Nanomi, Pushing the boundaries

Chiel Welink	***Analytical Chemist B***
Thijs Duursma	***Process Development Engineer B***

May 21th 2026

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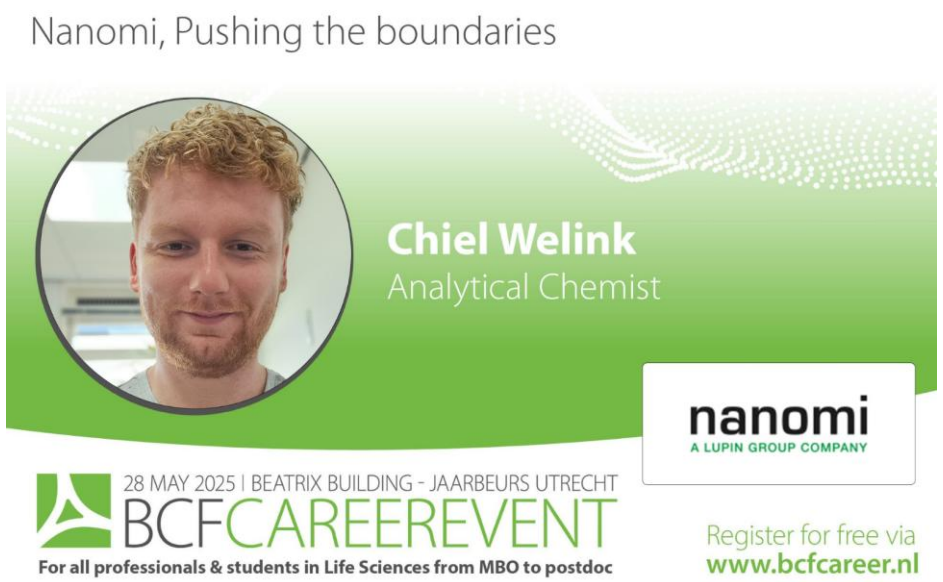
My background in a nutshell

Chiel Welink

Analytical chemist

2015 – 2019	BSc in Chemistry, at Saxion Enschede
2020 – now	Analytical Chemist (B), Nanomi



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My background in a nutshell

Thijs Duursma

Process Development Engineer

2015 – 2019	Bachelor Chemistry, Saxion Enschede
2019 – 2020	Jr. Process Development Engineer, Nanomi
2020 – 2022	Master Applied Nanotechnology, Saxion Enschede
2023 – now	Process Development Engineer B, Nanomi

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Nanomi – The Netherlands

Located in the green surroundings of Oldenzaal, Twente!

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Nanomi – The Netherlands

Nanomi is a leader in the field of microsphere and nanoparticle development of long-acting release injectables, and a subsidiary of Lupin Ltd. India.

Founded in 2004 as spin-off of the University of Twente. Acquired by Lupin in 2014.

Lupin's **R&D Center** of Excellence for **complex long-acting injectables**.

Therapeutic Areas: Generics & value-added drugs.

- Our **1st product** is a Generic in antipsychotics; a long-acting injectable, predominantly for the US market. Commercial since November 2025.
- **New 505(b)2/value-added drugs**. Portfolio is being established with potential hits in neuro-psy, respiratory, diabetes and obesity. Also, predominantly for the US market.
- **CDMO business** – building strategic partnerships for therapeutic areas and geographies outside Lupin's strategic focus.

Market Approach: Sales through Lupin Inc US, and possibly other Lupin entities / strategic partners.

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The team

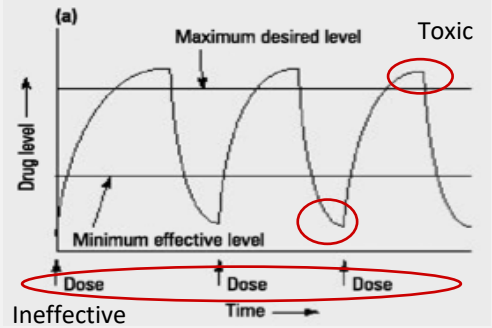
- We have an **enthusiastic team** with ambitious and talented people.
- We are a **dynamic, R&D-driven organization** with a constant focus on innovation and ground-breaking technologies. At Nanomi, initiative is valued, daring is rewarded, and we encourage you to explore and ‘push the boundaries!’

- Our team currently consist of ≥**50 employees**.
- Functions varying from **technical functions** (e.g. Lab Technician, (Senior) Analytical Chemist, (Senior) Engineer, Scientist, Tech Transfer Specialist etc.) to the **general supporting functions** e.g. Supply Chain, QA, Project Managers, etc.

