Department of Pharmaceutical Technology



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INFORMATION BROCHURE



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OUR MOTTO

THERE IS NO HIGH-QUALITY EDUCATION WITHOUT A HIGH-QUALITY R&D&I WORK.

GREETINGS FROM THE DEPARTMENT HEAD

Pharmaceutical technology is one of the most dynamically developing fields of the pharmaceutical sciences. In our department extensive research (R) work is done so that we are able to connect with industrial developments (D) and innovations (I). Every year, more than 10 PhD students take part in basic research, and we have a contact with domestic and international cooperating partners to work on common research projects. The results are published in leading prestigious journals. Our work is helped by laboratories equipped with modern machinery and instruments. We design innovative compositions and develop up-to-date technologies not only for the pharmaceutical industry but also for the cosmetic- and food industries. At present, we have 4 patents. The new knowledge is continuously expanded over our educational program. I hope that this introductory brochure will arouse your interest and we can welcome you as a partner in our department.

Prof. Dr. Piroska SZABÓ-RÉVÉSZ, DSc

STAFF OF THE DEPARTMENT (2015)

Piroska SZABÓ-RÉVÉSZ, DSc Zoltán AIGNER, PhD Géza REGDON JR., PhD Erzséber CSÁNYI, PhD Rita AMBRUS, PhD Szilvia BERKÓ, PhD Péter SIPOS, PhD Katalin KRISTÓ, PhD Mária BUDAI-SZŰCS, PhD Orsolya JÓJÁRT-LACZKOVICH/PhD Tamás SOVÁNY, PhD Péter LÁNG Klára HÓDI, DSc istván ERŐS, DSc Mihály KATA, DSc Mária HALÁSZNÉ OLASZ Gabriella MOLNÁR Ildikó VÍGH Éva LÁSZLÓNÉ NAGY Andrea SZALAI Piroska ZOLTÁNNÉ LAKATOS

Full Professor Associate Professor Associate Professor Associate Professor Assistant Professor Assistant Professor Assistant Professor Assistant Lecturer Assistant Lecturer Assistant Lecturer Assistant Lecturer Assistant Lecturer Professor Emerita Professor Emeritus Professor Emeritus Secretary Laboratory Assistant Laboratory Assistant Laboratory Assistant Laboratory Assistant Laboratory Assistant

Klára KOVÁCS Erika FECZKÓNÉ BODA Eszter LÁSZLÓNÉ MOLNÁR Eszter KESZÉG Mónika KRISZTIN liona SÁNDORNÉ BAKOS Ildikó OLÁH Barbara SIPOS Blanka SÜTŐ Boglárka BALÁZS Gabriella HORVÁT Tímea TARI Csilla BARTOS Katalin DÉR Gábor KATONA **Yasmine KORTEBY Keyhaneh KARIMI** Anita CHVATAL **Csaba BARTOS** Mónika BAKONYI **Orsolya GYULAI**

Laboratory Assistant Laboratory Assistant General Assistant General Assistant General Assistant General Assistant PhD student PhD student

RESEARCH GROUP FOR SOLID DOSAGE FORMS & DRUG DELIVERY SYSTEMS

The team has experience in the research and development of various solid dosage forms and drug delivery systems. The focus of the research activity is the better understanding and in silico modelling of conventional single-unit or multiparticulate dosage forms (tablets, capsules, coated dosage forms) and development of new innovative dosage forms (bioadhesive free films, ODT formulations, medicated chewing gums, SIP technology etc.). Besides the conventional APIs, intensive research is performed on the formulation of nanomaterials (titanate nanotubes, etc.) and macromolecular APIs (proteins/peptides) into solid drug delivery systems. In industrial cooperations the group undertakes Quality by Design driven formula and process optimization of solid dosage forms in the field of pharmaceutical, nutraceutical or food industry.



TEAM MEMBERS:

Géza REGDON jr. PhD associate professor-Team leader.

His specific research area is focused on the research and development of medicated free films, coated dosage forms and preparation of multiparticulate drug delivery systems with layering technology. He has special expertise in the field of thermoanalytics (DSC, TG, TG-MS).



