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APV NEWS



Nachrichten und Mitteilungen

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



*Abstract submission deadline
15 November 2019*

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Lokale Gruppen

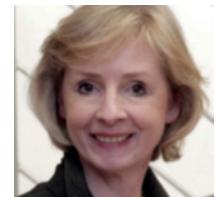
Mittwoch, 18. September 2019

Lokale APV-Gruppe Basel um 18:30 Uhr im Restaurant „Gifthüttli“, Schneidergasse 11, 4051 Basel (www.gifthuetli.ch).
Anmeldung erforderlich bis zum 13. September 2019 bei Dr. Lars Restetzki (lars.restetzki@roche.com).



Mittwoch, 25. September 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).



Lokale APV-Gruppe Berlin

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



Lokale APV-Gruppe Westfalen

Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Dr. Johanna Anlahr (johanna.anlahr@bayer.com).



Lokale APV-Gruppe Mecklenburg-Vorpommern

Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Katharina Tietz (katharina.tietz@uni-greifswald.de).



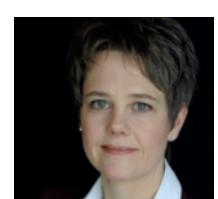
Lokale APV-Gruppe Nordrhein

Weitere Informationen und Angaben zu den nächsten Terminen erhalten Sie bei Klaus Wening (klaus.wening@grunenthal.com).



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

Monika Wentzlaff et al./ European Journal of Pharmaceutics and Biopharmaceutics 139 (2019) 85-92

Evaluation of the suitability of a fluidized bed process for the coating of drug-eluting stents

Monika Wentzlaff, Volkmar Senz, Anne Seidlitz

Drug-eluting stents are often coated using single-stent coating techniques. In pharmaceutical industry, single-tablet coating is unthinkable. Instead large batches of tablets are coated in fluidized bed apparatuses or pan coaters. Therefore, it was the aim of this work to evaluate whether stents can be coated using a fluidized bed process. For this purpose stents were coated with the model fluorescent drug triamterene embedded in ammonium methacrylate copolymer. Different stent lengths as well as different coating yields were assessed and also a drug-free topcoat was evaluated. The coated stents were analysed regarding coating layer mass, drug content, surface structure, coating thickness and drug release. Furthermore, coating yield and stent defect rate were examined. Except for one stent configuration good results were obtained without optimization of process parameters which indicates the suitability of the method to coat large amounts of stents simultaneously in principle. Drug release was tuneable over a wide range of time spans and a wide range of drug loadings was produced. Further work will be necessary to transform the results of this study from a model stent to a clinically relevant product.

Fabian Higel et al./ European Journal of Pharmaceutics and Biopharmaceutics 139 (2019) 123-131

N-glycans of complex glycosylated biopharmaceuticals and their impact on protein clearance

Fabian Higel, Theresa Sandl, Chi-Ya Kao, Nicole Pechinger, Fritz Sörgel, Wolfgang Friess, Florian Wolschin, Andreas Seidl

N-glycosylation is a common post-translational modification of biopharmaceutical products. Certain types of N-glycans have been shown to influence important properties of monoclonal antibody products including pharmacokinetics and effector functions. Complex biopharmaceuticals e.g. Fc fusion proteins may contain several N- and O-glycosylation sites. Domain specific characterization of two Fc fusion proteins showed an Fc N-glycosylation pattern comparable to IgG molecules. The receptor N-glycosylation was found to contain some larger and more complex N-glycans compared to the Fc part. Analyses of samples from non-clinical studies of the two studied fusion proteins indicate that their N-glycans impact pharmacokinetic properties. Interestingly, besides the type of N-glycan this influence on the pharmacokinetics depends also on the glycosylation site and thus the accessibility on the protein. The same type of N-glycan can influence the clearance of fusion proteins when located at the receptor part, but not if located at the Fc part. In this study, it is shown that N-glycans

with terminal galactose or N-acetylglucosamine residues have a negative impact on serum half-life when located at the receptor part. Terminal sialylation of galactose residues prevents this faster clearance even when only one sialic acid is present. O-acetylation, a modification of sialic acids does not impact pharmacokinetics. Thus, type and accessibility of N-glycan moieties of fusion proteins both play an important role in pharmacokinetics. Finally, detailed site specific analysis is critical in the development of biopharmaceuticals.