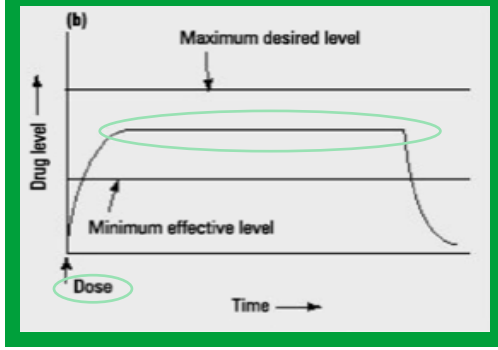
Competitive Edge: More effective drugs with less side effects

Immediate release

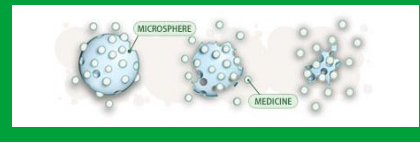
- Toxic drug levels
- Ineffective drug levels
- Multiple injections
- Poor patient compliance



Long-acting release particles

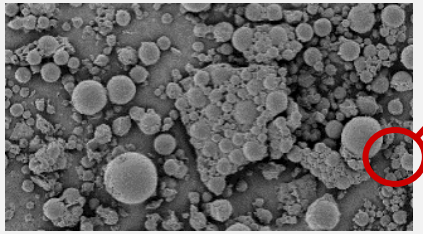


- Less side effects
- More effective
- Less injections (up to 1x/yr)
- High patient compliance

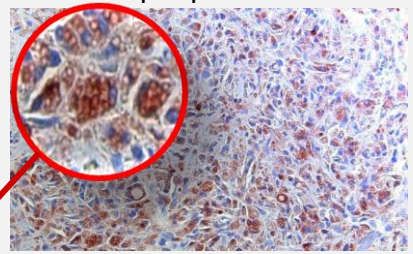


Traditional long-acting release products

- Pain and swelling
- Poor injectability
- Large needles
- Burst



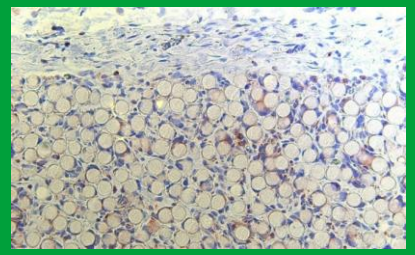
5 µm particles



Phagocytosis by macrophages (red):
Swelling and pain

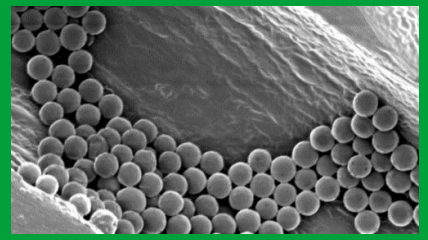
Nanomi long-acting release products

30 µm particles



No phagocytosis of particles

- No immune response
- Excellent injectability
- Small needles
- No Burst



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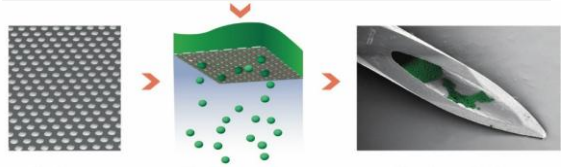
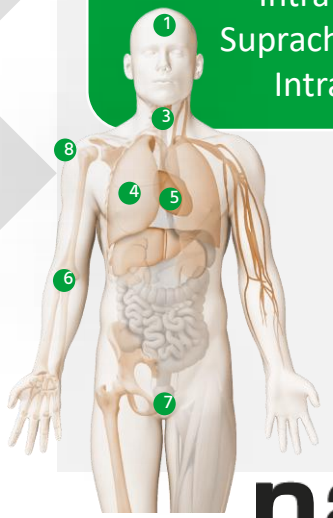
Developing enhanced applications with the benefits from Nanomi's platforms

Technology	Features	Benefits	Application
Nanomi Monodisperse Microspheres and Nanoparticles			
Controlled release	Tunable – low burst	Long dosing intervals	Sub cutaneous Intra muscular
	Biodegradable	Better Bioavailability	**Local delivery** Intra tumoral Intra ventricular Intra articular Intra arterial Suprachoroidal Intra ocular
Injection performance		Better Efficacy Better Safety	
	Excellent injectability	Smaller needles	
Secure Production			
	Small footprint	FDA filing, commercial scale	
	Fast & robust	No foreign particles	
	Scalable & high yield	Validated aseptic process performance	





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The Nanomi facilities and capabilities

Formulation Lab
Early-phase development

Cleanroom
Proof-of-concept ATM

Process Lab
Scale-up to commercial

Currently not 'yet' at NNM

GMP factory
Clinical & commercial production

'Scientific sound' ↔ **Validated**

- High throughput of API's
- Fit for purpose method/process development
- Proof of Concept

- 1 API for full development
- Validated methods/processes
- Complete control

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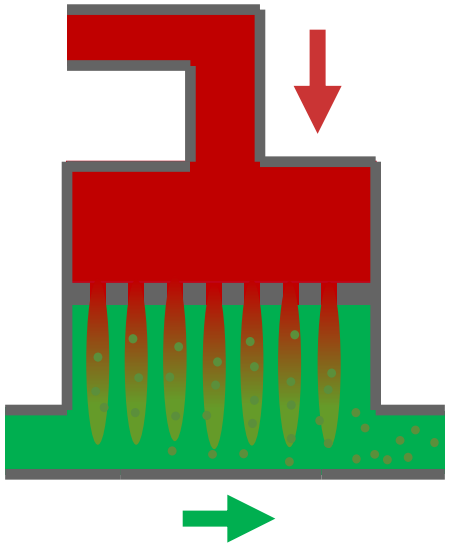
PrecisionSphere™ is unique and patent-protected

Two approaches, microspheres and nanoparticles:

1. Miscible solvents - nanoparticles
   - ‘Jetting’ of API in a miscible organic solvent into aqueous phase: nanoprecipitation (eg., small molecules)