Tamás SOVÁNY PhD

assistant lecturer

His research area is focused on studying the effect of drug-carrier interactions on the drug release from oral and implantable matrix systems, Design of Experiment and Artificial Neural Network based process optimization and modelling of mechano- and physicochemical properties of solid dosage forms. He is familiar with the performance and evaluation of vibrational spectroscopic measurements (FT-IR, NIR, Raman) and microscopic image analysis (SEM, μ CT).



Katalin KRISTÓ PhD

assistant lecturer

Her specific research area is the formulation and bioavailability optimization of biotechnologically produced proteins and peptide-like APIs. Development of intraoral dosage forms (bioadhesive free films and tablets, ODT and dental formulations, chewing gums).





INSTRUMENTS & MEASUREMENT METHODS

Analytical tests

Our group provides full scale of particle characterization including: size and shape analysis with sieves and microscopy, measurements of powder rheology, determination of surface free energy (OCA), bulk and true density, moisture content, compressibility, compactibility and tablettability of materials. We also provide measurement for dosage form characterization such as testing of drug dissolution, measurement of mechanical and bioadhesive properties of free films, granules and tablets with self-developed texture analysing system, and testing and evaluation of the swelling force of conventional tablets and swelling matrices Determination of minimal film forming temperature and other thermoanalytical characterisation.

Instruments

- **Strea 1** aeromatic fluid bed granulator and coater
- Freund CF-360 centrifugal granulator
- Zuma semi-automatic capsule filler
- ProCepT 4M8 high-shear granulator (PAT compatible)
- Korsch EKO instrumented eccentric tablet press
- Manesty M3 instrumented eccentric tablet press
- **Ronchi AM8S** instrumented rotary tablet press
- Dragex conventional dragee pan
- ProCepT 4M8 perforated drum coater (PAT compatible)
- Blisterboy blistering machine



There is no high-quality education without a high-quality R&D&I work.

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RESEARCH GROUP FOR

LIQUID & SEMI-SOLID DOSAGE FORMS & DRUG CARRIER SYSTEMS

The focus of the research activity of the team is to develop drug carrier systems for dermal, transdermal, ocular and periodontal applications. Besides the considerable experience in the research and development of various conventional liquid and semisolid dosage forms (solutions, suspensions, emulsions, creams and gels), intensive research is performed on the formulation of modern drug delivery systems such as lyotropic liquid crystals, nanoemulsions, solid lipid nanoparticles and biocompatible bioadhesive polymer based drug delivery systems. The instruments enable us to investigate the drug diffusion and penetration through different synthetic and biological membranes and to characterise the structural properties and rheological parameters of the formulations.



TEAM MEMBERS:

Erzsébet CSÁNYI PhD associate professor – Team leader.

Her specific research area is the development and biopharmaceutical investigation of dermal and transdermal systems. Her main topics are the characterisation of drug/vehicle-skin interaction and the modification of drug penetration through the skin layers.



Szilvia BERKÓ PhD

assistant professor

Her research area is the development of semisolid dosage forms, especially lipid nanocarrier systems (solid lipid nanoparticles, nanostructured lipid carriers). Another field is the modification of drug penetration through the skin in different ways such as using chemical penetration enhancers, electroporation technique or drug carrier systems and their combinations.



Mária BUDAI SZŰCS PhD

assistant lecturer

Her specific research area is the formulation and investigation of mucoadhesive dosage forms in order to increase the bioavailability of mucosal dosage forms. Her main areas are ocular drug deliveries. She deals with stimuli responsive polymers and examines their applicability in ophthalmic formulations using rheological, mucoadhesion and drug release measurements.









