

VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 January, 2026

Book of Abstracts





VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 January, 2026 – Szeged, Hungary

Greetings



Welcome to our 8th Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science!

Healthy & happy New Year for all of you! A new year is here with a new Szeged meeting!

... Once Upon a Time... there was a 12th Central European Symposium on Pharmaceutical Technology and Regulatory Affairs organized in our wonderful Szeged city in 2018, when our community decided to keep together our PhD students and post docs in order to share good practices and thoughts in science and life.

So, we are here for you with a three-day program, we are going to have the possibility to listen 31 verbal-, and 13 flash presentations organized into 9 sections. We have 80 participants (70 colleagues personally present!) registered from 12 countries, representing 15 universities.

It's a special event of 2026, as in the frame of CEEPUS program, *CEKA PharmTech Intensive Seminar and Network Meeting* is organized and hosted by the Institute of Pharmaceutical Technology and Regulatory Affairs. The Intensive seminar titled "*Preformulation Strategies in Pharmaceutical Technology Developments*" for PhD students and the **CEEPUS Network Meeting** for the coordinators are connected to our 8th Symposium. This gives a special possibility to strengthen our network and brings also new partners and friends.

Welcome all our Colleagues here in this network! I sincerely hope that you will find new cooperations and links between your research and the other presented projects and also with the representing institutions.

I wish you a pleasant stay here in Szeged. Enjoy the opportunity to visit Katalin Karikó exhibition at the Klebelsberg Library and Archives where her Nobel plaque is displayed. Feel the spirit of Szeged, the "City of Sunshine". Take a photo with the "cycling Einstein" bronze sculpture located in the courtyard of the Headquarters of the Hungarian Academy of Sciences' Szeged Regional Committee, where our Symposium takes place.

For those, who attend online: please feel free to ask questions and be active. Thanks to this digital era, you don't have the limitation - except you miss the specially warm welcome of the City and the University of Szeged.

Prof. Ildikó Csóka

Head of Institute of Pharmaceutical Technology & Regulatory Affairs
President of the Symposium

VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 JANUARY, 2026

SZEGED, HUNGARY



General Information

Date: 28–30 January, 2026

Location: Hybrid (University of Szeged, Faculty of Pharmacy, and online Zoom)

Congress Topics: Pharmaceutical technology, biotechnology and regulatory science

Types of presentations:

1. Oral presentation (10 min + 5 min discussion)
2. Flash presentation (3–5 min, pre-recorded)

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Edited: Kinga Budai and Luca Éva Uhljar

Photos: Tamás Sovány

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Co-organiser

Foundation for the Development of
Pharmacy Education at the University
of Szeged



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Committees

Head of the Scientific Committee

Rita Ambrus

Scientific Committee

Alenka Zvonar Pobirk, Slovenia
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CEKA PharmTech Intensive Seminar 2026

January 25-30, 2026 - Szeged, Hungary

Szeged, Faculty of Pharmacy, University of Szeged



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January 28-30, 2026 - Szeged, Hungary



CEKA PharmTech Network Meeting 2026

January 29-30, 2026 - Szeged, Hungary

Szeged, Faculty of Pharmacy, University of Szeged



CEKA PharmTech Intensive Seminar 2026

Szeged, January 25-30, 2026

Szeged, Faculty of Pharmacy, University of Szeged

Preformulation Strategies in Pharmaceutical Technology Developments Intensive Seminar

Sunday, 25 January – 14:00–16:00 CET

14:00–16:00 Welcome & Introduction, Sightseeing in Szeged

Monday, 26 January – 8:30–16:00 CET

*Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy,
University of Szeged (3rd floor, 6 Eötvös street, Szeged, H-6720)*

8:30–9:00 Welcome to the Institute of Pharmaceutical Technology and Regulatory Affairs

9:00–9:45 Lecture 1: **Preformulation strategies of lipid nanoparticles for dermal drug delivery** – **Szilvia Berkó**

9:45–10:30 Lecture 2: **Strategies of periodontal and ocular drug delivery research** – **Mária Budai-Szűcs**

10:30–11:00 Coffee Break

11:00–11:45 Lecture 3: **Oral protein delivery – formulation opportunities and preformulation aspects** – **Katalin Kristó**

11:45–12:30 Lecture 4: **Preformulation aspects of the utilization of inorganic nanoparticles in solid dosage forms** – **Tamás Sovány**

12:30–13:30 Lunch Break

13:30–16:00 **Lab tour** in the Institute of Pharmaceutical Technology and Regulatory Affairs



CEKA PharmTech Intensive Seminar 2026

Szeged, January 25-30, 2026

Szeged, Faculty of Pharmacy, University of Szeged

Tuesday, 27 January – 8:30–16:00 CET

Institute of Biology, Faculty of Science and Informatics, University of Szeged (52 Körzép fasor, Szeged, H-6726)

8:30–9:00 Welcome in the Institute of Biology

9:00–9:45 Lecture 5: **Particle engineering: top down and bottom up methods** – **Rita Ambrus**

9:45–10:30 Lecture 6: **Optimization of nanostructured systems** – **Gábor Katona**

10:30–11:00 Lecture 7: **Nano-Regulation** – **Bence Sipos**

11:00–11:30 Coffee Break

11:30–12:00 Lecture 8: **Pulmonary drug administration-case study** – **Mahwash Muhktar**

12:00–12:30 Lecture 9: **Nasal drug administration-case study** – **Maryana Salamah**

12:30–14:00 Lunch Break

14:00–16:00 **Experimental workshop: Inhalable particle characterization** – **Petra Party, Mahwash Muhktar, Bence Sipos**

Wednesday, 28 January – 10:00–16:00 CET

Participation at the VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

Thursday, 29 January – 9:00–17:00 CET

Participation at the VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

Friday, 30 January – 9:00–11:45 CET

Participation at the VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science



VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

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Short Program

Wednesday, 28 January – 10:00–16:00 CET

“SZAB Palace” - Headquarters of the Hungarian Academy of Sciences' Szeged Regional Committee (7 Somogyi street, Szeged, H-6720)

10:00–10:30 Registration

10:30–11:00 Conference opening – greetings

11:00–11:45 Plenary lecture 1.

11:45–12:15 Plenary lecture 2.

12:15–13:30 Lunch break

13:30–14:45 Oral Presentations – Session 1

14:45–15:00 Break

15:00–16:00 Oral Presentations – Session 2

19:00– Networking event

“Bohém Tanya” (6 Szentháromság street, Szeged, H-6722)



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Thursday, 29 January – 9:00–18:00 CET

“SZAB Palace” - Headquarters of the Hungarian Academy of Sciences' Szeged Regional Committee (7 Somogyi street, Szeged, H-6720)

9:00–10:15 Oral Presentations – Session 3

10:15–10:30 Coffee break

10:30–11:15 Flash Presentations – Session 1

11:15–11:30 Break

11:30–12:30 Oral Presentations – Session 4

12:30–13:30 Lunch break

13:45–15:00 Cultural Program – Visiting the Collection of Old Books and Manuscripts and the exhibition “Katalin Karikó’s journey to the Nobel Prize and beyond”

15:00–16:00 Oral Presentations – Session 5

16:00–16:15 Break

16:15–17:00 Flash Presentations – Session 2

Friday, 30 January – 9:00–11:45 CET

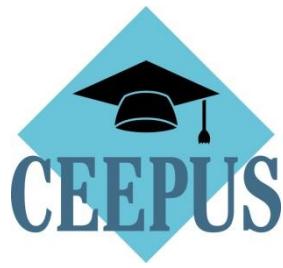
“SZAB Palace” - Headquarters of the Hungarian Academy of Sciences' Szeged Regional Committee (7 Somogyi street, Szeged, H-6720)

9:00–10:15 Oral Presentations – Session 6

10:15–10:30 Coffee break

10:30–11:30 Oral Presentations – Session 7

11:30–11:45 Closing Ceremony



CEKA PharmTech Network Meeting 2026

Szeged, January 29-30, 2026

Szeged, Faculty of Pharmacy, University of Szeged

CEKA PharmTech Network Meeting

Thursday, 29 January – 13:00–18:00 CET

*Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy,
University of Szeged (3rd floor, 6 Eötvös street, Szeged, H-6720)*

12:30–13:45 Participants Gathering & Welcome Reception

13:45–14:00 **Opening**

prof. Ildikó Csóka, Head of the Institute
assoc. prof. Szilvia Berkó, CEKA PharmTech Network Contact Person
prof. Jelena Paročić, CEKA PharmTech Network Coordinator

14:00–15:00 **Presentation of the Institute (Teaching and Research) & Lab tour**

15:00–17:00 **Session 1 – Work Plan for the Academic Year 2025/26**

Friday, 30 January – 9:00–14:45 CET

“SZAB Palace” - Headquarters of the Hungarian Academy of Sciences' Szeged Regional Committee (7 Somogyi street, Szeged, H-6720)

9:00–12:00 **Participation at the VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science**

12:00–12:30 Lunch Break

*Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy,
University of Szeged (3rd floor, 6 Eötvös street, Szeged, H-6720)*

12:30–14:30 **Session 2 – Strategic Planning and Joint Program Development**

14:30–14:45 **Closing**



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Schedule

Wednesday, 28 January – 10:00–16:00 CET

“SZAB Palace” - Headquarters of the Hungarian Academy of Sciences' Szeged Regional Committee (7 Somogyi street, Szeged, H-6720)

10:00–10:30 Registration

10:30–11:00 Opening Ceremony

Dr. Leona Kovács-Jerney (Deputy Director for General and International Affairs, University of Szeged)

Dr. Gerda Szakonyi (Vice-Dean of the Faculty of Pharmacy, University of Szeged)

Prof. Ildikó Csóka (President of the Symposium, Head of Pharmaceutical Technology Doctoral Program, University of Szeged)

11:00–11:45 Plenary Lecture 1.

Gábor Klivényi – *Computer Fluid Dynamics Models Validation in Pharmaceutical Applications*

11:45–12:15 Plenary Lecture 2.

Péter Ágoston – *Clinical Trials Overview: An Introduction to Clinical Research*

12:15–13:30 Lunch break

“EGIS room” – Faculty of Pharmacy (6 Eötvös street, Szeged, H-6720)

13:30–14:45 OP Session 1 – Chairs: Tamás Sovány, Krisztián Pamlényi

OP-1 – 13:30–13:45 **Rabia Ashfaq**, Anita Kovács, Szilvia Berkó, Mária Budai-Szűcs
Thermo-Responsive Mucoadhesive Nanocarrier Systems for Localized Periodontitis Therapy: Development, Characterization, and Biopharmaceutical Evaluation

OP-2 – 13:45–14:00 **Lina Ilayan**, Sina Matalqah, Hala Al-Dhagestani
Synthesis and Characterization of Bimetallic Nanoparticles Loaded with Chenopodium quinoa Extract: Assessment of Antibacterial and Cytotoxic Effects



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OP-3 – 14:00–14:15 **Hadi Shammout**, Krisztina Ludasi, Béla Hopp, Tamás Smausz, János Bohus, Orsolya Jójárt-Laczkovich, Martin Cseh, Judit Kopniczky, Tamás Sovány

Balancing laser marking efficiency and enteric film coated tablets integrity

OP-4 – 14:15–14:30 **Boglárka Gábor**, Dorina Gabriella Dobó, Ildikó Csóka

Formulation and characterization of propranolol hydrochloride-loaded liposomes

OP-5 – 14:30–14:45 **Maryana Salamah**, Ildikó Csóka, György Tibor Balogh, Gábor Katona

Lipid-based nanocarriers for intranasal delivery of Rifampicin

14:45–15:00 Break

15:00–16:00 OP Session 2 – Chairs: Mirjana Gašperlin, Nikola Geskovski

OP-6 – 15:00–15:15 **Hala Rayya**, Krisztián Pamlényi, Raghad Alsheikh, Dániel Nemes, Ildikó Bácskay, Géza Regdon jr., Katalin Kristó

Stability and in vitro evaluation of captopril-loaded mucoadhesive buccal films

OP-7 – 15:15–15:30 **Milica Martinović**, Ivana Nešić, Vanja Tadić, Ana Žugić, Marija Tasić-Kostov

Natural deep eutectic solvent-based green tea leaves extracts for hyaluronidase inhibition in skin care formulations

OP-8 – 15:30–15:45 **Hanan Mohammad**, Gábor Katona, Ildikó Csóka

Thiolated Albumin Nanocarriers for Improved Intranasal Delivery of Levodopa Methyl Ester

