novel analytical approaches to characterize particles in biopharmaceuticals

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Abbreviations

%	Percent
°C	Degree Celsius
µg	Microgram
µl	Microliter
µm	Micrometer
ABD	Area based diameter
AM	Acetoxymethyl
ANN	Artificial neuronal networks
APC	Antigen-presenting cell
API	Active pharmaceutical ingredient
ATR	Attenuated total reflection
AU	Absorbance unit
AUC	Area under the curve
BMI	Backgrounded membrane imaging
BSA	Bovine serum albumin
CAR-T	Chimeric antigen receptor T cells
CBMP	Cell-based medicinal product
CD3	Cluster of differentiation 3
CD4	Cluster of differentiation
ChP	Chinese Pharmacopeia
cMFI	Corrected mean fluorescence intensity
CNN	Convolutional neural network
CPA	Cryoprotectant agent
CQA	Critical quality attribute
DLS	Dynamic light scattering
DNA	Deoxyribonucleic acid
DMSO	Dimethylsulfoxide
DP	Drug product
DS	Drug substance
ECD	Equivalent circular diameter
ESD	Equivalent spherical diameter
ESZ	Electric sensing zone
Exp.	Expiration date
FBS	Fetal bovine serum
FDA	Food and Drug Administration
FFA	Free fatty acid

FIM	Flow imaging microscopy
FITC	Fluorescein isothiocyanate
FSC	Forward scatter
FTIR	Fourier transform infrared spectroscopy
g	Gram
h	Hour
HCl	Hydrogen chloride
His	Histidine
HVM	Holographic video microscopy
HSA	Human serum albumin
HMW	High molecular weight
HPLC	High performance liquid chromatography
ICH	International Council for Harmonisation
IEP	Isoelectric point
IgG	Immunoglobulin G
IgG1	Immunoglobulin G1
IgM	Immunoglobulin M
IL	Interleukin
INF	Interferon
kDa	Kilodalton
LNP	Lipid nanoparticle
LO	Light obscuration
LOD	Limit of detection
LOQ	Limit of quantification
LPS	Lipopolysaccharide
mAb	Monoclonal antibody
MC	Multicompendial
MFI	Micro-Flow Imaging
mg	Milligram
MHC	Major histocompatibility complex
min	Minute
ml	Milliliter
ML	Machine learning
mM	Millimolar
mm	Millimeter
moDC	Monocyte-derived dendritic cell
MRPS	Microfluid resistive pulse sensing

NaCl	Sodium chloride
ng	Nanogram
nl	Nanoliter
NIST	National Institute of Standards and Technology
NK	Natural killer
nm	Nanometer
NPI	Nanoparticulate impurity
NTA	Nanoparticle tracking analysis
p/ml	Particles per milliliter
PBMC	Peripheral blood mononuclear cell
PBS	Phosphate buffered saline
PDI	Polydispersity index
PDMS	Polydimethylsulfoxane
Ph.Eur.	European Pharmacopeia
PI	Propidium iodide
POE	Polyoxyethylene
PS	Polystyrene
PS20	Polysorbate 20
PS80	Polysorbate 80
PTFE	Polytetrafluoroethylene
PVDF	Polyvinylidene fluoride
QC	Quality control
R	Resistance
R^2	Coefficient of determination
RFI	Relative fluorescence intensity
RI	Refractive index
RMM	Resonant mass measurement
RNA	Ribonucleic acid
RPS	Resistive pulse sensing
rpm	Rounds per minute
RPMI	Roswell Park Memorial Institute
RT	Room temperature
s	Second
SEC	Size-exclusion chromatography
SEM	Scanning electron microscopy
SLS	Static light scattering
SMR	Suspended microchannel resonator

SSC	Side scatter
SVP	Subvisible (micro-meter sized) particle
T_{agg}	Aggregation temperature
TCR	T cell receptor
TFF	Tangential flow filtration
Tg	Glass transition temperature of the frozen state
TNF	Tumor necrosis factor
TRPS	Tunable resistive pulse sensing
UPLC	Ultra performance liquid chromatography
USP	United States Pharmacopeia
UV	Ultraviolet
V	Voltage
v/v	Volume per volume
w/v	Weight per volume
w/w	Weight per weight
λ	Wavelength

List of publications

1. **Grabarek AD**, Jiskoot W, Hawe A, et al. Forced degradation of cell-based medicinal products guided by flow imaging microscopy: explorative studies with Jurkat cells: Eur J Pharm Biopharm 2021; 167: 38-47. doi: 10.1016/j.ejpb.2021.07.004
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3. Sekulovic A, Verrijk R, Rades T, **Grabarek AD**, et al. Simultaneous automated image analysis and Raman spectroscopy of powders at an individual particle level. J Pharm Biomed Anal. 2021;193:113744. doi: 10.1016/j.jpba.2020.113744
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5. **Grabarek AD**, Bozic U, Rousel J, et al. What Makes Polysorbate Functional? Impact of Polysorbate 80 Grade and Quality on IgG Stability During Mechanical Stress. J Pharm Sci. 2020; 109(1):871-880. doi: 10.1016/j.xphs.2019.10.015
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7. Kwok PC, **Grabarek AD**, Chow MY, et al.(2015) Inhalable spray-dried formulation of D-LAK antimicrobial peptides targeting tuberculosis. Int. J. Pharm.; 491(1-2):367-74. doi: 10.1016/j.ijpharm.2015.07.001

Curriculum Vitae

Adam Grabarek was born on the 9th of December 1990 in Warsaw, Poland. After graduating from XXI Liceum Ogólnokształcące im. Hugonna Kołłątaja in Warsaw, he started his studies in Pharmacy at University College London. In 2013, Adam completed a research placement for his master research project at Hong Kong University where he obtained an academic mention with his thesis in peptide formulation entitled “Inhalable spray-dried formulation of D-LAK antimicrobial peptides targeting tuberculosis”. He obtained his Pharmacy degree (Second Class Honours, Upper Division) in 2015. In the subsequent year, after completing a pre-registration placement at Boots UK, Adam registered as a qualified pharmacist in the UK.

In September 2016, he started his PhD research at Leiden University under the supervision of Prof. Dr. Wim Jiskoot (LACDR, Leiden University) and Dr. Andrea Hawe at Coriolis Pharma in Munich, Germany, which resulted in this thesis. During his PhD he worked part time as a formulation scientist and represented Coriolis Pharma at international conferences on several occasions. He is currently working as a Scientist at Coriolis Pharma.