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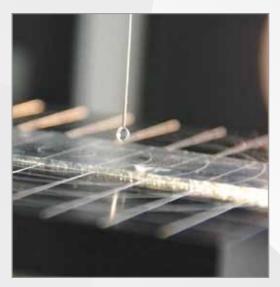
There are various methods for the testing of topical dosage forms among the services provided by the research group. The team provides rheological measurements of semisolid and liquid preparations and investigation of mucoadhesion properties. There is a possibility for in vivo testing of the water content of the stratum corneum, the trans-epidermal water loss, in vitro drug diffusion through synthetic membranes, ex vivo drug penetration through heat-separated human epidermis, animal skin and amniotic membrane and also in vivo skin penetration through living animal skin by the modified skinfold chamber model. The characterization of skin structure and drug penetration with RAMAN and FT-IR spectroscopy is also possible.

Instruments

- Hielscher UP 2005 "high shear" ultrasonic homogenizer
- Anton Paar Physica MCR 101 rheometer
- Courage-Khazaka MPA 9 multiprobe adapter system with CM 825Corneometer and TM 300 Tewameter
- HANSON SR 8 Plus Drug Dissolution Tester
- HANSON MICROETTEPLUS[™] Topical and Transdermal Diffusion Cell System



RESEARCH GROUP FOR SOLUBILITY IMPROVEMENT OF POORLY SOLUBLE DRUGS



The improvement of bioavailability of water insoluble drugs is a key issue of the recent pharmaceutical developments. Our team has special expertise in the research and development of formulations improving solubility by cyclodextrin inclusion complexation, solid solutions and solid dispersions with water soluble additives and amorphization. We have also much experience in the field of crystallization, spray-drying and lyophilization. The other topic of our research group is polymorph screening of API and relative stability investigations of polymorphs by Variable Humidity and Temperature XRPD. In industrial co-operations we undertake formulations of ophthalmic preparations, injections, structure examinations (DSC, DTG, FT-IR, XRPD), polymorph screening and relative stability investigations of polymorphs.



TEAM MEMBERS:

Zoltán AIGNER PhD associate professor

Team leader. His specific research area is focusing on the improvement of bioavailability of water insoluble drug materials both in case of solid and liquid dosage forms (injections and ophthalmic preparations).



Péter LÁNG assistant lecturer

His research area is focused partially on the research of solubility improvement of poorly-soluble drugs by different additives and polymorph screening methods and relative stability investigations of polymorphs.





MEASUREMENT METHODS

The research group provides services for the formulation of sterile/aseptic preparations, the development of protocols for the solubility improvement of various APIs.

The full characterisation of the physicochemical properties, polymorph screening and compatibility testing of drugs and drug candidates are also provided. The applied measurement methods include crystallographic and structure analysis with hot-humidity XRPD, FT-IR and Raman, characterisation of thermal behaviour with DSC and TG, pKa and logP and solubility measurements, and determination of resorption parameters with in vitro membrane diffusion tests.

Instruments

- Schmizo crystallization reactors with refrigerated circulators using Julabo thermostat
- Büchi 191-B spray dryer
- Binder vacuum drying chamber
- Scanvac Coolsafe lyophylizer
- Dataphysics OCA 20 optical contact angle measurement apparatus
- Pharmatest drug dissolution tester
- Metrohm automatic titrator

RESEARCH GROUP FOR

N anotechnology underwent an enormous improvement in the past decades. Therefore the main focus of our research work is the application of different preparation methods for particle size reduction (top down, bottom-up) and research and development of micro- and nanoparticle based drug delivery systems (DDS). In the field of nanomedicine, the development of nanocrystals and amorphous nanoparticles is important to improve drug solubility and nanosized drug delivery systems are relevant for target therapy (liposomes, niosomes, nanocomposites, etc.). Our special interest is turned to drug delivery across artificial and biological barriers containing in vitro, ex vivo and in vivo permeability studies and investigation of different systems/dosage forms with micro- and nanoparticles (liquid, semi-solid, solid), the use of alternative administration routes (intranasal and pulmonary) to reach the blood circulation and to target the brain.



TEAM MEMBERS:

Prof. Piroska SZABÓ-RÉVÉSZ DSc

full professor - Head of the Department and Team leader.

Her specific research field is the characterization of active agents by solidphase analysis, solubility, permeability, stability and development of DDS with micro- and nanomaterials for administration by alternative routes. She is an expert in the melt crystallization/technology applying dropping method.