OP-9 – 15:45–16:00 **Elika Valehi**, Zsófia Németh, Dorina Gabriella Dobó, Gábor Katona, Ildikó Csóka

Comparative In Vitro Evaluation of Oppositely Charged Donepezil-Loaded Liposomes for Intranasal Drug Delivery

19:00– Networking event

“Bohém Tanya” (6 Szentháromság street, Szeged, H-6720)



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9:00–10:15 OP Session 3 – Chairs: Mahwash Mukhtar, Mario Jug

OP-10 – 9:00–9:15 **Pia Berglez**, Barbara Sterle Zorec, Odon Planinšek, Alenka Zvonar Pobirk

Hot melt extruded solid dispersions of resveratrol with mesoporous silica: formulation development and characterization

OP-11 – 9:15–9:30 **Fatima Rajab**, Bence Sipos, Ildikó Csóka

Thermosensitive polymeric micelles as nanocarriers in nasal administration

OP-12 – 9:30–9:45 **József Bogner**, Bence Sipos, Gábor Katona, Ildikó Csóka

Risperidone-loaded surface-modified albumin nanocarriers for intranasal drug delivery

OP-13 – 9:45–10:00 **Yusra Ahmed**, Krisztián Kovács, Krisztina Ludasi, Orsolya Jójárt-Laczkovich, Tamás Sovány

Enhancing Drug Incorporation in FDM 3D-Printed Tablets Using Pan Coating Technique

OP-14 – 10:00–10:15 **Tabarek H. Mahmood**, Ali Al-Samydai, Mazen Al Sulaibi, Moath Alqaraleh, Anas Ibrahim Abed, Naeem Shalan, Alaa Alsanabrah, Shrouq Taiseer Alsotari, Hamdi Nsairat, Walhan Alshaer

Development of PEGylated Nano-Phytosome Formulation with Oleuropein and Rutin to Compare Anti-Colonic Cancer Activity with Olea Europaea Leaves Extract

10:15–10:30 Coffee break



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10:30–11:15 **FP Session 1** – Chairs: Janina Lulek, Petra Party

10:30–10:50 **Presentations FP-1 – FP-4**

FP-1 **Flóra Sendula**, Boglárka Szalai, Anita Kovács, Szilvia Berkó, Mária Budai-Szűcs

Combined ophthalmic nanoformulation of Dexamethasone for improved bioavailability

FP-2 **Ilgın Ünalı**, Fatima Rajab, Bence Sipos, Ildikó Csóka

Investigation of the nasal applicability and the effect of mucoadhesive excipients on thermosensitive polymeric micelles

FP-3 **Milana Vuković**, Mladena Lalić-Popovića, Nemanja Todorović, Jelena Čanji Panić, Dunja Vesković, Ivana Smiljanić, Jelena Jovičić-Bata

Pharmacopoeial mass uniformity testing of alpha-lipoic acid dietary supplements

FP-4 **Windah Anugrah Subaidah**, Gábor Katona, Ildikó Csóka

Design, optimization and characterization of rifampicin loaded albumin nanoparticle for nasal preparation

10:50–10:55 **Discussion FP-1 – FP-4**

10:55–11:10 **Presentations FP-5 – FP-7**

FP-5 **Nikolett Csáki-Kónya**, Péter Kovács, Ildikó Csóka

Juran quality model in energy management

FP-6 **Kinga Budai**, Mária Budai-Szűcs

Optimization of metronidazole loaded NLC for sustained antimicrobial effect in the local treatment of periodontitis

FP-7 **Jelena Štimac**, Maša Safundžić Kučuk, Anđela Nosić, Nensi Tomas, Jasmina Lovrić

In vitro biocompatibility testing during early-stage development of ophthalmic formulations using a 3D corneal epithelial model

11:10–11:15 **Discussion FP-5 – FP-7**



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11:15–11:30 Break

11:30–12:30 OP Session 4 – Chairs: Anita Hafner, Marcin Skotnicki

OP-15 – 11:30–11:45 **Ludovico Checchini**

An integrated in vivo genotoxicity framework for potency assessment of nitrosamines

OP-16 – 11:45–12:00 **Bence Sipos, Gábor Katona, Ildikó Csóka**

Controlling the drug release profile of nasal polymeric nanoparticles via hyaluronic acid

OP-17 – 12:00–12:15 **Teodora Tasevska, Luka Sharovikj, David Dodevski, Jovana Danova, Lina Livrinska Trpeska, Nikola Geskovski, Riste Popeski Dimovski, Katerina Goracinova, Maja Simonoska Crcarevska**

Assessing printability of semi-solid extrusion 3D printing systems: The impact of Avicel concentration

OP-18 – 12:15–12:30 **Lomass Soliman, Rita Ambrus**

Development and evaluation of levofloxacin dry powder for inhalation

12:30–13:45 Lunch break

“EGIS room” – Faculty of Pharmacy (6 Eötvös street, Szeged, H-6720)

13:45–15:00 Cultural Program – Visiting the collection of Old Books and Manuscripts and the exhibition “Katalin Karikó’s journey to the Nobel Prize and beyond”

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15:00–16:00 OP Session 5 – Chairs: Rita Ambrus, Alenka Zvonar Pobirk

OP-19 – 15:00–15:15 **Eslam Ramadan**, Norbert Varga, Edit Csapó, Katalin Kristó, Tamás Sovány

Preparation and optimization of lipid-polymer hybrid nanoparticles for oral protein delivery

OP-20 – 15:15–15:30

Mirna Perkušić, Anita Hafner

Development of advanced in situ gelling systems for nasal donepezil delivery

OP-21 – 15:30–15:45

Aleksandra Petković, Marija Krstić

Formulation and testing of the physical stability and in vivo efficiency of creams for skin application containing black goji berries extract

OP-22 – 15:45–16:00

Flórián Benkő, Nóra Zacsik, Katalin Kristó, Tamás Sovány

The effect of critical process parameters on the final product during high-shear granulation of mesoporous silica microparticles

16:00–16:15 Coffee Break

16:15–17:00 FP Session 2 – Chairs: Zsófia Németh, Gábor Katona

16:15–16:30 Presentations FP-8 – FP-10

FP-8

Teodora Glišić, Ivana Aleksić

Does the carrier type affect the CQAs of liquisolid tablets with atorvastatin calcium?

FP-9

Dilay Göksel, Rita Ambrus, Petra Party

Development of inhalable extra-fine particles of vancomycin for the treatment of local lung diseases

FP-10

Anna Kurucz, Ildikó Csóka

Patient centered pharmaceutical development and clinical trials: patient recruitment and retention

16:30–16:40 Discussion FP-8 – FP-10



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16:40–16:55 Presentations FP-11 – FP-13

FP-11 **Cong Khanh Truong**, Ildikó Csóka, Bence Sipos, Gábor Katona
Intranasal delivery of amphotericin B to the cerebrospinal fluid using a discoidal nano system

FP-12 **Dominika Csajbók**, Dorina Gabriella Dobó, Ildikó Csóka
Increasing the effectiveness of feasibility through early PI involvement

FP-13 **Aleksandra D. Čoškov**, Nemanja B. Todorović, Jelena M. Čanji-Panić, Zita J. Farkaš-Agatić, Ana S. Pilipović, Vesna B. Tepavčević, Nataša P. Milošević, Mladena N. Lalić-Popović
Physical characterization of 3D printed PVA capsules produced by fused deposition modelling

16:55–17:00 Discussion FP-11 – FP-13



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9:00–10:15 OP Session 6 – Chairs: Eliza Wolska, Heba Banat

OP-23 – 9:00–9:15 **Martin Deák**, Nur Aslan, Katalin Kristó, Tamás Sovány

Development of lysozyme-loaded self-emulsifying drug delivery systems using hydrophobic ion pairing

OP-24 – 9:15–9:30 **Dragana Zaklan**, Sara Šijan, Jovana Milutinov, Veljko Krstonošić, Nebojša Pavlović

Influence of guar gum on the stability and thermorheological properties of soy protein isolate-stabilized oil-in-water emulsions

OP-25 – 9:30–9:45 **Feria Hasanpour**, Oliwia Kordyl, Zuzanna Styrna, Barbara Jadach, Tomasz Osmalek, Ferhan Ayaydin, Mária Budai-Szűcs, Anita Kovács, Szilvia Berkó

Design and development of LCD-based 3D-printed microneedle arrays with hydrogel coating for local anesthesia

OP-26 – 9:45–10:00 **Maryam Abdulkhaled Oleiwi**, Ali Al-Samyai, Aya Y. Al-Kabariti, Khaldun M. Al Azzam, Simone Carradori, Walhan Alshaer

Codelivery of Raloxifene and Rutin as PEGylated Nanoliposomes: Formulation, Characterization, and Prophylactic Activity Against Breast Cancer

OP-27 – 10:00–10:15 **Zsófia Ilona Piszman**, Petra Party, Rita Ambrus

Development of a chlorpromazine containing dry powder inhaler for targeting systemic effect

10:15–10:30 Coffee break



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10:30–11:30 OP Session 7 – Chairs: Jelena Parožić, Marija Tasić-Kostov

OP-28 – 10:30–10:45 **Luca Éva Uhljar**, Tekla Jäger, Rita Ambrus
Preparation of orodispersible nanofibers

OP-29 – 10:45–11:00 **Josip Ljubica**, Jasmina Lovrić
Loteprednol etabonate-loaded nanoemulsions for the treatment of dry eye disease

OP-30 – 11:00–11:15 **Lina Livrinska Trpeska**, Aleksandra Ivanoska-Dacikj, Petre Makreski, Nikola Geskovski
Electrospinning as a versatile platform for engineering scaffolds in wound healing applications

OP-31 – 11:15–11:30 **Alaa Gamiel**, Mahwash Mukhtar, Rita Ambrus
Characterization of novel lornoxicam liquitables: In vitro permeability, cytotoxicity, and stability evaluation

11:30–11:45 Closing Ceremony



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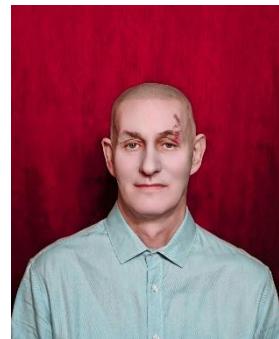
Plenary lectures



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Computer Fluid Dynamics Models Validation in Pharmaceutical Applications

Gábor Klivényi^{1,2}, Zs. Deák^{1,2}, Zs. Horvath^{1,2}, B. Jancsik²

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²Opulus Ltd. 2669 BayShore Dr. 17012 N, Miami FL 33133 USA

Computational Fluid Dynamics (CFD) has evolved into a powerful and widely adopted tool for analyzing and optimizing complex flow, heat, and mass transfer phenomena across many engineering disciplines. In the pharmaceutical industry, however, its broader potential remains underutilized, in part due to challenges in experimental validation and the interdisciplinary nature of pharmaceutical processes. This lecture introduces CFD to a non-specialist audience and demonstrates how validated CFD models can become reliable, decision-support tools in pharmaceutical development, manufacturing, and science.

The presentation begins with a concise overview of the historical development of CFD, followed by its gradual adoption in pharmaceutical applications such as solid dosage manufacturing, coating, drying, and containment. Emphasis is placed on the critical importance of experimental validation for ensuring model credibility—an aspect that is particularly demanding in pharmaceutical environments characterized by multiphase flows, transient conditions, and strict regulatory requirements.

A central focus of the lecture is the role of advanced in-process measurement technologies in bridging simulations and reality. The talk highlights the contribution of Opulus, a company that develops and manufactures a world-unique family of wireless data loggers (PBX family) specifically designed for challenging industrial environments. PBX-TH, PBX-THDP, and PBX-EO data loggers enable simultaneous, high-resolution measurements of temperature, humidity, pressure, and gas concentration within moving and enclosed systems. These capabilities provide unprecedented experimental datasets for the direct validation and refinement of CFD models under real process conditions.

Practical application examples are presented, including aqueous tablet coating and fluid bed processing, illustrating how validated CFD models can improve process understanding, reduce development time, mitigate scale-up risks, and support quality-by-design strategies. The lecture concludes with a forward-looking discussion on emerging applications, such as pharmaceutical packaging and plastic container processes (including blister and bottle systems), as well as the economic impact of CFD-driven optimization on development costs and manufacturing efficiency.

