be selected not only as function of the API, but also as function of the manufacturing process. Overall, hot melt extrusion showed to be most suited to reach high drug loadings for these naproxen-polymer combinations. This was in agreement with our finding that heat is an important energy input for mixing.

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Anna-Maria Pötzl · APV e.V.

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MINI Cooper S 5-Türer 100kW/136PS Automatik inkl. Metallic, Connected Navigation Plus, DAB-Tuner, 17" LM-Räder, PDC hinten, Chili Paket, Sitzheizung vorne, LED-Scheinwerfer etc.	30.269,00 €	299,00 €
Porsche 718 Boxster 220kW/300PS inkl. Navigation mit Porsche Connect, Doppelkupplungsgetrie-be PDK, Lederpaket mit Teilledersitzen, Bi-Xenon, 20" Carrera S Räder, ParkAssistent etc.	59.346,00 €	899,00 €
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