Commercial scale

API in
miscible organic solvent



Aqueous phase with emulsifier
containing **nanoparticles**

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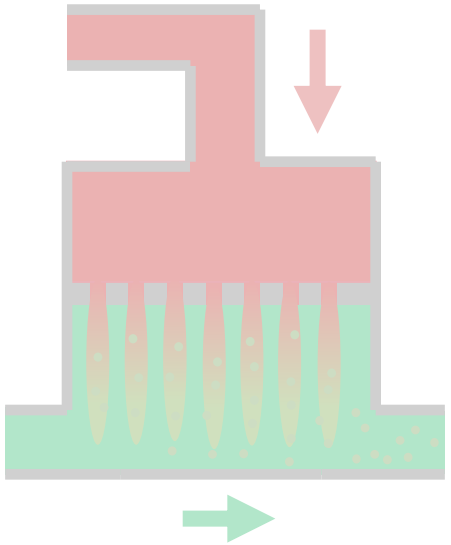
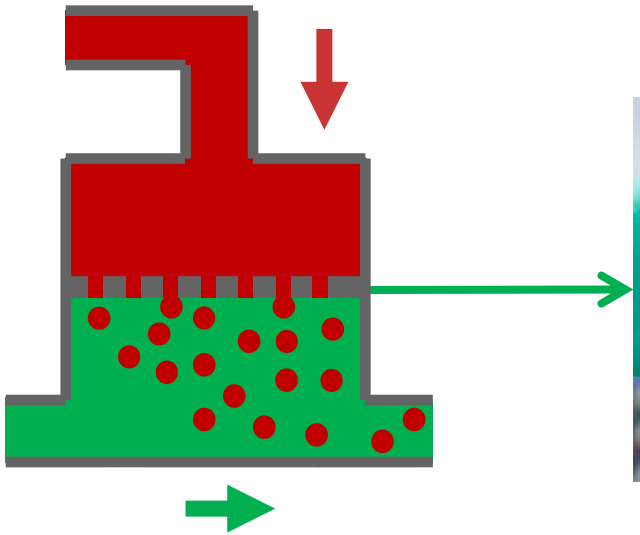


Aqueous phase with emulsifier
containing **nanoparticles**

2. Immiscible solvents - microspheres
   - Single emulsion droplet generation: o/w (e.g., small molecules)

GMP Commercial scale

API and biodegradable polymer
in immiscible organic solvent



Aqueous phase with emulsifier containing microdroplets,
hardening to **microspheres**, through solvent evaporation.

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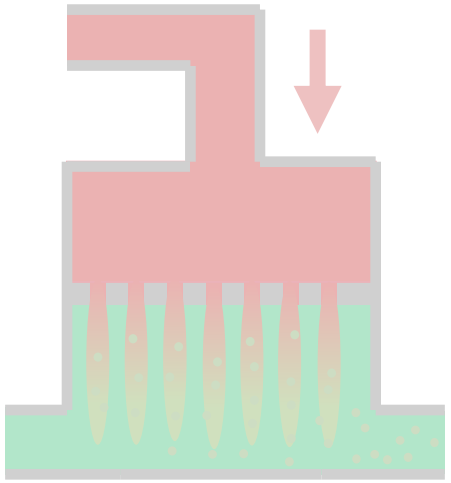
Two approaches, microspheres and nanoparticles:

1. Miscible solvents - nanoparticles
   - 'Jetting' of API in a miscible organic solvent into aqueous phase: nanoprecipitation (eg., small molecules)

2. Immiscible solvents - microspheres
   - Single emulsion droplet generation: o/w (e.g., small molecules)
   - Double emulsion droplet generation: w/o/w (e.g., peptides)

Commercial scale

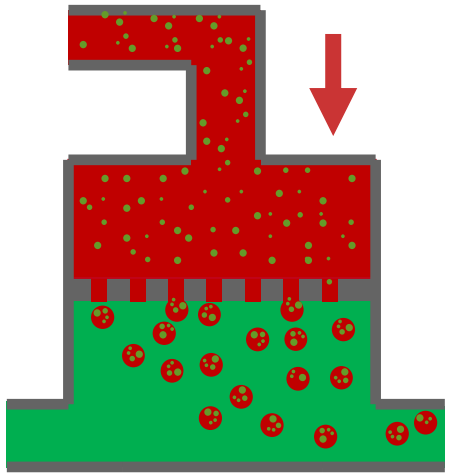
API in
miscible organic solvent



Aqueous phase with emulsifier
containing **nanoparticles**

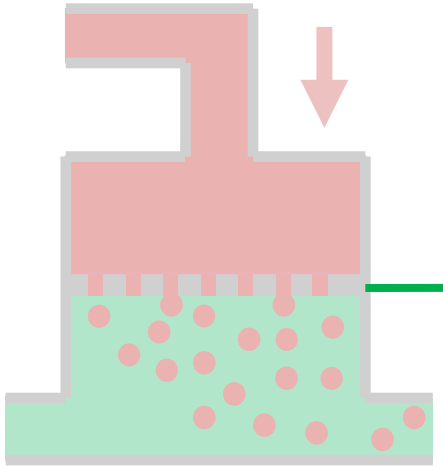
Add-on

API in aqueous droplets
in biodegradable polymer in immiscible
organic solvent



GMP Commercial scale

API and biodegradable polymer
in immiscible organic solvent



Aqueous phase with emulsifier containing microdroplets,
hardening to **microspheres**, through solvent evaporation.