By combining fundamental concepts, real-world case studies, and novel validation technologies, this lecture aims to demystify CFD for pharmaceutical scientists and engineers and to demonstrate its value as a robust, experimentally anchored tool for modern pharmaceutical innovation.



VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

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Clinical Trials Overview: An Introduction to Clinical Research

Péter Ágoston

MSD

Clinical trials are a cornerstone of evidence-based medicine, providing the scientific foundation for the development, evaluation, and approval of new medical interventions. This presentation offers a comprehensive overview of clinical trials, serving as an introduction to the fundamental principles of clinical research. It outlines the key phases of clinical trials, from early-phase safety assessments to large-scale efficacy studies and highlights their distinct objectives and methodological characteristics.

The presentation also addresses essential aspects of clinical trial design, including randomization, control groups, blinding, and outcome measures, emphasizing their role in ensuring scientific validity and reliability. Ethical and regulatory considerations, such as informed consent, patient safety, and compliance with international guidelines, are discussed to underscore the responsibilities of researchers in protecting study participants.

Additionally, the talk provides insight into the roles of various stakeholders involved in clinical research, including investigators, sponsors, regulatory authorities, and patients. By offering a structured and accessible overview, this presentation aims to enhance understanding of how clinical trials contribute to medical innovation and improved patient care.



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Abstracts

Oral presentations



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OP-01

DOI: [10.14232/syprtbrs.2026.24](https://doi.org/10.14232/syprtbrs.2026.24)



Thermo-Responsive Mucoadhesive Nanocarrier Systems for Localized Periodontitis Therapy: Development, Characterization, and Biopharmaceutical Evaluation

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Background: Periodontitis is a chronic inflammatory disease characterized by microbial infection–driven tissue destruction, where effective local drug delivery remains challenging due to limited retention and rapid clearance from periodontal pockets. Nanostructured lipid carriers (NLCs) and *in situ* gelling systems offer a promising strategy to enhance localized, sustained therapy.

Methods: In this study, apigenin (AP) and clove essential oil (CEO) were co-incorporated into NLCs, which were subsequently embedded in thermoresponsive polymer *in situ* gels at varying polymer concentrations. The formulations were comprehensively characterized for particle size, morphology, thermal behavior (DSC), chemical distribution (Raman mapping), rheological and gelling properties, mucoadhesion, and *in vitro* drug release kinetics.

Results: TEM and DSC analyses confirmed the successful formation of spherical, well-dispersed NLCs present in an amorphous state. Incorporation of NLCs significantly enhanced gel strength, reduced gelation time, and slightly increased gelation temperature compared to blank polymeric gels. Mucoadhesive testing demonstrated a concentration-dependent increase in adhesive force and work of adhesion, with NLC-loaded gels exhibiting up to a two-fold improvement over corresponding blank formulations. *In vitro* release studies revealed sustained AP release from NLCs and NLC-loaded gels over 48 hrs, following predominantly Korsmeyer–Peppas kinetics, indicative of diffusion-controlled transport mechanisms.

Conclusions: The developed AP and CEO loaded NLC-based *in situ* smart gels exhibit favorable physicochemical properties, strong mucoadhesion, and prolonged drug release, highlighting their potential as an effective localized delivery system for periodontal therapy.

Acknowledgement

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Synthesis and Characterization of Bimetallic Nanoparticles Loaded with *Chenopodium quinoa* Extract: Assessment of Antibacterial and Cytotoxic Effects

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The rise of multidrug-resistant bacteria and cancer as significant global health issues has intensified the quest for innovative therapeutic agents that are both efficacious and biocompatible. This study prepared copper–silver bimetallic nanoparticles (Cu–Ag BNPs) by an eco-friendly, plant-mediated approach utilizing *Chenopodium quinoa* seed extract as a natural reducing and stabilizing agent. The characterization of the Cu–Ag BNPs validated the effective synthesis. UV–Vis spectroscopy identified distinct plasmonic absorption peaks for both silver and copper, whilst Fourier-transform infrared spectroscopy (FTIR) demonstrated the existence of functional groups from quinoa extract that facilitate reduction and stabilization. Transmission electron microscopy (TEM) revealed primarily spherical nanoparticles with average dimensions in the nanometric range of 40.53nm-91.77 nm, although dynamic light scattering (DLS) indicated a limited size distribution varied from 101.9nm to 176.4 nm and a polydispersity index suggestive of homogeneity. Zeta potential tests varied from -11.6mV to -27.0 mV , indicating considerable colloidal stability. The BNPs exhibited notable antibacterial efficacy against a wide array of ATCC standardized pertinent Gram-positive and Gram-negative pathogens, including *Salmonella typhi*, *Listeria monocytogenes*, *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, *Acinetobacter johnsonii*, *Enterococcus faecalis*, *Serratia marcescens*, *Escherichia coli*, *Staphylococcus aureus*, and *Acinetobacter lwoffii* with a zone of inhibition ranging between 15 mm and 19 mm using agar-well diffusion method and OD of 6.13% to 71.4%. Following 24 hours of treatment with BNPs at 100 $\mu\text{g}/\text{mL}$. The BNPs were tested for quorum sensing inhibition using *C. violaceum* strain with a zone of 15mm and IC₅₀ of 4.79 μM , indicating that Cu–Ag BNPs can disrupt bacterial communication networks essential for virulence and biofilm development. The MTT test was employed to assess cytotoxicity in human colorectal cancer cell lines HCT-116. The BNPs had a dose-dependent antiproliferative impact, with IC₅₀ values of $1.3 \pm 0.14\text{ }\mu\text{g}/\text{mL}$ for HCT-116. The results indicate that Cu–Ag BNPs produced with *Chenopodium quinoa* seed extract possess antibacterial, anti-quorum sensing, and cytotoxic properties. Their environmentally friendly production, wide-ranging effectiveness, and biocompatibility render them excellent candidates for future usage in antibacterial and anticancer therapy.

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Balancing laser marking efficiency and enteric film coated tablets integrity

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Laser-based QR code marking directly onto oral solid dosage forms (OSDFs) provides a package of benefits in the healthcare sector. This study applied an ultrafast Ti:sapphire laser to mark traceable QR codes on enteric film-coated tablets, supplementing package-level serialization for anti-counterfeiting.

Ibuprofen tablets underwent direct compression followed by dual-layer film coating. The inner layer was a gastro-resistant formulation (Acryl-EZE® MP, Colorcon, Hungary), and the outer layer was an immediate-release, colored coating (Opadry®, Colorcon, Hungary). QR codes were engraved on the tablet surfaces via laser ablation using varied parameters (e.g., pulse number and laser energy). Post-processing, the tablets were characterized to assess changes in their functional performance.

Marking achieved sufficient speed, precision, and capacity for small batches. In addition, the readability of QR code depended strongly on laser parameters and coating types. By optimizing laser settings and coating thickness, selective ablation of the outer layer was achieved while preserving the integrity and functionality of the gastro-resistant coating. These findings have been confirmed by *in vitro* dissolution test, scanning electron microscopy measurements, and Raman spectrometry where no chemical decomposition of drug or even the tablet core was detected.

In conclusion, ultrafast Ti:sapphire laser marking holds promise for OSDF design. However, careful consideration of formulation and processing conditions before application is required, particularly when talking about modified-release tablets.

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Formulation and characterization of propranolol hydrochloride-loaded liposomes

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Liposomes are employed as carrier systems, thereby safeguarding active pharmaceutical agents (APIs). They facilitate the incorporation of both lipophilic and hydrophilic drug molecules, ensuring targeted drug delivery. The properties of the liposomes are influenced by their lipid composition, surface charge, size, and method of preparation [1]. The modification of the charge of the phospholipid bilayer was achieved through the incorporation of stearylamine (SA) or dicetyl phosphate (DCP) membrane additives. The objective of this study was to successfully incorporate propranolol hydrochloride and to enhance encapsulation efficiency (EE%).

The synthesis of liposomes was conducted by using the thin-film hydration method. The molar ratios of the samples, as determined in a previous study [2], were found to be 8.5:4.5:6.5 for PC: CH: DCP, 12:5:5 for PC:CH:SA, 2.53:0.63:4.06:2.64 for DPPC:DSPC:CH:SA, and 2.53:0.63:1.53:3.96 for DPPC:DSPC:CH:DCP. Trehalose was present at a concentration of 5 w/w%, while propranolol hydrochloride was present at concentrations of 10, 20, or 50 w/w%, as indicated in the composition. The DLS technique was employed for the purpose of size, PDI and zeta potential measurements. Furthermore, the in vitro release was sustained. The structure was examined via FT-IR and Raman spectroscopy.

Several factors support the appropriateness of the 20% propranolol hydrochloride concentration. Firstly, the size of the samples (100-261 nanometers), and the zeta potential was 14-30 mV for the SA samples and -26 to -36 mV for the DCP samples. Thirdly, the PDI was found to be approximately 0.3. The parameters demonstrate stability. The FT-IR and Raman spectra indicated the incorporation of propranolol hydrochloride into the liposomes. Moreover, SA and DCP samples demonstrating comparable outcomes. The drug release (60-100%) comprised reference samples (API without liposomes) and propranolol hydrochloride containing liposomes in varying concentrations. In the majority of cases, the API containing liposomes demonstrated higher levels of release in comparison to the reference samples. Following extensive analysis, the incorporation process was deemed to have been successful, with the resultant material exhibiting the expected physical and chemical properties.

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Lipid-based nanocarriers for intranasal delivery of Rifampicin

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This study aimed to prepare rifampicin-loaded cubosomes (RIF-CUBs) followed by coating with chitosan (CUB-CS) for intranasal administration to improve the stability, solubility and bioavailability of RIF.

RIF-CUBs were prepared using a melt dispersion emulsification method [1], with different types of Pluronic® (F127 and F108). Then, chitosan 1% w/v was used to prepare CUB-CS. The prepared formulations were characterized regarding to Z-average, PDI, Zeta Potential, EE%, in vitro drug release, ex vivo nasal permeability (ETT-TUKEB: IV/3880-1/2021/EKU), in addition to the chemical stability.

The results showed the suitability of RIF-CUBs and CUB-CSs as a drug carrier; where Z-average <200 nm, PDI <0.5, ZP >|±30| mV. CUB-CSs demonstrated higher EE% values comparing to RIF-CUBs. In addition, the release rate was higher at pH 5.6 than pH 7.4, and only RIF-CUB1 had higher release rate than pure RIF while the other formulations showed more controlled release at both conditions. The ex vivo results showed that RIF diffusion from the prepared formulations was higher than pure RIF. Finally, the chemical stability of RIF was improved by utilizing RIF-CUBs and CUB-CSs.

In conclusion, utilizing of cubosomes as a drug carrier of RIF for intranasal delivery system could be a promising approach to improve the stability and bioavailability of RIF.

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Stability and *in vitro* evaluation of captopril-loaded mucoadhesive buccal films

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Buccal films offer an effective alternative to traditional oral dosage forms by improving drug bioavailability and patient adherence. Chitosan is a key polymer for such films due to its biodegradability, mucoadhesion, and permeation-enhancing properties, which can be further improved by salification with ascorbic acid. Captopril, an ACE inhibitor used for hypertension and heart failure, is administered orally. It undergoes hepatic first-pass metabolism, resulting in a bioavailability of 60–75%. Thus, buccal delivery of captopril can enhance bioavailability and overcome the limitations associated with the oral route. In our previous work, captopril-loaded chitosan ascorbate buccal films were successfully formulated and optimized. In this work further investigations were carried out with regard to the biocompatibility, permeability, and stability. Stability test of drug-free and drug-loaded films was conducted under controlled temperature and humidity. Cytotoxicity and permeation were also evaluated using an *in vitro* buccal cell line model. Stability evaluation revealed changes in mechanical properties of the prepared films during storage. Spectroscopic analyses suggested that the observed variations were predominantly associated with physical changes within the film matrix due to moisture uptake rather than chemical degradation. Cytotoxicity testing demonstrated acceptable cellular compatibility of the polymeric system, supporting its suitability for buccal application. Furthermore, *in vitro* permeability test indicated that the films were capable of enhancing buccal captopril transport. Overall, our findings provide supportive evidence for the potential of chitosan-ascorbate buccal films application as a captopril delivery system, while underscoring the need for suitable packaging during storage.

