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PUBLICATION LIST

PL2609: Key publications on the characterization of nanoparticle drug and gene delivery systems by FFF-MALS-DLS

Summary

This document lists key publications using AF4- MALS-DLS for the characterization of nanoparticle drug delivery systems (nanoDDS), including nanoparticles for delivering small molecules, proteins, DNA, RNA and other therapeutics.

Characterization of drug products: methodology, validation and cross-comparisons

- Asymmetric-flow field-flow fractionation for measuring particle size, drug loading and (in)stability of nanopharmaceuticals. The joint view of European Union Nanomedicine Characterization Laboratory and National Cancer Institute-Nanotechnology Characterization Laboratory

  Caputo, F. et al. *J. Chromatograph A* **1635**, 461767 (2021)

  https://doi.org/10.1016/j.chroma.2020.461767

- Measuring particle size distribution of nanoparticle enabled medicinal products, the joint view of EUNCL and NCI-NCL. A step by step approach combining orthogonal measurements with increasing complexity

  Caputo, F. et al. *J. Controlled Release* **299**, 31-43 (2019). https://doi.org/10.1016/j.jconrel.2019.02.030

- Measuring particle size distribution by asymmetric flow field flow fractionation: a powerful method for the preclinical characterization of lipid-based nanoparticles

  Caputo, F. et al. *Mol. Pharm.* **16** (2), 756-767 (2019). https://doi.org/10.1021/acs.molpharmaceut.8b01033

- Are existing standard methods suitable for the evaluation of nanomedicines: some case studies.

  Gioria, S. et al. *Nanomedicine* (Lond) **13**(5), 539-554 (2018). https://doi.org/10.2217/nnm-2017-0338

- FFF-MALS method development and measurements of size and molecular weight

  Mehn, D. from EU Nanomedicine Characterization Laboratory web site, http://www.euncl.eu/about-us/assay-cascade/PDFs/PCC/EUNCL-PCC-022.pdf?m=1468937868&

Liposomes and lipid nanoparticles

- Improved multidetector asymmetrical-flow field-flow fractionation method for particle sizing and concentration measurements of lipid-based nanocarriers for RNA delivery

  Mildner, R. et al. *European Journal of Pharmaceutics and Biopharmaceutics* **163**, 252-265 (2021) https://doi.org/10.1016/j.ejpb.2021.03.004

- Physical characterization of liposomal drug formulations using multi-detector asymmetrical-flow field flow fractionation

  Parot, J. et al. *J. Controlled Release* **320**, 495-510 (2020).

https://doi.org/10.1016/j.jconrel.2020.01.049

- Mechanism and kinetics of the loss of poorly soluble drugs from liposomal carriers studied by a novel flow field-flow fractionation-based drug release-/transfer-assay.

  Hinna, A. H. et al. *J. Controlled Release* **232,** 228-37 (2016). https://doi.org/10.1016/j.jconrel.2016.04.031

- Size fractionation and size characterization of nanoemulsions of lipid droplets and large unilamellar lipid vesicles by asymmetric-flow field-flow fractionation/multi-angle light scattering and dynamic light scattering.

  Vezocnik, V. et al. *J. Chromatography A* **1418**, 185-91 (2015). https://doi.org/10.1016/j.jconrel.2016.04.031

- Application of Asymmetric Flow Field-Flow Fractionation hyphenations for liposome–antimicrobial peptide interaction

  Iavicoli, P. et al *J. Chromatography A* **1422**, 260-269 (2015). https://doi.org/10.1016/j.jconrel.2016.04.031

- Determination of size distribution and encapsulation efficiency of liposome-encapsulated hemoglobin drug substitutes using asymmetric flow field-flow fractionation coupled with multi-angle light scattering

  Arifin, D., Palmer, A. *Biotechnology Progress* **19**(6), 1798-1811 (2003)

Polymersomes

- Toward functional synthetic cells: In-depth study of nanoparticle and enzyme diffusion through a cross-linked polymersome membrane

  Gumz, H. et al. *Advanced Science* (2019). https://doi.org/10.1002/advs.201801299

- An alternative route to dye-polymer complexation study using asymmetrical flow field-flow fractionation