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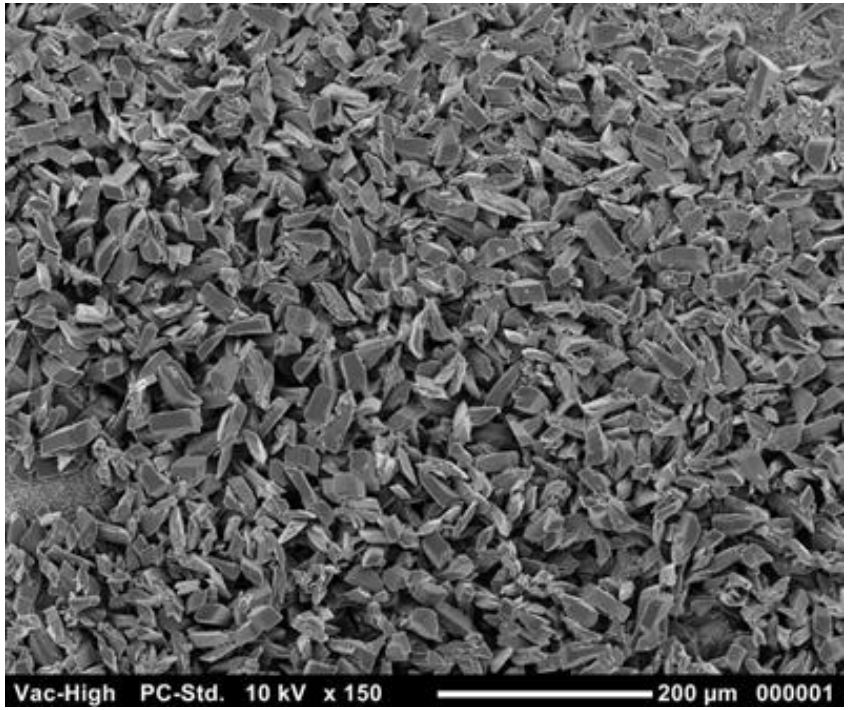
PrecisionSphere™ is unique and patent-protected

Two approaches, microspheres and nanoparticles:

1. Miscible solvents - nanoparticles
   - ‘Jetting’ of API in a miscible organic solvent into aqueous phase: nanoprecipitation (eg., small molecules)



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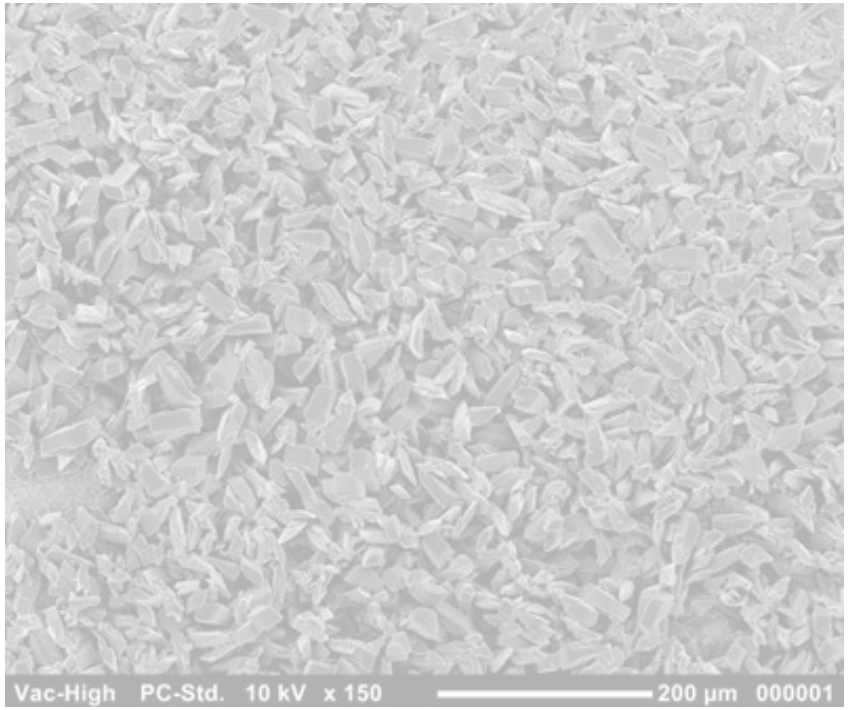
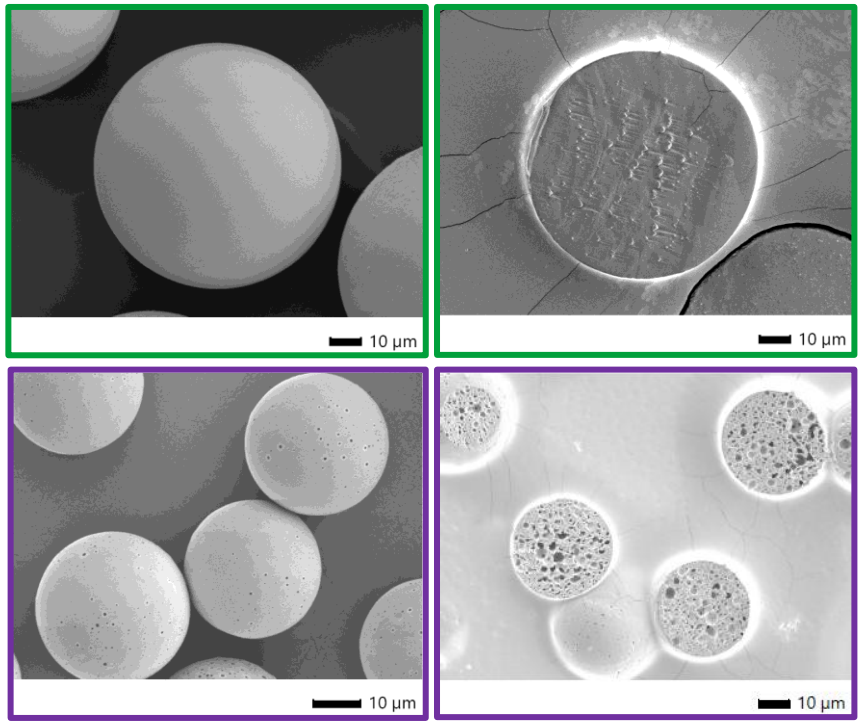