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Natural deep eutectic solvent-based green tea leaves extracts for hyaluronidase inhibition in skin care formulations

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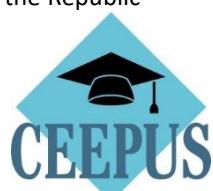
Natural deep eutectic solvents (NaDES) are becoming more popular as novel "green" extraction solvents. Previous studies have demonstrated their high potential for extraction of polyphenols, as well as for obtaining extracts with better antioxidant activity compared to conventional extracts made with water and ethanol [1]. In the current study, a NaDES composed of betaine and urea was employed for the extraction of bioactive compounds from dried green tea (*Camellia sinensis*) leaves, with a focus on evaluating anti-hyaluronidase activity. Hyaluronidase is an enzyme involved in the degradation of hyaluronic acid, a glycosaminoglycan crucial for maintaining skin hydration and elasticity. The excessive activity of this enzyme leads to skin dehydration and wrinkle formation, hence its inhibition represents a relevant tool in anti-aging strategies. The anti-hyaluronidase activity was determined using a turbidimetric method which quantifies turbidity originating from undigested hyaluronic acid in the presence of potential inhibitors [2]. The results demonstrated that the betaine–urea NaDES extract exhibited significant anti-hyaluronidase activity, with an IC_{50} value of 6.28 ± 0.4 mg/mL. This inhibitory effect was approximately twice as strong as that of the corresponding water and ethanol extracts, which showed IC_{50} values greater than 13 mg/mL, although it remained lower than the positive control, tannic acid ($IC_{50} = 0.026$ mg/mL). These results highlight the potential of NaDES-based green tea extracts as effective sources of bioactive compounds for anti-aging and dermocosmetic applications.

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Thiolated Albumin Polymer for Improved Intranasal Delivery of Levodopa Methyl Ester

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Background: Intranasal delivery bypasses the blood-brain barrier but is limited by rapid mucociliary clearance. To overcome this, thiolated polymers are used to enhance mucosal retention via covalent disulfide bonding with mucus glycoproteins.

Aim: This study aimed to develop and characterize a novel mucoadhesive drug delivery system for the intranasal administration of Levodopa Methyl Ester (LDME) utilizing cysteine-modified Bovine Serum Albumin (BSA-Cys) as a nanocarrier.

Methods: BSA-Cys was synthesized by conjugating L-cysteine to BSA at three distinct molar ratios (1:1, 55:1, and 100:1) using EDC/NHS coupling chemistry, and characterized using FT-IR, DSC, TGA, and XRPD. Performance was evaluated through drug release studies, texture-based mucoadhesion testing, and PAMPA permeability assays.

Results: Comprehensive solid-state characterization (FT-IR, DSC, TGA, and XRPD) confirmed the successful removal of free cysteine and the preservation of an amorphous protein matrix, which is ideal for rapid drug dissolution. Ellman's assay validated the presence of accessible thiol groups across all formulations. Thiolated BSA derivatives exhibited significantly superior mucoadhesive properties compared to native BSA; Notably, the 100:1 conjugate achieved the highest total adhesive work (58.1 Nm mm), indicating strong resistance to mechanical clearance. *In vitro* release studies demonstrated that the modification sustained drug release in PBS and SNES. Furthermore, the BSA-Cys formulation demonstrated an increase in drug flux in the PAMPA model compared to the control, attributed to the "thiol effect" on membrane permeability.

Conclusion: This thiolated albumin platform successfully enhances the mucosal residence and permeability of LDME. Future research will focus on structural confirmation via NMR/CD, alongside cytotoxicity and stability testing for neurological applications.

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Comparative In Vitro Evaluation of Oppositely Charged Donepezil-Loaded Liposomes for Intranasal Drug Delivery

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Background: Intranasal administration provides a direct and non-invasive route for central nervous system (CNS) drug delivery; however, many therapeutic agents still exhibit limited permeability across the nasal mucosa. This study aimed to develop and compare the physicochemical and functional characteristics of oppositely charged liposomes loaded with donepezil hydrochloride (DPZ), using dicetyl phosphate (DCP) and stearylamine (SA) as charge-modifying excipients.

Methods: Liposomes were prepared using a phosphatidylcholine/cholesterol molar ratio of 7:2 through the thin-film hydration technique, followed by probe sonication to obtain nanosized vesicles. The formulations were characterized in terms of vesicle size, zeta potential, and encapsulation efficiency using dynamic light scattering and UV-visible spectrophotometry. The influence of DCP and SA (0.5–2 molar ratios) on vesicle size, surface charge, drug-release kinetics, permeability across a synthetic nasal membrane, and mucoadhesion was systematically evaluated.

Results: Incorporation of DCP led to decreased vesicle size and accelerated drug release, whereas SA increased vesicle size and enhanced mucoadhesion. Both charge inducers significantly improved DPZ encapsulation efficiency (60–80%) due to modification of the lipid bilayer structure. DCP-containing liposomes exhibited superior *in vitro* nasal permeability compared with the plain DPZ solution, while SA-modified vesicles demonstrated stronger mucoadhesive properties.

Conclusion: Both negatively and positively charged liposomal formulations improved the intranasal delivery potential of donepezil. Higher DCP concentrations (PC:CH:DCP 7:2:2) favored permeability, whereas lower SA levels (PC:CH:SA 7:2:0.5) enhanced mucoadhesion. These findings highlight surface-charge modulation as a promising strategy for optimizing liposomal carriers for CNS-targeted intranasal therapy. This work forms part of a broader research program in which dopamine-loaded and vincristine-loaded intranasal liposomal formulations are concurrently being developed to further advance nanocarrier-based nose-to-brain drug-delivery systems.

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Hot melt extruded solid dispersions of resveratrol with mesoporous silica: formulation development and characterization

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Resveratrol (RSV) is a polyphenolic compound with promising pharmacological activity yet limited oral bioavailability due to poor aqueous solubility [1]. This study aimed to develop and characterize RSV solid dispersions (SDs) produced by hot melt extrusion (HME) with reduced crystallinity and high RSV content to support potential bioavailability enhancement. Pre-formulation screening using differential scanning calorimetry (DSC) was conducted on physical mixtures of RSV with Eudragit® EPO, PEG 6000, and HPMC-AS, alone or in combination with PEG 6000 in ratio 1:1, to identify most promising polymer(s) and RSV loadings. Based on the obtained results, RSV loadings of 20–40% w/w were selected for SD development. HME formulations were prepared using single polymers or their combinations with PEG 6000 in ratios 1:1, 1:2, and 2:1, together with mesoporous silica carrier (Syloid® 244 FP/Neusilin® US2) at a fixed polymer-to-carrier ratio 2:1, representing a novel formulation approach for RSV in HME-based SD development. The extrudates were cryo-milled and assessed for RSV content and its solid-state characteristics by HPLC and DSC analysis. The share of RSV in SD was primarily influenced by the polymer system used, followed by the type of mesoporous silica carrier. Polymer blends with PEG 6000, particularly HPMC-AS/PEG 6000 systems, showed a higher share of RSV in SD compared to other polymer(s), with the use of Syloid® and 20% w/w RSV loading generally resulting in a higher share of RSV in SD. DSC demonstrated a reduction of the RSV melting endotherm in most SDs, consistent with a lower contribution of crystalline RSV to the melting endotherm and suggesting at least partial amorphization of RSV. The extent of the reduction depended mainly on the polymer system and silica carrier used. Overall, the Syloid® 244 FP-based formulation composed of HPMC-AS/PEG 6000 (1:2) and 20% w/w RSV exhibited the most favorable combination of RSV content and reduced melting endotherm and was therefore selected as a basis for further formulation and performance study.

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Thermosensitive polymeric micelles as nanocarriers in nasal administration

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Utilizing thermosensitive polymeric nanocarriers for the intranasal delivery of antidepressants offers a promising strategy to overcome key challenges such as delayed therapeutic onset and systemic adverse effects, which are major contributors to treatment failure. This study seeks to exploit the temperature-responsive properties of Pluronic polymers to develop and evaluate intranasal citalopram-loaded polymeric micelles (CT-PM), with the goal of improving therapeutic efficacy.

According to initial studies, rotary evaporator was utilized to create CT-PM by employing Pluronic® F127 and Poloxamer® 188 as polymeric micelles generators and freeze-drying method was applied on the aqueous product to stabilize it. Thereafter, comprehensive investigations were conducted to evaluate the final product attributes, encompassing the micelle size transformation at nasal temperature, size distribution, entrapment efficiency, thermodynamic solubility, and X-ray powder diffraction. Moreover, *in vitro* studies (drug release and diffusion) were carried out in nasal conditions and micelles stability was inspected in biological media and different storage environments.

Prepared formulation revealed a preferred LCST value (31 °C) with a monodisperse distribution (polydispersity index < 0.3), which ensures stability at ambient temperature and triggered drug release at nasal conditions. It also achieved remarkably improved drug solubility with approximately 90% entrapment efficiency and amorphous transformation. Additionally, 25-fold increase in *in vitro* drug release from CT-PM was observed accompanied with 4- fold enhancement in *in vitro* drug diffusion. Storage stability test demonstrated appropriate stability in both states, liquid and solid, and accepted behaviour was displayed after incubation in biological solutions. This advanced nanoscale platform represents a promising approach for targeted antidepressant delivery to the brain, offering a more rapid therapeutic effect while minimizing systemic side effects. Further studies are planned to evaluate its cytotoxicity profile and *in vivo* pharmacokinetic behaviour.

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Risperidone-loaded surface-modified albumin nanocarriers for intranasal drug delivery

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Background: Risperidone is a first-line drug used in central nervous system-associated disorders, limited by the blood-brain barrier (BBB), hindering its permeation and bioavailability, which creates a significant need for enhancement of permeated concentration to the brain to achieve an effective dosage with as few excipients as possible. These targets can be achieved via the application of fine-engineered human serum albumin nanoparticles (HSA-NPs) due to their bioavailability and biodegradable properties; however, limitations are also present in the form of their limited encapsulation capability and targetability. In this ongoing research, we are optimizing and characterizing the HSA-NPs by the application of polymers to enhance these absent properties of HSA-NPs and to open the intranasal route to enhance the effective brain targeting of our model drug.

Methods: A modified coacervation method was employed to synthesize risperidone-loaded HSA-NPs (RIS-NPs) using Poloxamer 407 (P407). To determine the optimal formulation, a 2^3 factorial design has been set for the determination of HSA and polymer concentrations optimal for our DDS. The colloidal characterization of NPs was measured via dynamic light scattering. Drug binding was measured by HPLC after centrifugation at 4°C and 14,000 rpm for 15 min. The *in vitro* drug release studies were conducted in dialysis bags (molecular weight cut-off: 12 – 14 kDa) and were carried out at nasal conditions and simulated blood conditions.

Results: The characterization studies showed a clear effect on size based on the concentrations of HSA and P407. Most of the formulations were acceptable; however, higher concentrations showed aggregation. The drug binding efficiency shows no clear correlation and is approximately 60% which correlates with the literature data, so no alterations were observed. The drug release studies revealed a close-to-burst-like drug release profile. The formulations with 30 mg/ml HSA concentrations provided a higher overall solubility than the initial, with the respective values varying between 80% to 100%.

Conclusion: RIS-NPs were successfully prepared and characterized and showed an improved pharmacokinetic profile based on our drug release studies. The modification of HSA-NPs with P407 was also favourable, as it contributed to the improvement of drug release under nasal conditions, followed by a steady profile.

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Enhancing Drug Incorporation in FDM 3D-Printed Tablets Using Pan Coating Technique

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Drug incorporation into Fused Deposition Modelling (FDM) printed tablets can be achieved either by hot melt extrusion (HME) of drug loaded filaments or impregnation of filaments or the printed devices. With HME, the drug and polymer are first melted together and then extruded using a heated nozzle. While, impregnation involves immersing in a highly concentrated drug solution. Loading drug into 3D-printed tablets by deposition of active pharmaceutical ingredient solution by controlled spraying of liquid droplets with pan coating may be novel, automated, accurate, and reproducible alternatives for loading. The project aims the comparison of loading methods to produce paracetamol containing polylactic acid (PLA) based FDM printed tablets. A FDM printer was used to print plain tablets with a honeycomb infill shape. A Pan coater was used for spraying of paracetamol solution onto the 3D printed tablets. The resulting tablets were assessed for drug content, friability%, drug distribution (Raman mapping), Structural Analysis (FT-IR), and dissolution performance. More than 85% loading was achieved for pan coating technique. Paracetamol tablets met USP standards with a weight loss of less than 1%. No appearance or disappearance of peaks was observed in FT-IR analysis, indicating drug-polymer compatibility. Raman mapping showed that the API was distributed mainly on the surface of tablets. Over 80% release in 30 minutes was observed. FDM combined with controlled post-printing drug loading presents a rapid, cost-effective, and flexible novel approach for manufacturing personalized immediate-release tablets.