Rita AMBRUS PhD

assistant professor

The special field of her research interest is particle engineering containing nano- and microcrystal preparation applying different kinds of integration and disintegration procedures in the cases of poorly water soluble drugs, formulation of nasal and dry powder inhaler (DPI) systems. She has experience with DSC, XRPD, FTIR measurements, PSA and SEM techniques and in silico and in vitro studies.





Peter SIPOS PhD assistant professor

His key research activity is the development of API containing micro- and nanoparticles for sustained, controlled and targeted release drug delivery (liposome, niosome). He has experience with factorial design based formulations and with structural analysis Raman, FTIR, NIR measurements and HPLC, DSC, PSA techniques, ex vivo, in vivo studies.



Orsolya JÓJÁRT-LACZKOVICH PhD assistant lecturer

Her main scientific field is the pharmaceutical technological amorphization of active and auxiliary agents and the investigation of amorphous form with different solid state investigation methods. Additionally, her research area is conventional liposomes as carrier systems in nanotechnology.

PREFORMULATION/FORMULATION

We are developing protocols for nasal and pulmonary formulations using different technologies and investigation methods to formulate products suitable for scaling-up. We also have protocol for the production of PEGylated and non-PEGylated liposome formulations for cell targeting. We are looking for the innovative processes and compositions therefore we also investigate the patent background of the topic.

Instruments

- Retsch PM 100 planetary ball mill for dry milling procedure
- High pressure homogenizer
- Hielscher UP 2005 "high shear" ultrasonic homogenizer
- Büchi 191-B spray dryer
- Aglient RP-HPLC system
- Malvern Mastersizer apparatus
- Andersen cascade impactor for aerodynamic characterization
- Side-bi-side horizontal diffusion cell



INSTRUMENTS FOR ADVANCED ANALYSIS

THE DEPARTMENT HAS INSTRUMENTS FOR THE ADVANCED ANALYSIS OF THE PHYSICOCHEMICAL PROPERTIES OF APIS, STRUCTURE OR PARTICLE-PARTICLE INTERACTIONS IN DOSAGE FORMS AND DRUG DELIVERY SYSTEMS.

The thermal behaviour of materials may be investigated with a Mettler-Toledo TGA/ DSC1 system and the analysis of the gases produced is carried out with a Pfeiffer mass spectrometer. The main performance characteristics include: temperature range from room temperature to 1100°C; heating rate: 0.01-50°K/min). The DSC stand-alone system works in the temperature range: -60-450 °C and is suitable for a modulated program too.

The **MS system** applies multiple ion detection in min. 128 channels with long-lasting double filament in a mass range of 1–300 amu. It has a low detection value (<1ppm) and transfer line temperatures up to 350°C.

The inclusion of TG, DSC and MS data is possible in a uniform coordinate system.

The instruments for vibration spectroscopy provide a wide range of possibilities for analysing data from the fields of solid materials (tablets, coated tablets, capsules, powders, crystals, pulverized materials etc.), semisolid materials (ointments, creams, pastes, foams, etc.), liquid materials (solutions, emulsions, suspensions, oils, etc.), food products (fruits, honey, etc.), pieces





such as paintings, textiles. Amongst others, the instruments may be applied for determination of active materials, investigation of stability and aging and determination of moisture content, evaporation kinetic, fat and oil content etc. in the fields of pharmaceutical, nutraceutical or food industry, agriculture and forensic science.

Our Thermo Scientific Avatar 330 FT-IR

apparatus provides excellent qualitative and quantitative information in the 400–4000 cm-1 spectral range, with the help of its transmission (for powders), diffuse reflectance (for powders and tablets) or HATR measurement module (for liquids, semisolid preparations or films).

The Thermo Scientific Antaris II FT-NIR

analyzer is instrumented with transmission (for the investigation of liquid and semisolid systems), tablet transmission (for the investigation of solid dosage forms), spinner (for the measurement of powders and particulate materials) modules and with a fibre optic probe, which enables the analysis of materials without the opening of the primary packaging. The spectral range of the spectrometer is 12000–3800 cm-1 (833–2630 nm), the resolution is 4 cm-1.