2. Immiscible solvents - microspheres
   - **Single emulsion** droplet generation: o/w (e.g., small molecules)
   - **Double emulsion** droplet generation: w/o/w (e.g., peptides)



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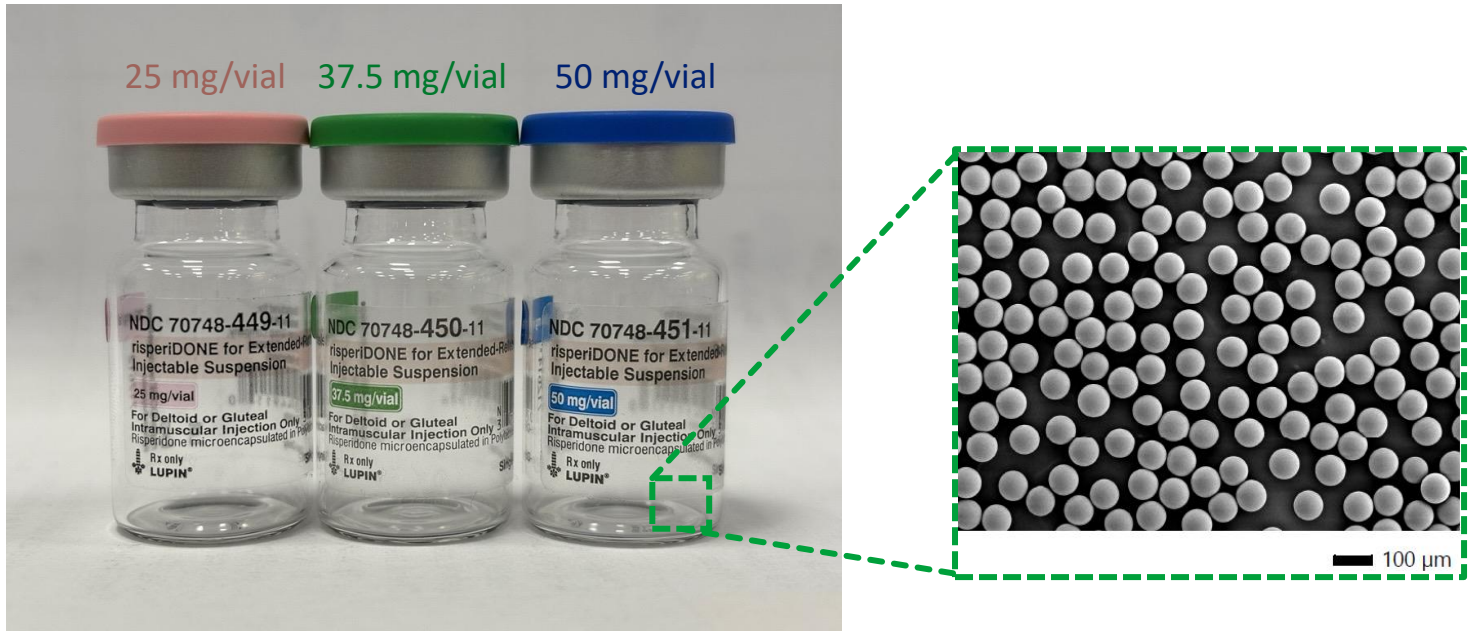
1st product with Nanomi's PrecisionSphere™ technology

Risperidone-loaded microspheres as antipsychotic:

2 week Extended-Release Injectable Suspension (ERIS)

3 strengths:

- 25 mg/vial
- 37.5 mg/vial
- 50 mg/vial



Commercial since November 2025

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Analytical chemistry

1. Microspheres

2. Nanosuspensions

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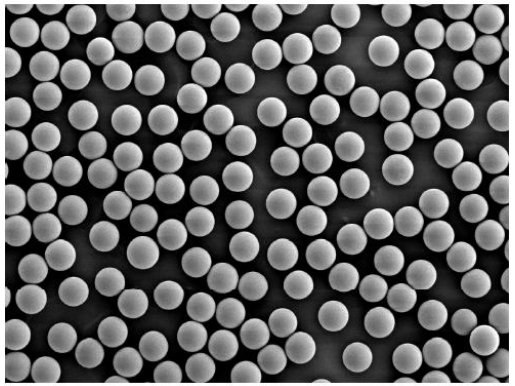
Microspheres