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Development of PEGylated Nano-Phytosome Formulation with Oleuropein and Rutin to Compare Anti-Colonic Cancer Activity with Olea Europaea Leaves Extract

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Olive leaf extract is a valuable source of phenolic compounds; primarily, oleuropein (major component) and rutin. This natural olive leaf extract has potential use as a therapeutic agent for cancer treatment. However, its clinical application is hindered by poor pharmacokinetics and low stability. To overcome these limitations, this study aimed to enhance the anticancer activity and stability of oleuropein and rutin by loading them into PEGylated Nano-phytosomes. The developed PEGylated Nanophytosomes exhibited favorable characteristics in terms of size, charge, and stability. Notably, the anticolon cancer activity of the PEGylated Nano-phytosomes loaded with oleuropein ($IC_{50}=0.14 \mu M$) and rutin ($IC_{50}=0.44 \mu M$) surpassed that of pure oleuropein and rutin alone. This outcome highlights the advantageous impact of Nano-phytosomes to augment the anticancer potential of oleuropein and rutin. These results present a promising pathway for the future development of oleuropein and rutin Nano-phytosomes as effective options for passive tumor-targeted therapy, given their improved stability and efficacy.

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An integrated *in vivo* genotoxicity framework for potency assessment of nitrosamines

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Since their first identification as pharmaceutical impurities in 2018, nitrosamines have represented one of the most critical challenges in pharmaceutical quality and regulatory science due to their high mutagenic and carcinogenic potential and the resulting extremely restrictive acceptable intake limits. For nitrosamine drug substance-related impurities, acceptable intake limits are often constrained by the absence of compound-specific carcinogenicity data, leading to the reliance on conservative default values. To address this gap, an integrated *in vivo* genotoxicity assessment framework has been designed to generate sensitive and regulatory-relevant genotoxicity data within a single repeated-dose study design, while also providing mechanistic insight. This approach combines the erythrocyte Piga gene mutation assay for the detection of somatic mutations, the alkaline Comet assay for the assessment of primary DNA damage across multiple target tissues, and high-sensitivity error-corrected next-generation sequencing to detect ultra-rare mutations and characterize mutational spectra.

The integrated application of these complementary endpoints within the same cohort of animals enables the generation of high-resolution, tissue-specific mutational profiles while maximizing scientific output in accordance with 3Rs principles. The framework is designed to be readily compatible with regulatory safety assessment workflows and to support benchmark dose modelling approaches aimed at defining compound-specific acceptable intake limits.

Overall, the proposed testing strategy provides a structured approach within the regulatory framework to support the risk assessment of nitrosamine drug substance-related impurities lacking carcinogenicity data, addressing a critical gap in current regulatory practice without the need for dedicated carcinogenicity studies.

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Controlling the drug release profile of nasal polymeric nanoparticles via hyaluronic acid

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Controlled drug release via the nasal route is a challenging area of pharmaceutical technology, yet it offers numerous benefits. As a general observation, nasal drug delivery is rapid due to the highly vascularized nasal mucosa, despite mucociliary clearance limiting residence time on the nasal surface. Mucoadhesive excipients, such as hyaluronic acid, can act in two ways: either they prolong residence time, thereby increasing the likelihood of drug release and permeation, or they can act as permeability enhancers. The current study aimed to demonstrate the concentration-dependent behavior of hyaluronic acid on the drug release profile of polymeric micelles, a novel nanocarrier used for alternative administration routes.

The nanocarriers were prepared via nano spray-drying, followed by a particle characterization using laser diffraction and scanning electron microscopy. Liquid-state characterization techniques included dynamic light scattering and the determination of solubility enhancement-related parameters. *In vitro* drug release and permeability studies were conducted in nasal conditions. Our results highlight the importance of conducting rigorous foundational research to determine whether selecting the most promising excipient yields benefits. The particle size and morphology of the spray-dried particles varied with the hyaluronic acid concentration. At lower concentrations, they exhibited smaller particles but higher polydispersity, whereas at higher concentrations, aggregation was observed. This aggregation also translated into our liquid-state studies, as larger micelles and greater polydispersity were observed. A clear and statistically significant effect was also observed in the drug release and permeability studies, as controlled drug release was observed at higher concentrations, which may be suitable for numerous therapeutic indications.

Thus, the importance of the question of which is more important: appropriate colloidal structure or fitting the potential therapeutic indication has arisen, and, as a general opinion, a structured optimization study must always be conducted to determine the potential of the developed nanocarriers.

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Assessing printability of semi-solid extrusion 3D printing systems: The impact of Avicel concentration

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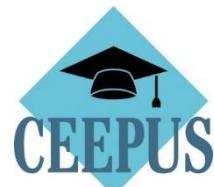
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The increasing need for patient-specific dosing emphasizes the importance of flexible drug delivery systems tailored to individual therapeutic needs. In this context, the aim of this study was to fabricate 3D-printed tablets using cefixime as a model drug and to investigate the effect of Avicel PH102 concentration on the rheological properties, printability, and mechanical stability of the printed tablets. Accordingly, cefixime and Avicel PH102 were first geometrically mixed as dry powders and subsequently incorporated into previously prepared Poloxamer 407 (P407) hydrogel. Concentrations of P407 and cefixime were fixed at 20% (w/w), while the Avicel PH102 content was set at 0.9%, 2% and 4% (w/w). Rheological characterization was conducted using oscillatory amplitude sweep and three-interval thixotropy tests, while printability was assessed on a semi-solid extrusion 3D bioprinter through filament formation and layer adhesion experiments. Cylindrical tablets were printed and dried at room temperature, followed by measurement of mass and dimensional parameters to assess shape retention. All formulations exhibited gel-like behavior with shear-thinning properties and structural recovery after high shear. The 2% Avicel formulation produced the longest filaments and the most consistent tablet dimensions after drying, reflecting an optimal balance between flow during extrusion and structural recovery. At the intermediate Avicel PH102 concentration, elastic strength, thixotropic recovery, and extrusion stability were more favorable than in 0.9% and 4% formulations, allowing consistent layer stacking and dimensional fidelity. These results highlight the importance of excipient concentration in SSE 3D printing and indicate that an appropriate Avicel PH102 content contributes to consistent tablet stability and reproducibility, critical for individualized therapy.

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Development and evaluation of levofloxacin dry powder for inhalation

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Levofloxacin (LEVO) is an effective fluoroquinolone antibiotic against *Pseudomonas aeruginosa* infections in cystic fibrosis patients [1]. This research aims to develop and evaluate a carrier-free LEVO dry powder inhaler via nano-spray drying of an initial nanosuspension, achieving high drug loading, favorable physicochemical properties, and deep lung deposition, offering a convenient alternative to nebulized formulations.

Nanocomposite microparticles were produced through a two-step method, nanosuspension preparation via wet milling using HPMC K4M and tween 80 as stabilizers [2], followed by nano-spray drying [3] with leucine (LEU) utilizing 1:1, 1:2, and 1:3 LEVO: LEU molar ratios. All prepared formulations were investigated in terms of particle size, structure, thermal behavior, morphology, rheology, biopharmaceutical, and aerodynamic performance.

The processing of LEVO produced particles with a median size $D_{0.5}$ of 2–3 μm , exhibiting a monodisperse pattern with a span of less than 2. Scanning electron microscopy revealed microspheres with slight corrugation in the 1:2 and 1:3 ratios' formulations, which is beneficial for aerosolization by reducing interparticle cohesion. This was confirmed by the aerodynamic investigation using the Andersen Cascade Impactor, which recorded a high fine particle fraction (60–70%). Thermal analysis, specifically differential scanning calorimetry, confirmed the formation of new cocrystals of LEVO and LEU. The powder density decreased upon spray drying, and a marked enhancement in solubility along with rapid drug release (>90% within 10 minutes) was observed.

Hence, LEVO powder for inhalation was successfully developed and demonstrated advantageous properties, offering a promising approach for local treatment of infections.

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Preparation and optimization of lipid-polymer hybrid nanoparticles for oral protein delivery

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Oral delivery of peptide/protein drugs is hindered by poor bioavailability due to their instability and limited systemic absorption. Multiple approaches have been proposed to overcome these challenges. Amongst them, lipid-polymer hybrid nanoparticles (LPHNs) may provide a promising solution by combining the structural stability of polymers with the biocompatibility of lipids to enhance peptide protection and absorption through biological barriers. The aim of this work is to design a cost-effective LPHN formulation and systematically optimize the factors affecting their physicochemical characteristics.

LPHN formulations were prepared by a combination of two simple methods: ionic gelation for preparation of polymeric cores, and ethanol injection method for lipid shell formation. Experimental design approach was implemented to study and optimize the factors affecting nanoparticle properties such as particle size, polydispersity index (PDI), zeta potential, and protein encapsulation efficiency (EE).

Polymer core optimization revealed that pH and temperature were the most significant factors, with the optimal core exhibiting a particle size of 235.1 nm, PDI of 0.061, zeta potential of -19.74 mV, and EE of 61.55%. On the other hand, Lipid shell optimization indicated that Aqueous/Organic volume ratio (A/O ratio) had the most significant effect on particle size, PDI, and EE, followed by the Lipid/Polymer mass ratio (L/P ratio). The final optimized LPHN formulation had a particle size of 258.16 nm, PDI of 0.277, zeta potential of -39.02 mV, and EE of 70.41%. These findings suggest that LPHNs prepared via simple, protein-friendly methods may offer a promising platform for oral protein delivery.

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Development of advanced *in situ* gelling systems for nasal donepezil delivery

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Alzheimer's disease is chronic and progressive neurodegenerative disorder. Donepezil, an acetylcholinesterase inhibitor, is the first-line drug for symptomatic treatment of dementia and is predominantly available as oral solid dosage forms. However, oral administration is associated with several limitations: first-pass metabolism, gastrointestinal side effects, and limited brain delivery due to poor penetration across the blood–brain barrier. Nasal drug administration represents a promising alternative for bypassing the blood–brain barrier, enabling direct nose-to-brain delivery primarily *via* the olfactory nerve and, to a lesser extent, the trigeminal nerve. Deposition to a targeted region of the nasal cavity, mucosal retention time, and drug release profile are critical factors for optimised therapeutic outcome of nasally administered drug.

In this study, donepezil-loaded chitosan/mannitol microspheres were successfully prepared as a dry powder delivery system using spray drying technique equipped with an ultrasonic nozzle. In parallel, a liquid *in situ* gelling system for nose-to-brain delivery was formulated as a thermosensitive solution containing donepezil, chitosan, and β -glycerophosphate. A design of experiments (DoE) approach enabled optimisation of formulation, process, and administration parameters, yielding advanced powder and liquid *in situ* gelling formulations with desirable characteristics. Both systems exhibited suitable rheological and spraying properties, with particle and droplet sizes appropriate for nasal administration. Nasal deposition studies demonstrated high olfactory deposition for both formulations. Moreover, the systems showed favourable biopharmaceutical performance, including prolonged drug release, adequate mucoadhesion, pronounced permeation-enhancing effects, and non-irritating behaviour. Overall, the systematic formulation approach yielded promising nasal donepezil delivery systems, providing a basis for further *in vivo* evaluation.



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Formulation and testing of the physical stability and *in vivo* efficiency of creams for skin application containing black goji berries extract

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Introduction: Black goji berries, *Lycium ruthenicum* Murr., have proven medicinal properties that came from present secondary metabolites. Due to their positive effects, they can be used in skin treatment. Creams were used as a base because of the good feeling they leave on the skin and their good appearance. In order to select the optimal formulation, it is necessary to examine the physical, chemical and microbiological stability.

The aim: The aim of the study is to formulate and test the physical stability of creams containing black goji berries extract, and then conduct *in vivo* efficiency testing on the skin of healthy volunteers.

Material and Methods: During the study, four active creams were formulated, two lipophilic with Abil EM ®90 and two hydrophilic with glycerol-monostearate SE as emulsifiers. Creams containing glycerol-monostearate SE, were not used for further testing because of phase separation. The examined parameters to assess physical stability included: electrical conductivity, phase separation and pH. For *in vivo* efficiency testing, due to better organoleptic properties, just one active cream was used. The examined parameters included: transepidermal water loss, erythema index, friction, hydration and pH.