Our Thermo Scientific DXR Dispersive Raman

Microscope is instrumented with 532 and 780 nm lasers, a fibre optic probe and with an Olympus microscope and video camera for the characterization and identification of small particles, and chemical mapping characterization of surface areas and subsurfaces of various samples and dosage forms. The distribution of elements within the sample is supported with x-y area maps and x-z maps. The spectroscope provides high-resolution depth profiling and subsurface analysis on transparent and semi opaque samples. Excellent for characterizing coatings, multi-layer laminates, thin films, inclusions and subsurface defects (1 μ m x-y spatial resolution and 2 μ m depth resolution) and is instrumented with a hot stage (-190°C +600°C) for the investigation of the thermal stress on the structure of the studied materials.

Our X-ray analytical instrument group contains a **Bruker D8 Advance** powder X-ray and a **Philips MiniPal PW 4025** energy dispersion X-ray spectrometer apparatus.

The Bruker D8 Advance powder X-ray apparatus may be used for the identification of materials, determination of crystal structure, investigation of amorphous and crystalline mixtures, polymorph screening. As a speciality, it is instrumented with an MRI Basic hot-humidity chamber with ANS-Sycoshot combined humidity and temperature controller and VÅNTEC-1 detector. The maximum 2-Theta range simultaneously provides 12 degree in-situ measuring possibility under the following conditions: 25–50°C/95% RH, 50–90°C/temperature dependent RH and until max 200°C without the controlling of the humidity.

The Philips MiniPal PW 4025 energy dispersion X-ray spectrometer may be used for elemental analysis (Na-U), homogeneity and/or impurity investigation and contents determination of solid, semisolid or liquid dosage forms, herbal extracts, foods, or in the field of forensic science.

SELECTED PUBLICATIONS

RESEARCH GROUP FOR SOLID DOSAGE FORMS

A. Kelemen, M. Gottnek, G. Regdon jr., K. Pintye-Hódi New equipment for measurement of the force of adhesion of mucoadhesive films JOURNAL OF ADHESION SCIENCE AND TECHNOLOGY 29 1360-1367 (2015)

É. Bölcskei, G. Regdon Jr, T. Sovány, D. Ghanam, K. Knop, P. Kleinebudde, K. Pintye-Hódi Preparing of pellets by extrusion/spheronization using different types of equipment and process conditions DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY 40 762-764 (2014)

K. Nikowitz, K. Pintye-Hódi, G. Regdon jr Study of the recrystallization in coated pellets - Effect of coating on API crystallinity EUROPEAN JOURNAL OF PHARMACEUTICAL SCIENCES 48 563-571 (2013)

K. Kristó, K. Pintye-Hódi Effects of pharmaceutical processing on pepsin activity during the formulation of solid dosage forms PHARMACEUTICAL DEVELOPMENT AND TECHNOLOGY 18 17-21 (2013)

T. Sovány, K. Papós, P. Kása, I. Ilic, S. Srcic, K. Pintye-Hódi Application of Physicochemical Properties and Process Parameters in the Development of a Neural Network Model for Prediction of Tablet Characteristics AAPS PHARMSCITECH 14 511-516 (2013)

RESEARCH GROUP FOR

NANOTECHNOLOGY

A Martins, P. Sipos, K. Dér, J. Csábi, W. Miklos, W. Berger, A. Zalatnai, L. Amaral, J. Molnár, P. Szabó-Révész, A. Hunyadi Ecdysteroids sensitize MDR and non-MDR cancer cell lines to doxorubicin, paclitaxel, and vincristine but tend to protect them from cisplatin BIOMED RESEARCH INTERNATIONAL 2015: Paper 895360 8 (2015)

Cs. Bartos, Á. Kukovecz, R. Ambrus, G. Farkas, N. Radacsi, P. Szabó-Révész Comparison of static and dynamic sonication as process intensification for particle size reduction using a factorial design CHEMICAL ENGINEERING AND PROCESSING 87 26-34 (2015)