Anja Hoffmann et al./ European Journal of Pharmaceutics and Biopharmaceutics 139 (2019) 240-245

Ultra-fast disintegrating ODTs comprising viable probiotic bacteria and HPMC as a mucoadhesive

Anja Hoffmann, Rolf Daniels

Orodispersible tablets (ODTs) are a convenient dosage form and a recent trend in formulation development. The fast disintegration is accompanied by rapid removal of the active principle and the excipients from the mouth due to saliva flow and swallowing. Probiotic bacteria are a promising strategy to fight disease with bacterial aetiology in the mouth, but a certain residence time in the oral cavity is inevitable to exert their positive effects. The addition of a mucoadhesive polymer, like hydroxypropyl methylcellulose (HPMC), is an auspicious strategy to prolong this residence time. Nevertheless, the disintegration time of the tablets should still meet the acceptance level from the FDA (<30 s). To reach intimate contact of bacteria and mucoadhesive polymer on the one hand and to support fast disintegration on the other hand, granulation of probiotic bacteria and mucoadhesive HPMC with a methacrylic acid copolymer was performed first. Moreover, high mucoadhesion could be obtained because bacteria and mucoadhesive polymer could interact more strongly with the mucosa after the ODT disintegrated and the methacrylic acid copolymer dissolved in the pH neutral saliva.

Vivek Thakare et al./ European Journal of Pharmaceutics and Biopharmaceutics 140 (2019) 67-77

Investigation of drug product and container-closure interactions: A case study of diluent containing prefilled syringe

Vivek Thakare, Bettina Mayr, Andrej Artenjak, Dimitrios Nianios, Maike Sest, Martin Müller, Oleg, V. Maltsev, Kajetan Nowicki, Andre Mischo, Christian Ehrenstrasser, Matthias Fink, Silvia Thanhaeuser, Alessandra Cerretti

Prefilled syringes (PFS) constitute a widely used medical device for drug delivery particularly for the drugs of biological origin. Interactions between the product contents and the components of the PFS play a critical role in determining the

suitability of selected PFS. A diluent (with benzyl alcohol/BzOH as a preservative) containing PFS used for reconstitution of the lyophilized product revealed a systematic decrease in the BzOH content during accelerated and stress stability program. Investigation was carried out to understand and identify the underlying causes of this phenomenon. BzOH has a varying propensity to bind to the rubber components (stopper and tip-cap) of the PFS. Vapor permeation behavior across the tip-cap of the PFS was studied via headspace-gas chromatography-mass spectroscopy (HS-GC-MS) enabled analysis. Depending on the properties of the rubber components, BzOH can not only bind but also traverse across them, resulting in a systematic loss during the course of the stability. PFS can allow not only water vapor permeation across the tip-cap as shown in previous studies, but also molecules like benzyl alcohol. This phenomenon stresses the need for careful selection of the components of the primary packaging and also provides an opportunity to deploy novel tools like HS-GC-MS in the early selection of the optimal primary packaging configuration.

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Anna-Maria Pötzl · APV e.V.

Leasing auch für andere Investitionsgüter

Leasing und Finanzierung von Investitionsgütern zu günstigen Konditionen:

- ✓ schont das Eigenkapital
- ✓ verbessert das Rating
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- ✓ erhöht die Eigenkapitalquote

Sehr interessant auch für Nutzer von Maschinen für die Pharmaindustrie:

- ✓ niedrige Leasingraten statt hoher Kaufpreise
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- ✓ Abdeckung der kompletten Produktpalette

Unser Kooperationspartner bietet Leasing von Neu- und Gebrauchtfahrzeugen zu Sonderkonditionen an. Alle Marken und Modelle sind lieferbar. Die nachfolgende Tabelle gibt nur wenige aktuelle Beispiele möglicher Modelle und Marken wieder.

NEU: Vorführwagen (VfW) aus dem Leasing-Pool und Dienst-/Werkswagen (DW) zu attraktiven Konditionen erhältlich.

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Anfragen bitte an apv@apv-mainz.de, das Leasing-Unternehmen wird sich dann mit Ihnen in Verbindung setzen.