Results: The tested creams retained their characteristic odour and homogeneous appearance, with a colour changing to pink. The electrical conductivity was 0.0 μ s/cm, no phase separation was observed during centrifugation, while there was a difference between the initial pH values and those measured later ($p \leq 0.05$). No significant difference was observed in the efficiency parameters compared to placebo cream and untreated skin ($p > 0.05$). The friction showed an increase after 7 and 14 days of application compared to the basal value ($p \leq 0.05$).

Conclusion: Both creams showed physical stability except for a slight discolouration. Although the test cream showed some effects, a study on diseased skin would provide much better insight into the potential effects of cream.



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The effect of critical process parameters on the final product during high-shear granulation of mesoporous silica microparticles

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Mesoporous silica is widely used as a carrier in pharmaceutical solid dosage forms due to its high specific surface area, large pore volume, and excellent adsorption capacity. However, its poor powder flowability—caused by irregular particle shape, small particle size, and low bulk density—create challenges during both batch and continuous manufacturing. Wet granulation can improve these properties, but it can reduce drug-loading capacity by decreasing surface area by blocking pores. This study aimed to develop a binder-free high shear granulation process and to evaluate the influence of key process parameters on granule quality.

Mesoporous silica (Neusilin FH1) and microcrystalline cellulose (Comprecel 101) were used as raw materials, with purified water as granulation liquid. Granulation was performed using a high shear granulator. A full factorial 2^2 experimental design with a center point was applied to assess the effects of impeller speed and liquid dosing speed. The prepared granules were dried, sieved, and characterized for particle size, size distribution, particle morphology, yield percentage, flow properties, crushing strength, moisture content, and compressibility.

The results showed significant differences between batches. Granulation successfully improved powder flowability compared to raw materials. The higher impeller speed combined with the lower dosing speed produced granules with an increased crushing strength. Improvements in particle size distribution and yield were also observed in selected batches. The improvement in sphericity is consistent with the powder flow characteristics.

In conclusion, mesoporous silica can be effectively granulated using purified water alone, indicating that binders are unnecessary under optimized conditions. The developed method significantly improves flowability while maintaining functionality, offering a promising approach for processing mesoporous silica in pharmaceutical applications.

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Development of lysozyme-loaded self-emulsifying drug delivery systems using hydrophobic ion pairing

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Introduction: Oral administration of protein-based therapeutics is limited by gastrointestinal pH, enzymatic degradation and the intestinal barrier. Therefore, developing stable oral formulations with improved bioavailability is a major challenge as an alternative to currently available invasive delivery routes. In this study, lysozyme-loaded, lipid-based self-emulsifying drug delivery systems (SEDDS) were developed and converted into solid dosage form via adsorption onto mesoporous silica to enable tableting.

Methods: Lysozyme was formulated as a hydrophobic ion pair with sodium lauryl sulfate to improve stability and solubility. Liquid SEDDS were prepared using a three-factor constrained mixture design and the emulsifiers (Tween 20/80, Span 20/80) were combined based on a 2² factorial design and Miglyol 810 as the oil phase. The stability parameters of the resulting emulsions were evaluated. Solid SEDDS were obtained by adsorbing the liquid systems onto mesoporous silica (Neusilin UFL2), and compressibility was investigated as a function of liquid load. Artificial neural networks (ANN) were used to analyze the correlations.

Results: A design space enabling the preparation of SEDDS with optimal properties was established. A 1:1 SEDDS-to-silica ratio proved optimal and formulations containing Tween 20 exhibited the most favorable compressibility. ANN modeling identified surface tension as the most influential factor affecting compressibility, allowing reliable prediction of tableting performance.

Conclusion: This systematic investigation of these innovative drug delivery systems can contribute to improving the oral bioavailability of proteins by providing deeper insight into the role of individual formulation components.

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Influence of guar gum on the stability and thermorheological properties of soy protein isolate-stabilized oil-in-water emulsions

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The increasing demand for naturally derived alternatives to synthetic excipients, driven by the principles of "green pharmacy" and the extensive application of emulsions in pharmaceutical and cosmetic formulations, has increased interest in proteins and polysaccharides as emulsion stabilizers. In this context, soy protein isolate (SPI) and guar gum (GG) have demonstrated considerable potential.

Fifteen oil-in-water (O/W) emulsions containing jojoba, linseed or silicone oil stabilized with 3% SPI and 0-0.15% GG were prepared using a rotor-stator homogenizer. Organoleptic properties, pH and physical stability (centrifugal stress testing, temperature cycling and creaming index) were assessed. Rheological and thermorheological properties were determined from flow curves and amplitude, frequency, and temperature sweep tests. Additionally, three zinc oxide-containing emulsions (5% ZnO, 3% SPI and 0.15% GG) were prepared and characterized.

All emulsions exhibited acceptable organoleptic properties and pH values suitable for topical application. Formulations containing 0.15% GG demonstrated superior physical stability, with a pronounced influence of the oil phase type. Rheological characterization revealed rheopectic behavior dependent on GG concentration and oil phase type. Emulsions containing 0.15% GG were predominantly viscous and thermoresponsive, exhibiting a sol-gel transition temperature. ZnO incorporation increased elasticity and altered thermoresponsive behavior.

The combination of 3% SPI and 0.15% GG represent a promising approach for developing physically stable and thermoresponsive O/W emulsions, particularly jojoba oil-containing systems, suitable for topical therapeutic and cosmetic applications.

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Design and development of 3D-printed microneedle arrays with hydrogel coating for local anesthesia

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Coating microneedle arrays (MNAs) with drug-loaded hydrogels offers a precise and minimally invasive strategy for the dermal and transdermal delivery of local anesthetics. Recent advances in additive manufacturing have improved the accuracy and accessibility of microneedle fabrication with high resolution, cost efficiency, and rapid prototyping. In this study, lidocaine-coated MNAs were developed to achieve rapid and effective local dermal anesthesia. Two microneedle geometries with identical heights, base dimensions, and inter-needle spacing were compared in terms of insertion efficiency, mechanical robustness, coating uniformity, drug loading, release behavior, and skin permeation.

Two hydrogel formulations with differing polymer concentrations were used for multilayer dip coating. The rheological characterization demonstrated viscoelastic behavior, with the optimized hydrogel exhibiting superior mechanical strength, adhesion, and spreadability, ensuring uniform and reproducible coating along microneedle shafts.

In vitro and ex vivo insertion studies showed consistent penetration depths without needle fracture or deformation under controlled compression mimicking the thumb pressure force. In vitro drug release studies demonstrated rapid lidocaine release followed by pH-driven non-monotonic diffusion behavior. Moreover, geometry-dependent performance was observed and proved that despite the higher drug loading due to the larger lateral surface, sharper geometry with mechanically stronger tips resulted in more efficient skin penetration, as confirmed by Raman mapping.

These findings demonstrate that 3D-printed hydrogel-coated MNAs can provide predictable, rapid and effective local anesthesia through optimized geometry and coating design.

Acknowledgement

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Codelivery of Raloxifene and Rutin as PEGylated Nanoliposomes: Formulation, Characterization, and Prophylactic Activity Against Breast Cancer

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Purpose: Breast cancer is the leading cause of cancer-related deaths among women. Chemotherapy faces challenges such as systemic toxicity and multidrug resistance. Advances in nanotechnology have led researchers to develop safer and more efficient cancer treatment methods.

Methods: The thin-film hydration method was employed to synthesize PEGylated nanoliposomes (NLs) loaded with raloxifene (RLX) and a combination of RLX and rutin. The NLs were characterized using a ZetaSizer® instrument, transmission electron microscopy (TEM), and high-performance liquid chromatography (HPLC) analysis. The encapsulation of RLX and rutin was confirmed, and cell viability assays were conducted against breast cancer and normal endothelial cell lines.

Results: The encapsulation efficiency significantly increased in the mixed formulation, with RLX reaching 91.28% and rutin 78.12%, indicating successful encapsulation. These NLs remained stable for up to two months at room temperature and one month at 4°C, demonstrating a biphasic release pattern. After 24 hours, approximately 17% of RLX was released from the NLs and 25% from the mixed NLs. In contrast, 55% of rutin was released from the NLs and 70.4% from the mixed NLs within 72 hours. The inclusion of rutin or RLX in the liposomal formulation reduced cytotoxicity against breast cancer cell lines, as indicated by the 3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay. However, it improved safety in normal human cells and tissues.

Conclusion: PEGylated NLs loaded with RLX and rutin demonstrated safe anti-breast cancer effects, outperforming mixed NLs, suggesting the potential for a safer and more targeted treatment. Further investigations are needed into clinical translation.

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Development of a chlorpromazine containing dry powder inhaler for targeting systemic effect

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Dry powder inhalers (DPIs) are used to delivery drugs directly to the lungs. While primarily used in the treatment of respiratory diseases, such as asthma and COPD, they also offer potential for systemic drug delivery. With pulmonary delivery the liver's first-pass metabolism can be avoided, thereby reducing the required effective dose and potentially minimizing side effects.

Our aim was to develop a chlorpromazine-containing (CPZ) DPI using nano-spray drying with appropriate excipients. In addition to the active ingredient, we used pullulan and leucin as excipients to achieve adequate aerodynamic properties. To optimize the production protocol and minimize the number of samples in the testing phase we applied the Placket-Burman and Box-Behnken experimental designs during the preliminary experiments. The spray-drying was executed using the Büchi Nano Spray Dryer B90. We expected the finished DPI formulations to have spherically shaped, micro-sized particles and suitable aerodynamic properties.

In DPI, the particle size was determined by laser diffraction, the shape by scanning electron microscopy, the crystallinity of the materials by X-ray powder diffraction, the chemical structure by Fourier transform infrared spectroscopy, the *in vitro* aerodynamic properties by Andersen cascade impactor, and the cytotoxicity using the A549 cell line. During the *in vivo* experiments the DPI was administered into the lungs of male rats and the CPZ concentration in the lungs and systemic circulation was examined.

In conclusion, we successfully developed a highly optimized production process for CPZ-containing DPIs, achieving exceptionally high fine particle fraction (FPF>95%), precise deposition, and excellent aerodynamic properties (MMAD>2 μ m).

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Preparation of orodispersible nanofibers

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The primary objective of this study was to develop a diclofenac-loaded, orodispersible formulation produced via double-needle electrospinning. To enable the vertical arrangement of two needles, a custom needle holder was designed and fabricated using 3D printing. During the optimization of the drug-free PVP carrier system, the influence of polymer concentration on fiber morphology and average fiber diameter was systematically examined. Electrospinning was feasible for solutions containing 7.5–15 w/w% PVP. At lower concentrations, insufficient viscosity resulted in electrospraying, yielding smooth-surfaced nanoparticles. The optimized material characteristics and processing parameters were subsequently applied to fabricate drug-loaded nanofibers.

Comprehensive characterization was performed, including assessments of morphology, crystallinity, chemical interactions, encapsulation efficiency, drug distribution, in vitro disintegration, in vitro dissolution, cytocompatibility, and 6-month stability. The results demonstrated that the electrospun product formed an amorphous solid dispersion with excellent encapsulation efficiency and a homogeneous distribution of diclofenac within the nanofiber matrix. Disintegration occurred within approximately 5 s in artificial saliva and around 41 s on an artificial tongue model. Complete dissolution in artificial saliva was achieved within 10 min.

Overall, a promising formulation was developed with rapid disintegration, immediate drug release, and good stability. Additionally, a new in vitro dissolution method ("AS-to-FaSSGF") was developed to obtain a bigger picture of drug dissolution throughout the gastrointestinal tract.