Cs. Mártha, O. Jójárt-Laczkovich, P. Szabó-Révész Effect of Co-Grinding on Crystallinity of Clopidogrel Bisulfate CHEMICAL ENGINEERING & TECHNOLOGY 37 1393-1398 (2014)

R. Ambrus, M. Gergely, A. Zvonar, P. Szabó-Révész, E. Sipos The role of co-spray-drying procedure in the preformulation of intranasal propranolol hydrochloride ACTA CHIMICA SLOVENICA 61 601-607 (2014)

A. Pomázi, R. Ambrus, P. Szabó-Révész Physicochemical stability and aerosolization performance of mannitol-based microcomposites JOURNAL OF DRUG DELIVERY SCIENCE AND TECHNOLOGY 24 397-403. (2014)

RESEARCH GROUP FOR

SEMISOLID DOSAGE FORMS

G. Horvát, B. Gyarmati, Sz. Berkó, P. Szabó-Révész, B.A. Szilágyi, A. Szilágyi, J. Soós, G. Sandri, M.C. Bonferoni, S. Rossi, F. Ferrari, C. Caramella, E. Csányi, M. Budai-Szűcs Thiolated poly(aspartic acid) as potential in situ gelling, ocular mucoadhesive drug delivery system EUROPEAN JOURNAL OF PHARMACEUTICAL SCIENCES 67 1-11 (2015)

B. Balázs, G. Farkas, O. Berkesi, R. Gyulai, Sz. Berkó, M. Budai-Szűcs, P. Szabó-Révész, L. Kemény, E. Csányi Protein structure is changed in psoriatic skin on the unaffected region – imaging possibility with ATR-FTIR spectroscopy MICROCHEMICAL JOURNAL 117 183-186 (2014)

Sz. Berkó, B. Balázs, B. Sütő, G. Erős, B. Gál, A. Sztojkov-Ivanov, C. Soica, P. Szabó-Révész, L. Kemény, I. Zupkó, E. Csányi Monitoring of skin penetration and absorption with a new in vivo experimental model FARMACIA 62 1157-1163 (2014)

G. Erős, Zs. Kurgyis, I.B. Németh, E. Csizmazia, Sz. Berkó, P. Szabó-Révész, L. Kemény, E. Csányi The irritant effects of pharmaceutically applied surfactants JOURNAL OF SURFACTANTS AND DETERGENTS 17 67-70 (2014)

Sz. Berkó, M. Maroda, M. Bodnár, G. Erős, P. Hartmann,
K. Szentner, P. Szabó-Révész, L. Kemény, J. Borbély,
E. Csányi Advantages of cross-linked versus linear
hyaluronic acid for semisolid skin delivery systems
EUROPEAN POLYMER JOURNAL 49 2511-2517 (2013)

RESEARCH GROUP FOR SOLUBILITY IMPROVEMENT

T. Tari, Z. Fekete, P. Szabó-Révész, Z. Aigner Reduction of glycine particle size by impinging jet crystallization INTERNATIONAL JOURNAL OF PHARMACEUTICS 478 96-102 (2015)

P. Láng, E. Várkonyi, J. Ulrich, P. Szabó-Révész, Z. Aigner Analysis of the polymorph changes of a drug candidate JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS 102 229-235 (2015)

I. Fülöp, Á. Gyéresi, M. Deli, L. Kiss, M.D. Croitoru, P. Szabó-Révész, Z. Aigner Ternary solid dispersions of oxicams: dissolution and permeability study FARMACIA 63 286-295 (2015)

C. Trandafirescu, Á. Gyéresi, Z. Szabadai, M. Kata, Z. Aigner Solid-state characterization of bifonazolecyclodextrin binary systems. Note I FARMACIA 62 521-531 (2014)

P. Láng, V. Kiss, R. Ambrus, G. Farkas, P. Szabó-Révész, Z. Aigner, E. Várkonyi Polymorph screening of an active material JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS 84 177-183 (2013)



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