Kfz-Leasing

NEU: Alle Fahrzeuge mit der Abgasnorm Euro 6d-Temp

Hersteller/Typ	Listenpreis	mtl. Rate
Audi Q2 30 TFSI "LW" 85kW/115PS inkl. Klimaautomatik, Einparkhilfe hinten, Connectivity-Paket, LED Scheinwerfer, Sitzheizung vorn, Gepäckraumklappe elektrisch, 16" LM-Räder etc.	24.857,00 €	259,00 €
Audi A5 Sportback sport 40 TFSI "LW" 140kW/190PS S tronic inkl. MMI Navi, S line Exterieur+Sport+selection, Technology selection, Panorama-Glasdach, PDC v+h, 20" LM-Räder etc.	51.029,00 €	519,00 €
Audi Q7 50 TDI quattro 210kW/286PS tiptronic inkl. Audi connect, MMI Navigation plus, Audi sound system, Audi drive select, Klimaautomatik, PDC hinten, Tempomat, 18"LM-Räder etc.	56.555,00 €	559,00 €
BMW 118i Sport Line 103kW/140PS inkl. Business Paket, PDC, LED Scheinwerfer, Tempomat, Sportsitze Fahrer/Beifahrer, 17" LM-Räder, Lichtpaket, Ablagenpaket etc.	27.983,00 €	259,00 €
BMW 320i Limousine Advantage 135kW/184PS inkl. Automatic, Business Paket, BMW Live Cockpit Plus, Klimaautomatik, PDC, Tempomat, Sitzheizung Fahrer/Beifahrer, 16"LM-Räder etc.	36.008,00 €	319,00 €
BMW X4 xDrive20i Advantage 135kW/184PS inkl. Automatic, Live Cockpit Plus, Klimaautomatik, M Sportfahrwerk, Sitzheizung vorne, Innen-/Aussenspiegel-/Ablagenpaket, 18" LMR etc.	43.950,00 €	399,00 €
Mercedes B 180 AMG-Line "VFW" 100kW/136PS inkl. Automatik, AMG-Styling, Navi-Paket/MBUX, Klimaautomatik, Sitzheizung vorn, Park-Assistent, LED-Scheinwerfer, Business Paket etc.	35.635,00 €	329,00 €
Mercedes C 180 T AMG-Styling "VFW" 115kW/156PS inkl. Automatik, Navi, volldig. Instrumenten-Display, Rückfahrtkamera, PDC, Sitzheizung vorn, LED-Scheinwerfer, Business Paket Plus etc.	40.125,00 €	399,00 €
Porsche Macan 180kW/245PS inkl. Doppelkupplungsgetriebe, LED-Scheinwerfer mit Porsche Dynamic Light System, PDC v+h+Kamera, Klimaautomatik, PCM+Connect Plus Navigation etc.	52.275,00 €	719,00 €
Porsche 718 Cayman 220kW/300PS inkl. Doppelkupplungsgetriebe (PDK), Klimaautomatik, Navi+Porsche Connect, LED-Scheinwerfer mit PDLS Plus, PDC v+h+Kamera, Sitzheizung vorn etc	55.225,00 €	699,00 €
Renault ZOE "LIFE" R110 Z.E. 40 Phase II 41kWh inkl. Batteriemiete, CCS Ladeanschluss 50kWDC, Full Service, Klimaautomatik, Online-Infotainmentsystem R-Link Evolution etc.	20.141,00 €	225,00 €
Renault KADJAR BUSINESS Edition Tce 140 GPF inkl. Full Service, 17" LMR Evado Ganzjahresreifen, Winterkompletttrad, R-LINK2 mit Navi, Klimaautomatik, PDC v+h, Spurhaltewarner etc.	24.856,00 €	179,00 €
Renault MEGANE Grandtour BUSINESS Edition Tce 140 GPF inkl. Full-Service, Perlmutt-Weiß, Ganzjahresreifen, R-Link 2 mit Navi, 2-Zonen Klimaautomatik, PDC, Sicherheitstrennnetz etc.	21.756,00 €	139,00 €
Renault TALISMAN Grandtour BUSINESS Edition Tce 225 EDC GPF inkl. Full-Service, Ganzjahresreifen, Voll-LED, 2-Zonen-Klimaautomatik, PDC, R-Link 2 Navi, ACC, Sitzheizung vorne etc.	33.641,00 €	179,00 €
Skoda Scala Style 1,0l TSI 85kW/115PS inkl. Metallic, Businesspaket, Navi, DAB+, Klimaautomatik, Voll-LED-Scheinwerfer, Panoramaglasdach, PDC hinten, Tempomat, 17" LM-Räder etc.	22.403,00 €	199,00 €
Skoda Octavia Combi RS 2,0l TSI 180kW/245PS DSG inkl. Navi Columbus + Assistenzpaket, Paket Challenge Pro, PDC v+h, Sitzheizung vorn, GRA, LED Scheinwerfer, 18" LM-Räder etc.	34.992,00 €	259,00 €
Skoda Kodiaq RS 2,0l TDI 4x4 176kW/240PS DSG inkl. Business Paket Columbus, Navi, elektr. Heckklappenbedienung, Sunset, LED-Scheinwerfer, Climatronic, Memory, Tempomat etc.	44.227,00 €	389,00 €