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Loteprednol etabonate-loaded nanoemulsions for the treatment of dry eye disease

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Dry eye disease is a complex disorder marked by disrupted tear film homeostasis and inflammation of the ocular surface. Oil-in-water nanoemulsions offer an effective strategy for incorporating drugs with low water solubility and show strong potential for managing dry eye disease. The main goal of this research was to develop biopharmaceutically optimized nanoemulsions for delivering loteprednol etabonate (LE) to the eye. Loteprednol etabonate (LE) is a corticosteroid well suited for the treatment of dry eye disease, as it is rapidly metabolized into an inactive form and has a favorable safety profile. Beyond formulating LE-loaded nanoemulsions, the research aimed to establish *in vitro* methods for their biopharmaceutical evaluation, guided by the key physiological and structural characteristics of the ocular surface. A method for assessing nanoemulsion stability on the ocular surface under biorelevant dilution with artificial tear fluid was successfully developed. The influence of medium complexity and shear stress mimicking blinking on nanoemulsion stability was examined. A quality-by-design approach enabled the optimization of LE nanoemulsions and identified the formulation and processing parameters most critical to achieving consistent drug content. This process identified a lead nanoemulsion with suitable physicochemical properties for ocular administration, robust long-term stability, and compatibility with membrane filtration as a sterilization method. A high-throughput *in vitro* corneal epithelial model was established to evaluate biocompatibility, and the lead LE nanoemulsion showed excellent biocompatibility. Additionally, a novel approach combining dilution and ultrafiltration was developed to study LE distribution between the oil and aqueous phases under biorelevant dilution. Results confirmed that LE dominantly remains in the oil phase even at high dilutions, suggesting that its likely partitions from the oil droplets into the corneal epithelium. The feasibility of transforming LE nanoemulsions into a dry form was also demonstrated. Using electrospinning, the nanoemulsions were converted into hydrophilic, biocompatible nanofibers that rapidly dissolve in aqueous medium and regenerate the original nanoemulsion upon reconstitution.

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Electrospinning as a versatile platform for engineering scaffolds in wound healing applications

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Electrospinning is a highly adaptable and scalable technique for the fabrication of nanofibrous scaffolds with high surface area, tunable porosity and structural similarity to the extracellular matrix, making it particularly attractive for wound healing applications. In this study, coaxial electrospinning was employed to develop drug-loaded poly(lactic acid) (PLA) and poly(ethylene oxide) (PEO) nanofibrous formulations for potential wound-healing applications. The fibers were designed with a PEO core containing clindamycin hydrochloride and diclofenac diethylamine (7:3 ratio) and a PLA shell intended to regulate drug release while maintaining structural integrity. To systematically evaluate the influence of processing conditions on fiber morphology, a Taguchi design of experiments (L9 orthogonal array) was employed, examining polymer solution concentration, applied voltage and flow rate. Scanning electron microscopy revealed that polymer concentration was the most influential parameter affecting fiber diameter homogeneity, followed by flow rate and applied voltage. The optimal electrospinning conditions (11 wt% PLA, 10 kV, 2 mL·h⁻¹) produced fibers with the lowest coefficient of variation, indicating improved uniformity. Raman and near-infrared spectroscopy confirmed the presence of both polymer components, while characteristic drug signals were attenuated due to encapsulation within the PLA shell. Drug content analysis by high-performance liquid chromatography demonstrated homogeneous drug distribution, with recovery values exceeding 90%. Dissolution studies showed rapid release behavior, with approximately 90% of both drugs released within the first hour, attributed to partial shell discontinuity and the inherent brittleness of PLA. Water uptake studies indicated favorable swelling properties, while biodegradability assessment revealed an initial mass loss within the first week followed by a plateau, consistent with degradation governed primarily by the PEO-rich core. Overall, these results demonstrate the suitability of PLA/PEO coaxial electrospun fibers as drug-loaded nanofibrous formulations, while indicating the need for further formulation refinement to achieve prolonged and controlled drug release.

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Characterization of novel lornoxicam liquitables: In vitro permeability, cytotoxicity, and stability evaluation

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Lornoxicam, a potent nonsteroidal anti-inflammatory drug, is commonly used to manage pain and inflammatory conditions. However, its poor aqueous solubility limits therapeutic efficacy by causing variable and delayed absorption, alongside gastrointestinal risks from conventional oral formulations. Liquitables, an innovative dosage form, address these issues to enhance bioavailability.

The objective of this study was to assess the *in vitro* permeability, cytotoxicity, and stability of optimized lornoxicam liquitables.

Apparent permeability coefficients (Papp) were determined for the formulated liquitables [1]. Cytotoxicity was evaluated in Caco-2 cells using the MTT assay (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide). Stability was tested in a desiccator at $25 \pm 2^\circ\text{C}/50 \pm 5\%$ relative humidity, simulating ambient conditions; tests included drug content determination and structural analyses via X-ray powder diffraction (XRPD), differential scanning calorimetry (DSC), and thermogravimetric analysis (TGA) at 0, 3, and 6 months. In addition to dissolution studies in pH 1.2 medium.

In vitro permeability testing revealed a statistically significant increase in the apparent permeability coefficient (Papp) relative to the pure lornoxicam ($p < 0.05$). MTT assay revealed no significant reduction in cell viability at therapeutic concentrations. After storage drug content remained >98%.

In conclusion, these findings establish lornoxicam liquitables as a stable, rapidly dissolving, and permeable formulation with favourable safety profile supporting its potential as an effective and patient-centric oral dosage form for rapid action.

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Abstracts

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Combined ophthalmic nanoformulation of Dexamethasone for improved bioavailability

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Eye drops are the most commonly used topical preparations for eye diseases. In general, they have a low bioavailability due to the natural elimination mechanisms of the eye. There are two main lines of action to increase bioavailability: increasing retention time and increasing penetration. Dexamethasone (DXM) has poor water solubility, so it is difficult to formulate in eye drops. Moreover, it is mainly used in suspension form, which does not help its penetration and retention. Nanostructured lipid carriers (NLCs) allow dissolution of lipophilic active substances, while increasing corneal penetration of the active ingredients as a nanodispersion.

Our aim was to formulate an eye drop, which is able to increase the residence time of the active substance on the cornea and to improve its penetration. NLCs were prepared and combined with temperature sensitive polymer to form an *in situ* gelling eye drop.

The physical and chemical properties of the starting materials and their mixtures, and the particle size, zeta potential, entrapment efficiency of the nanolipids were investigated. Rheological measurements were used to analyse the flow properties and gelling temperature of the smart gels. *In vitro* mucoadhesion measurements were performed on artificial mucosa. Drug release from the smart systems was evaluated using dialysis membranes. Penetration was investigated with *ex vivo* porcine eyes examination, supplemented with Raman mapping.

The size of the nanocarrier was between 100-200 nm, and zeta potential suggested a sterically stabilization. The gelling temperature of the systems was shifted by the NLCs. The polymer-NLC combination resulted in a good adhesion property and had a strong effect on drug release. On the basis of the Raman mapping, NLCs accumulated in the stroma section of the cornea.

As conclusion, the combination of NLC and polymer resulted unexpected structural changes, but based on the tests and results obtained, it can be optimized for the desired purpose.

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Investigation of the nasal applicability and the effect of mucoadhesive excipients on thermosensitive polymeric micelles

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Neuropsychiatric disorders like depression and schizophrenia present significant therapeutic challenges because the blood-brain barrier limits drug access to the brain. Additionally, conventional oral drugs often cause systemic side effects. This study aimed to develop and compare intranasal thermosensitive polymeric micelles using Pluronic F127, Poloxamer 188, and tocophersolan for the delivery of citalopram (CT) and risperidone (RIS). The primary goal is to improve brain targeting. To increase mucosal adhesion and structural stability, the micelles were loaded in two different gelling polymers: Chitosan (CH) and Hyaluronic Acid (HyA).

CT and RIS-loaded micelles were prepared using the thin-film hydration method. Different concentrations of CH and HY, ranging from 0.1% to 1%, were investigated. The effects of these adhesive polymers on the Z-average, polydispersity index (PDI), and lower critical solution temperature (LCST) were measured using dynamic light scattering (DLS). *In vitro* drug-release profiles were investigated for all samples under simulated nasal conditions at 35 °C to ensure the system operates at nasal-cavity temperature.

The LCST results for CT-CH (0.1 and 0.5%) and CT-HyA (0.1 and 1%) showed preferred values of 28, 33, 29, and 27 °C, respectively, with PDI < 0.3. In contrast, the RIS-CH formulation exhibited undesirable LCST and PDI values, whereas RIS-HyA at 0.25% and 0.75% demonstrated favorable LCST values of 29 °C and 28 °C, respectively, along with a homogeneous size distribution. Moreover, drug release studies revealed a significant enhancement compared to raw drug suspensions.

These findings confirm that loading thermosensitive polymeric micelles in gelling polymers is an effective strategy to improve the nasal delivery of both citalopram and risperidone. Further studies are required to assess *in vitro* and *in vivo* permeability, mucoadhesive characteristics, and cytotoxicity.

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Pharmacopoeial mass uniformity testing of alpha-lipoic acid dietary supplements

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Uniformity of mass is a fundamental quality attribute that reflects the manufacturing consistency of solid oral dosage forms. In this study, mass variation testing was performed on a total of 17 commercial alpha-lipoic acid (ALA) dietary supplements (DS), including 14 capsule formulations and three tablet formulations. The testing was conducted in accordance with the requirements of the chapter 2.9.40. of the European Pharmacopoeia, 10th edition.

Among the tested products, one tablet formulation and three capsule formulations failed to comply with the pharmacopoeial acceptance criteria for mass uniformity. The compliant products were predominantly characterized by relatively simple formulations, typically containing ALA as the main active ingredient, combined with conventional excipients such as microcrystalline cellulose, magnesium stearate, silicon dioxide, and hydroxypropyl methylcellulose- or gelatin-based capsule shells. In some cases, a limited number of additional active substances, including B-group vitamins, zinc oxide, glutathione, or vitamin D, were present without adversely affecting mass uniformity. In contrast, the non-compliant formulations generally exhibited increased compositional complexity, incorporating multiple active ingredients such as vitamins, minerals, flavonoids, and trace elements, together with a broader range of excipients, including inorganic fillers and modified starches. The non-compliant tablet formulation contained ALA, gelatin, calcium carbonate, and modified starch.

Overall, the findings indicate that formulation composition and excipient selection may influence mass uniformity outcomes in ALA dietary supplements. Mass non-uniformity may compromise dose consistency between individual units, highlighting uniformity of mass as a simple yet meaningful test for assessing manufacturing consistency of ALA dietary supplements.

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Design, optimization and characterization of rifampicin loaded albumin nanoparticle for nasal preparation

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Rifampicin is a macrocyclic antibiotic drug, which has low bioavailability due to its poor water solubility. To overcome this limitation, its formulation into nanoparticles can be advantageous. Albumin nanoparticles have attracted growing attention as promising carriers for alternative drug delivery routes, such as nasal administration. However, the optimization of rifampicin-albumin nanoparticles for nasal preparation remains underexplored. Therefore, this research aimed to develop rifampicin-albumin nanoparticles with good physical properties for nasal preparation. The nanoparticles were synthesized with desolvation method using bovine serum albumin, ethanol as a desolvating agent, and glucose as a cross-linker. The Plackett–Burman design was employed to investigate the most influential parameters for particle size (average hydrodynamic diameter) and polydispersity index (PDI). The parameters involved in the formulation are albumin concentration, ratio drug-albumin, cross-linker concentration, stirring rate, volume of desolvating agent, incubation time, and temperature. The Pareto chart identified the three most influential parameters as temperature, albumin concentration, and incubation time. After confirming these influential factors, the future research will focus on identifying their effect on particle size, PDI, zeta potential, drug entrapment efficiency, and drug loading using the Box–Behnken design. The optimized formulation will be further characterized by morphology, drug release, nasal retention and permeability, as well as the minimum inhibitory concentration against relevant pathogens.

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Juran quality model in energy management

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The 2022 energy crisis significantly challenged the operational management of domestic higher education institutions, highlighting the need for systematic and sustainable energy management strategies. This research proposes the adaptation of the Juran Quality Model, grounded in the principles of Quality by Design (QbD), to the implementation and optimization of ISO 50001 energy management systems. The study focuses on three dimensions: quality planning through stakeholder expectation mapping, quality control via the development of energy performance indicators, and quality improvement by integrating risk-based approaches.

Stakeholder analysis, KPI development, and integrated risk management form the methodological core, ensuring that energy management aligns with both operational efficiency and sustainability objectives. By bridging traditional quality management practices with contemporary energy standards, this research aims to create a measurable and systematic framework that enhances organizational performance, supports ISO 50001 certification, and strengthens ESG reporting within higher education institutions. The findings are expected to contribute to the interdisciplinary understanding of quality-driven energy management and inform strategic decision-making in the higher education sector.