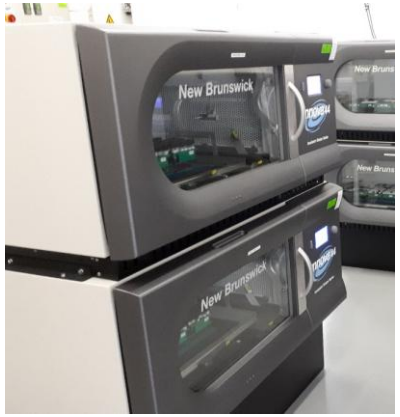
- API loaded polymer -> Drug loading (%) -> HPLC-UV
- Glass transition temperature -> DSC
- Particle size -> Coulter counter
- In vitro release -> Sample & Separate

- Morphology -> SEM



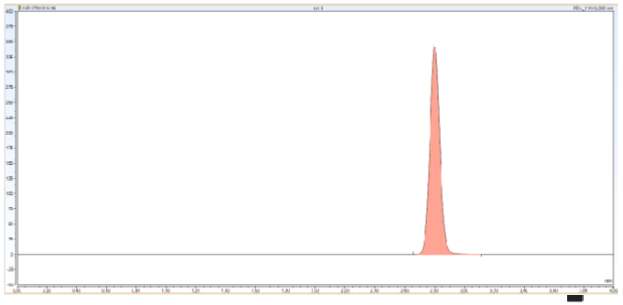
Microspheres

Weeks/months



t0, t1 day, t1 week .....

HPLC-UV



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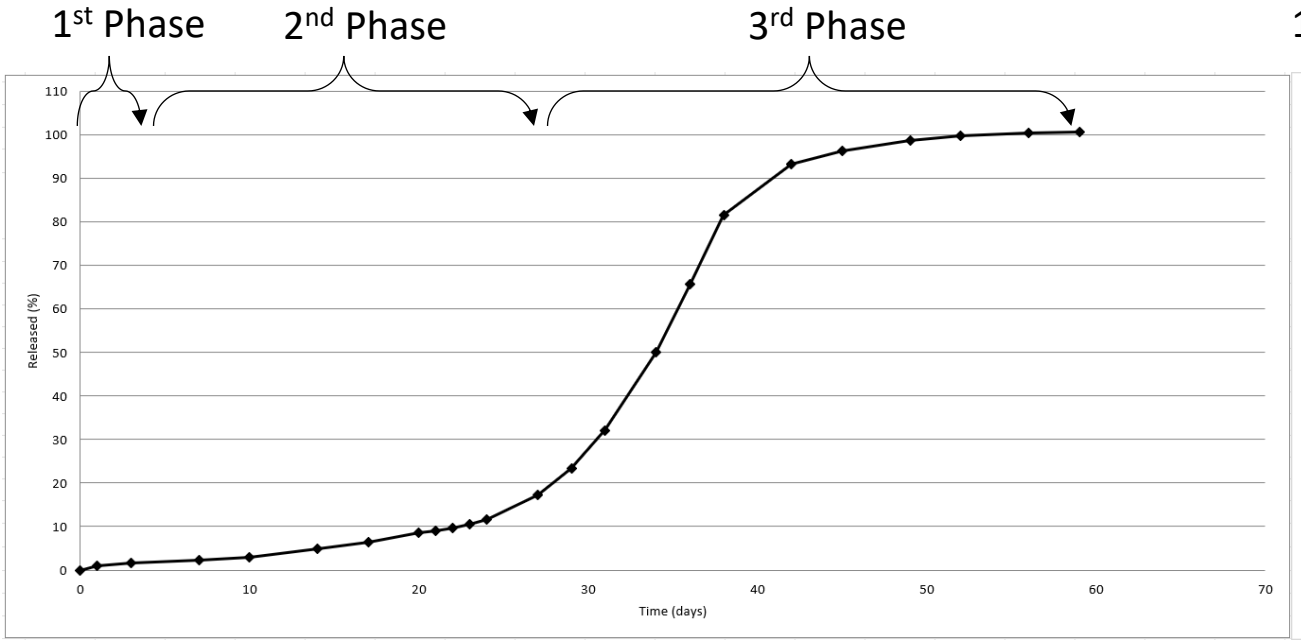
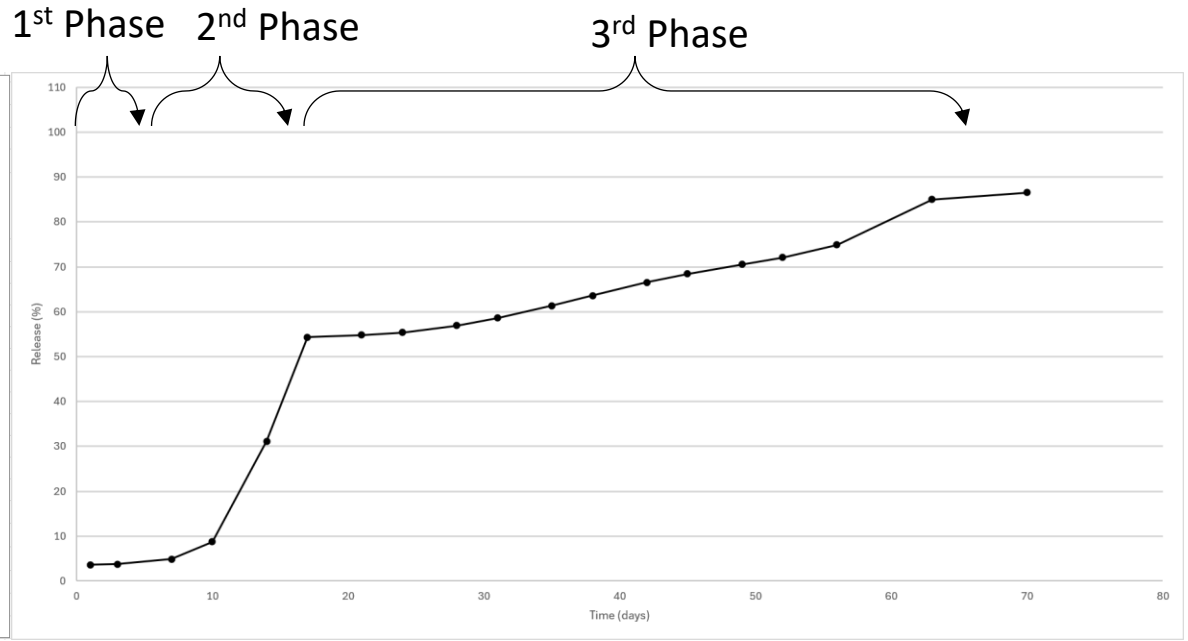
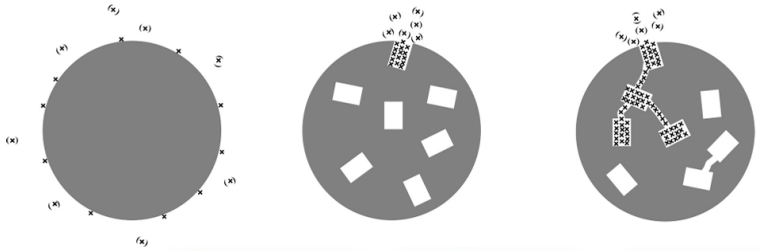
In vitro release microspheres

