Fraunhofer IMM

Fraunhofer Institute for Microengineering and Microsystems IMM

Nanoformulation platform

Fraunhofer IMM nanoparticle formulation systems – from lab-scale to production-scale

Nanodrugs and vaccines

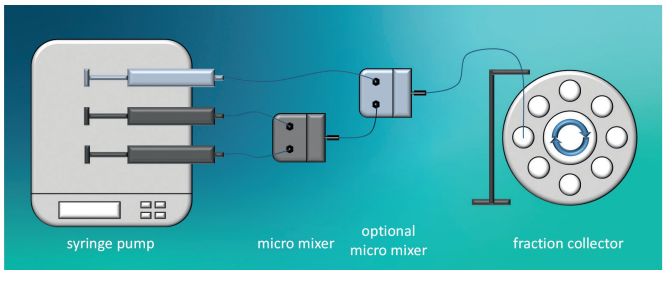
The current pandemic situation has highlighted the need for scalable technologies to produce mRNA vaccines that are based on lipid nanoparticles. The usage of lipid nano-particles intends to protect the mRNA from degradation and facilitates their transport into cells. While the scaling of production capacities for mRNA itself could quickly be achieved, the scalable production of the lipid nanoparticles turned out to be a bottleneck. Moreover, the formation of nanotransporters is limited by the access to high performing and safe lipid or polymer materials. Therefore, the design and development of new materials are urgently required including but not limited to mRNA vaccines. Many potential applications in the field of nanomedicine can be addressed, including advanced cancer therapy and theranostics.

Fraunhofer IMM: Long record in micro- and nanotechnology

Our large portfolio of different mixing principles and micromixers concepts combined with the expertise in process development, nanosynthesis and nanoanalytics enables us to offer *customized R&D services* for your specific application. We are experienced in the controlled self-assembly of a variety of amphiphils including phospholipids, cationic lipids and PEG-lipids as well as a broad range of polymeric materials and hybrid nanomaterials. Knowledge and IP in the field of inline-analytics of nanomaterials as well as micromixer based nanoformulation technology will help to accelerate your advanced developments.

Lab-scale systems

The application of nanomaterials as drug delivery systems offers great potential for future therapeutic capabilities, follow-up generations of vaccines and targeted medication, whereby laboratory research is essential as a basis for success. In the context of sustainable chemistry, our *Nanoformulation R&D* allows multiple series of experiments for process and product development to be carried out on a laboratory scale in a resource-efficient manner that saves cost-intensive educts. Scale-up and high reproducibility of our processes are ensured by the large choice within our technology portfolio and our scientific expertise in the field of nanosynthesis.



Scalable nanoformulation platform technology

Our system offers a platform of highest flexibility by combining our in-house micromixers with a powerful pulsation-free liquid

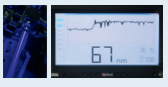
Nanoformulation scale

Synthesis:
Controlled mixing

Downstream processing (tangential flow filtration)

Process control system (PCS 7)

Inline analytics:
Flow-DLS



delivery with precise flow rates from a few microliters up to several decaliters. This not only enables fundamental research, but also ensures a simplified transition into clinical application in a GMP-compliant fashion.

With our *Nanoformulation Scale*, already optimized small-scale laboratory experiments can be easily and efficiently scaled up to high volumes not limited to several decaliters. This opens up the possibility to build up pilot scale plants and provides a pathway for the rapid and straightforward conduct of preclinical studies. Within our micromixer portfolio we have developed a micromixer for large flow rates and product volumes up to 100 l per working day. This micromixer variant is equipped with hygienic triclamp connectors and manufactured in stainless steel.

Experimental conditions

We translate:

- sample volume (1 ml → 100 l)
- flow rate range (1 ml/min → 2000 ml/min)

Your benefits

- proved scalability
- material saving
- controlled self-assembly/nanoparticle formation
- fast and secure process development
- continuous formulation process
- inline analytics

At Fraunhofer IMM researchers possess extensive knowledge and many years of experience in the continuous, micromixer-based development and production of nanoparticle systems. Combining the physicochemical understanding of versatile nanoparticle synthesis in the micromixer and nanoanalytics enables us to quickly react to customer requirements for future nanoparticle systems. At Fraunhofer IMM, we offer additionally advanced inline-analytic tools for improved process control and accelerated development.

Conclusion

The presented platforms offer the possibility to develop and manufacture high quality nanomaterials from milliliter up to decaliter scale to further boost a successful translation of innovative nanomedical solutions.

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For further information, please see the following references: *Nanoscale Adv.* 2020, 2, 4510-4521; *Chemical Engineering and Technology* 2019, 42(10), 1-11; *Macromolecular Chemistry and Physics* 2016, 218(2), 1600347; *Macromolecules* 2015, 48(20), 7396-7409; *Nanoscale* 2013, 5, 11385-11393.