  Boye s. et al., *J Chromatogr A* **1217**(29), 4841-9 (2010). https://doi.org/10.1016/j.chroma.2010.05.036

Exosomes

- Separation and characterization of extracellular vesicles from human plasma by asymmetrical flow field-flow fractionation

  Wu, B. et al. *Analytica Chimica Acta* **1127**, 234-245 (2020). https://doi.org/10.1016/j.aca.2020.06.071

- Asymmetric-flow field-flow fractionation technology for exomere and small extracellular vesicle separation and characterization

  Zhang H., Lydem, D. *Nature Protocol* **14**(4), 1 (2019). doi: 10.1038/s41596-019-0126-x

- Identification of distinct nanoparticles and subsets of extracellular vesicles by asymmetric flow field-flow fractionation.

  Zhang, H. et al. *Nature Cell Biology* **20**, 332-343 (2018). https://doi.org/10.1038/s41556-018-0040-4

- Size dependent lipidomic analysis of urinary exosomes from patients with prostate cancer by flow field-flow fractionation and nanoflow liquid chromatography-tandem mass spectrometry

  Yang, J.S. et al. *Anal. Chem.* **89**(4), 2488-2496 (2017). https://doi.org/10.1021/acs.analchem.6b04634

- Size characterization and quantification of exosomes by asymmetrical-flow field-flow fractionation

  Sitar, S. et al, *Anal. Chem.* **87** (18), 9225-33 (2015). doi: 10.1021/acs.analchem.5b01636

- A review of exosome separation techniques and characterization of B16-F10 mouse melanoma exosomes with AF4-UV-MALS-DLS-TEM

  Petersen, K.E. et al. *Anal. Bioanal. Chem.* **406**(30), 7855-7866 (2014). https://doi.org/10.1007/s00216-014-8040-0

Virus-like particles

- Quantitative characterization of virus-like particles by asymmetrical flow field flow fractionation, electrospray differential mobility analysis, and transmission electron microscopy

  Pease, L.F. et al. *Biotechnology and Bioengineering* **102**(3) 845-855 (2009). https://doi.org/10.1002/bit.22085

- Characterization of virus-like particle assembly for DNA delivery using asymmetrical flow field-flow fractionation and light scattering

  Citkowicz, A., Petry, H. *Anal. Biochem.* **376**, 163-172 (2008). https://doi.org/10.1016/j.ab.2008.02.011

- Quantitative analysis of virus-like particle size and distribution by field-flow fractionation

  Chuan, Y.P. et al. *Biotechnology and Bioengineering* **99**(6) 1425-1433 (2008). https://doi.org/10.1002/bit.21710

- Quaternary size distribution of soluble aggregates of glutathione-S-transferase-purified viral protein as determined by asymmetrical flow field flow fractionation and dynamic light scattering

  Lipin, D.I., Lua, L.H.L., Middelberg, A.P.J. *J. Chromatography A* **1190**(1-2), 204-2012 (2008). https://doi.org/10.1016/j.chroma.2008.03.032

AAVs and other viruses

- Quantitation of influenza virus using field-flow fractionation and multi-angle light scattering for quantifying influenza A particles

  Bousse, T. et al. *J. Virolog. Meth.* **193**(2), 589-596 (2013). https://doi.org/10.1016/j.jviromet.2013.07.026

- Biophysical characterization of influenza virus subpopulations using field flow fractionation and multiangle light scattering: correlation of particle counts, size distribution and infectivity

  Z. Wei et al *J. Virolog. Meth.* **144**(1-2), 122-132 (2007). https://doi.org/10.1016/j.jviromet.2007.04.008

Additional modalities

- Flow field-flow fractionation and multi-angle light scattering as a powerful tool for the characterization and stability evaluation of drug-loaded metal–organic framework nanoparticles

  Roda, B. et al. A*nalytical and Bioanalytical Chemistry* **410**(21), 5245-5253 (2018). https://doi.org/10.1007/s00216-018-1176-6

- In depth characterization of physicochemical critical quality attributes of a clinical drug-dendrimer conjugate

  Sonzini, S. et al. *International Journal of Pharmaceutics* **637**, 122905 (2023) https://doi.org/10.1016/j.ijpharm.2023.122905