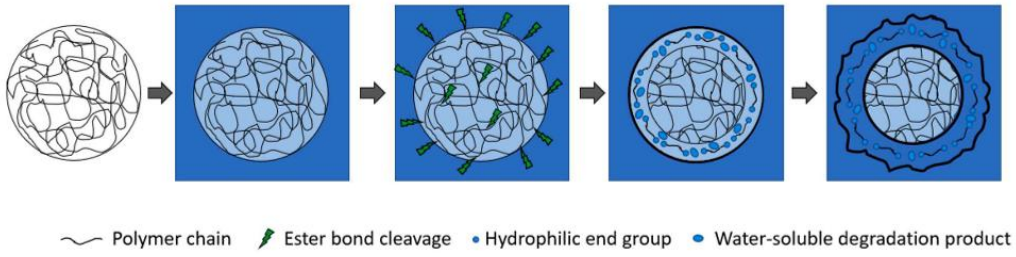




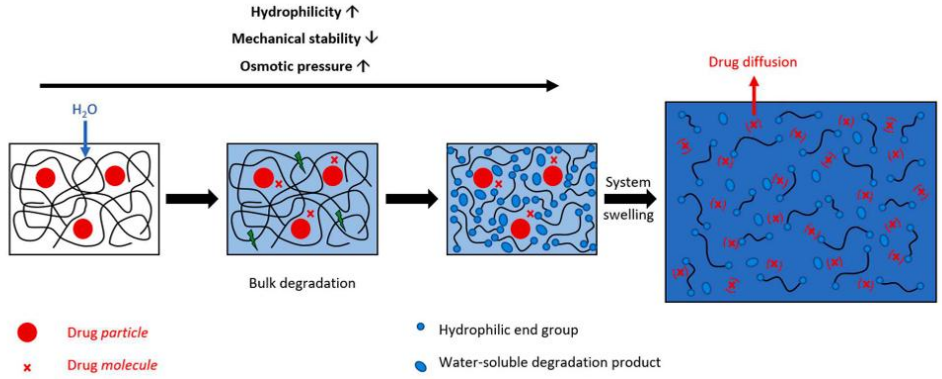
Burst release ->



Surface erosion ->



Bulk erosion ->



Source: Siepmann, J., & Siepmann, F. (2025). Release mechanisms of PLGA-based drug delivery systems: A review. International Journal of Pharmaceutics: X, 10, 100440. https://doi.org/10.1016/j.ijpx.2025.100440