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Optimization of metronidazole loaded NLC for sustained antimicrobial effect in the local treatment of periodontitis

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Introduction: Periodontitis is a severe oral disease that affects the lives of millions around the world. The cause of this condition is the formation of the chronic inflammation of the teeth and the surrounding tissues caused by the overgrowing presence of various periodontopathogen microbials. Without proper treatment this condition can lead to permanent damages such as the loss of teeth, the necrosis of the surrounding bone tissue and even various systemic disorders.

The aim of this research is to sustain and control the local antimicrobial effect of metronidazole by encapsulating it to nanostructured lipid carriers (NLC).

Materials and methods: For the liquid lipid component of the NLC-s various essential oils were tested, those that have antimicrobial and antioxidant activity which can complement the effect of metronidazole. Preliminary tests were conducted to find the suitable essential oil, solid lipid and surfactant and the range of their concentrations within they can form a stable NLC system. A 2^3 full factorial design was used in order to optimize the formulation of the NLC. In the factorial design total lipid content, solid lipid content and surfactant concentration were changed as independent variables. Particle size, polydispersity index, zeta potential and encapsulation efficiency were measured for every sample as dependent variables. These parameters were measured right after preparation and 4 weeks later as well, to serve as a stability test.

Results: According to the results of the factorial design, the total lipid content has the strongest effect on the NLC's properties, besides the surfactant concentration also had some impact on it.

Conclusion: After all it can be said, that with the help of the factorial design an optimized composition for metronidazole loaded NLC-s was successfully made. Incorporating metronidazole in NLC systems can elongate its antimicrobial effect, which can be a desirable feature in the local treatment of periodontitis.

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***In vitro* biocompatibility testing during early-stage development of ophthalmic formulations using a 3D corneal epithelial model**

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Biocompatibility screening is an essential early step in preclinical studies of topical ophthalmic formulations. Given the increasing awareness of the cytotoxic effects of certain ophthalmic preservatives, it is crucial to assess the risks associated with topical application of the tested formulations. *In vitro* 3D cell models offer a physiologically relevant and ethically preferable approach for biocompatibility testing under well-controlled experimental conditions. Formulation biocompatibility should be evaluated following both single- and multiple-dose treatment.

In our study, biocompatibility testing was conducted during the development of a preservative-free latanoprost formulation. For this purpose, an extended-throughput 3D corneal epithelium model was employed, based on an immortalized human corneal epithelial cell line (HCE-T) cultured on polycarbonate inserts in a 96-well plate format. Biocompatibility screening was performed using complementary viability assays (MTT and CellTiter-Glo® 3D) and a cytotoxicity assay (LDH-Glo™). While viability assays determine the number of viable cells in a 3D cell culture, the LDH assay assesses plasma membrane integrity by measuring the release of the soluble, stable cytosolic enzyme lactate dehydrogenase (LDH).

The results demonstrated that benzalkonium chloride, used as a preservative, significantly reduced cell viability and caused plasma membrane damage, whereas preservative-free latanoprost formulations did not exhibit cytotoxic effects on cells following either single- or multiple-dose exposure.

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Does the carrier type affect the CQAs of liquisolid tablets with atorvastatin calcium?

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Liquisolid technique is a simple and cost-effective method to enhance the dissolution of poorly soluble drugs. Porous carriers are crucial in these formulations, as their physicochemical properties and compaction behaviour determine the amount of liquid phase, and therefore drug, that can be incorporated, as well as the overall processability and characteristics of liquisolid systems. In this study, liquisolid tablets were prepared using three different porous carriers (Neusilin®US2, Syloid®XDP3050, and Fujicalin®) to investigate the effect of carrier type on compaction behaviour and dissolution. Compaction properties (tensile strength, work of compression, elastic recovery, and detachment and ejection stresses) were measured, alongside contact angle and dissolution testing. All three carriers produced tablets with acceptable mechanical strength (>1.7MPa) and moderate elastic recovery (21–31%). Tablets with Syloid® required the highest net work of compression, reflecting carrier's rigid, brittle structure. Tablets with Fujicalin® showed the highest ejection stress, likely due to lower liquid-loading capacity. In contrast, the formulation with Neusilin®, which had the highest liquid load, demonstrated the lowest detachment and ejection stresses, and the lowest net work of compression and elastic recovery, indicating efficient plastic deformation and effective liquid distribution. Dissolution testing showed that formulations with Neusilin® and Syloid® achieved rapid and complete drug release, with Syloid® being faster (80% in 5 min), consistent with its high wettability (contact angle 17°). In comparison, tablets with Fujicalin® released the drug more slowly and incompletely, likely due to poor wettability (contact angle 52°) and fragmentation as dominant compression mechanism leading to higher tensile strength. These results demonstrate that choice of porous carrier strongly affects compaction behaviour, which, together with wettability, governs drug dissolution from liquisolid tablets.

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Development of inhalable extra-fine particles of vancomycin for the treatment of local lung diseases

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Dry powder inhalers (DPIs) enable efficient pulmonary drug delivery. Furthermore, targeted deposition in deep lung regions can be achieved with extra-fine particles (<2 µm). While vancomycin hydrochloride effectively treats Methicillin-resistant *Staphylococcus aureus*, systemic administration is often hindered by poor lung penetration and dose-related toxicity. Therefore, the aim of this work was to develop vancomycin-loaded DPI formulations to maximize local therapeutic concentrations while mitigating systemic side effects.

DPI formulations were produced via a single-step nano spray drying method at optimized ratios, followed by comprehensive physicochemical and aerodynamic characterization. Mannitol and leucine were utilized as excipients to optimize particle morphology and aerosolization.

Laser diffraction revealed a homogeneous particle size distribution under 2 µm (D50: 1.250 µm), critical for bypassing upper airway retention. Scanning electron microscopy images showed that leucine formed a wrinkled shell to reduce cohesion, while mannitol ensured structural integrity. Differential scanning calorimetry and Fourier transform infrared spectroscopy were conducted to elucidate solid-state properties and molecular interactions. Additionally, flow properties, density, and drug content were determined. The formulation exhibited acceptable flowability (Carr Index: 19.99; Hausner Ratio: 1.25). *In vitro* lung deposition properties were evaluated using the Andersen Cascade Impactor. Results demonstrated superior aerodynamic performance, with a mass median aerodynamic diameter of 1.48 µm and a fine particle fraction of 87.73 %.

In conclusion, nano spray-dried vancomycin particles possess suitable aerodynamic properties, particle size distribution, and ideal aerodynamic characteristics. This DPI system represents a promising carrier for treating pulmonary infections with high local efficacy and reduced systemic risk.

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Patient centered pharmaceutical development and clinical trials: patient recruitment and retention

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The aim of this work was to investigate the determinants influencing patient recruitment and retention in clinical trials from a patient-centered perspective. Clinical research represents the evidentiary basis for medical innovation and public health protection; however, participant enrollment remains one of the most persistent operational challenges within the clinical development process. Delays in recruitment compromise external validity, prolong timelines, and increase development costs.

Existing literature identifies a multifactorial set of barriers, including patient-level, investigator- and site-level, and logistical constraints. Patient-related determinants such as limited health literacy, perceived risk, mistrust toward research, and competing life priorities have been shown to reduce willingness to participate [1,3]. On the investigator and site side, protocol complexity, administrative workload, and insufficient institutional support hinder adequate engagement, while communication gaps further exacerbate participant hesitancy [2–4]. In parallel, logistical and infrastructural constraints—ranging from travel distance to scheduling burden—contribute to both delayed enrollment and participant attrition [2,5].

This study employs structured questionnaires administered to physicians, current trial participants, and the general population, complemented by in-depth interviews. Quantitative and qualitative evaluation will enable the identification and segmentation of motivational drivers, behavioural determinants, and knowledge gaps. Based on these findings, non-financial, ethically compliant motivation strategies will be developed for investigators and sites, accompanied by patient-facing educational materials to improve public awareness and acceptance of clinical research.

Expected outcomes include an evidence-based framework to enhance recruitment efficiency, improve representativeness, and shorten trial timelines, thereby supporting patient-centered clinical development, improving feasibility and operational predictability, and ultimately facilitating the timely translation of novel therapies into clinical practice.

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Intranasal delivery of amphotericin B to the cerebrospinal fluid using a discoidal nano system

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Cryptococcal meningitis is a severe fungal infection in which the fungus invades the body and enters the cerebrospinal fluid (CSF). Intravenous amphotericin B (AmB) remains a first-line treatment. However, systemic AmB achieves limited CSF exposure because of poor water solubility and unfavourable distribution. Intrathecal administration can increase CSF concentrations, but it is associated with significant risk and technical complexity.

The proposed study investigates the feasibility of delivering AmB to the CSF via intranasal administration using a discoidal nanoscale delivery system (nanodiscs). AmB can be incorporated into a lipid bilayer, mainly composed of lecithin and cholesterol, stabilised at the edges by various copolymers. Nanodiscs would be prepared by lipid film hydration to form multilamellar vesicles, followed by controlled disruption into bilayer discoidal nanoparticles.

The methodology relies on colloidal and nasal applicability studies. Particle size and size distribution would be characterised by dynamic light scattering, transmission electron microscopy (TEM), and small-angle X-ray scattering (SAXS), alongside the determination of zeta potential as a relevant nanoparticle characteristic. Structural investigations via thermoanalysis and X-ray powder diffraction would also be carried out, alongside the determination of nanoparticle–active substance interactions using vibrational spectroscopy. *In vitro, ex vivo, and in vivo* nasal applicability studies would also be performed.

With ongoing research and the determination of the correlation between nanoparticle characteristics and permeability profile, an enhanced drug delivery system would be developed to address such unmet clinical needs.

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Increasing the effectiveness of feasibility through early PI involvement

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The objective of this study was to examine the impact of the Principal Investigator's (PI) early involvement in the feasibility phase on the efficiency of clinical trial start-up processes and the number and cost of protocol amendments. Amendments to clinical trial protocols are a frequent occurrence and can result in significant financial expenditure [1]. These amendments are often the consequence of an inadequate evaluation of site capabilities, patient population characteristics, and the practical realities of clinical procedures during the initial planning stages [2].

The present research is grounded in a mixed-methodology approach, integrating qualitative interviews with investigators, clinical research associates (CRAs), and sponsor representatives, complemented by the analysis of real-life clinical trial initiation cases. A particular emphasis was placed on identifying feasibility-related gaps that resulted in protocol modifications, delayed recruitment, or site withdrawal.

The study evaluates how structured early PI engagement—including protocol review, patient pathway assessment, and feasibility-driven feedback—can prevent such issues. Findings indicate that involving the PI early significantly improves feasibility accuracy by aligning protocol requirements with real clinical settings [2, 3]. Sites where investigators reviewed protocols during feasibility showed fewer amendments, faster recruitment, and better protocol adherence.

Early PI input also enabled identification of unrealistic inclusion/exclusion criteria, excessive visit burden, and impractical procedures before regulatory submission. This supports the view that feasibility should not be treated as a purely operational task but as a strategic, multidisciplinary process requiring strong clinical leadership. Integrating investigators early allows sponsors to design more realistic protocols, reduce unnecessary amendments, and improve trial efficiency [1, 4].

The study highlights early PI involvement as a key factor in successful and cost-effective clinical trial initiation. The financial and timeline impact of amendments further underlines this need, as amendments are consistently associated with increased cost and delays [5, 6].

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Physical characterization of 3D printed PVA capsules produced by fused deposition modelling

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Additive manufacturing, or 3D printing is gaining significant importance as an advanced technology in pharmaceutical drug production. Among different printing techniques, fused deposition modelling (FDM) received attention due to its layer-by-layer deposition process for the fabrication of hollow structures intended for oral drug delivery [1]. The aim of this work was to produce empty and water filled capsules using FDM with polyvinyl alcohol (PVA) at 30% and 60% infill densities, and to perform their physical characterization including visual assessment of appearance, mass, hardness, and dimensional measurements, immediately after printing and after 7 days of storage. All produced capsules were yellowish in colour, slightly transparent, and rectangular with rounded edges. The empty formulations with 60% and 30% infill (F60e and F30e) had similar mass values. All formulations had similar hardness immediately after printing. Formulations filled with 100 µl of water (F60 and F30) showed a significant reduction in hardness after 7 days of storage. The greatest increase in capsule height and width was observed after 7 days in the formulation with 30% infill filled with 100 µl of water (F30). Using FDM 3D printing, PVA capsules with different infill densities were successfully produced. Overall, the findings expand current knowledge on the physical properties of 3D-printed PVA capsules.

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