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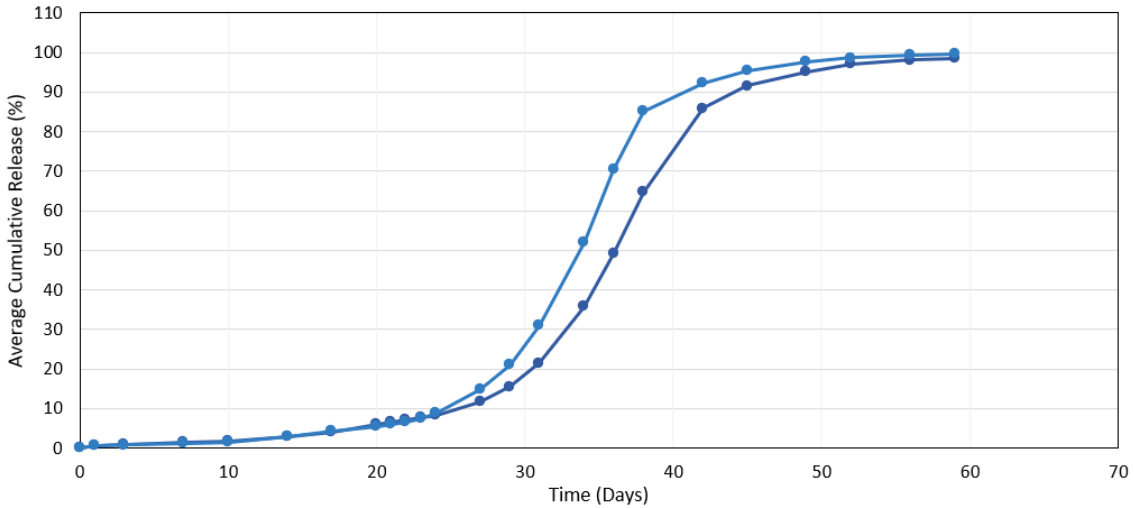
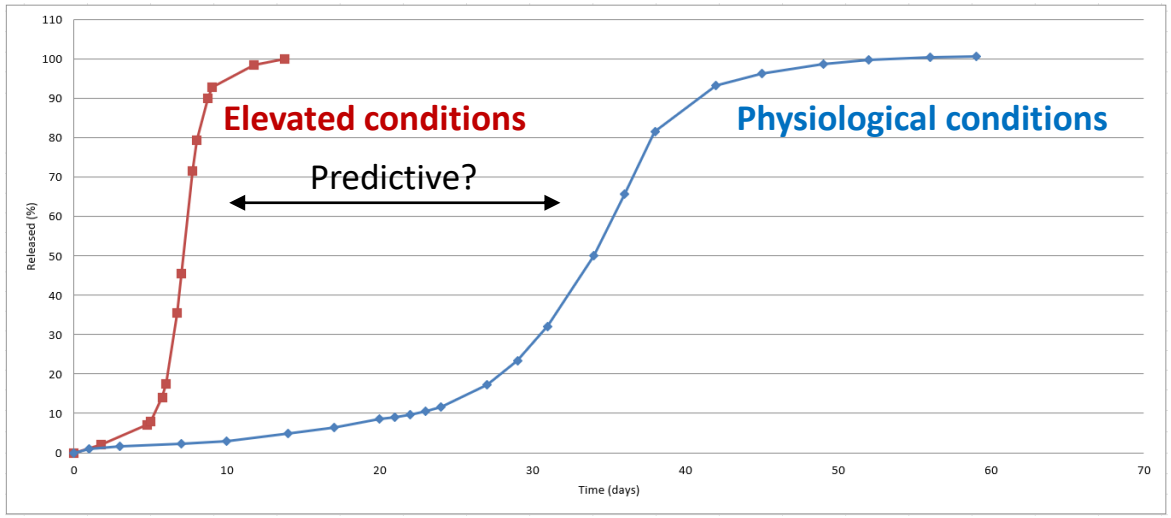
In vitro release microspheres



Different polymers, same conditions



Accelerated vs biorelevant conditions

Parameter
Medium composition (pH, buffer, surfactant, osmolality)
Temperature
Shaking speed
Sampling scheme
Media refreshment

Discriminate between polymers

Animal or clinical trial for in vivo data -> IVIVC

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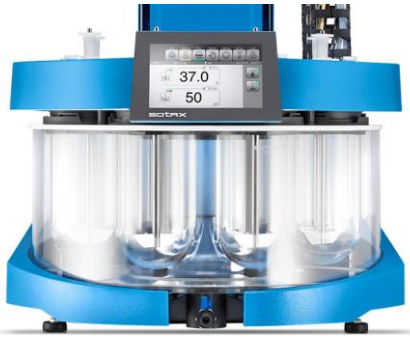
Nanosuspensions

- No polymer -> API concentration -> HPLC-UV
- Polymorphic forms -> XRD
- Particle size -> DCS
- In vitro release -> USP2 dissolution

- Morphology -> SEM

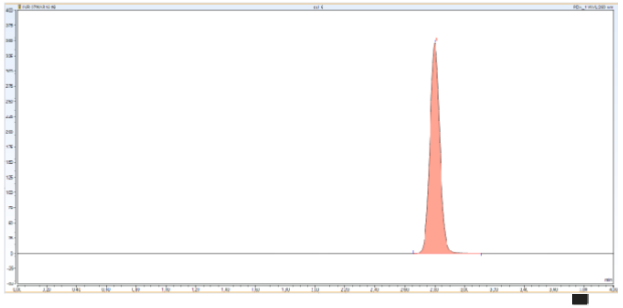
Nanosuspension

Hours/days



t0, t1 hour, t2 hour .....

RP-HPLC



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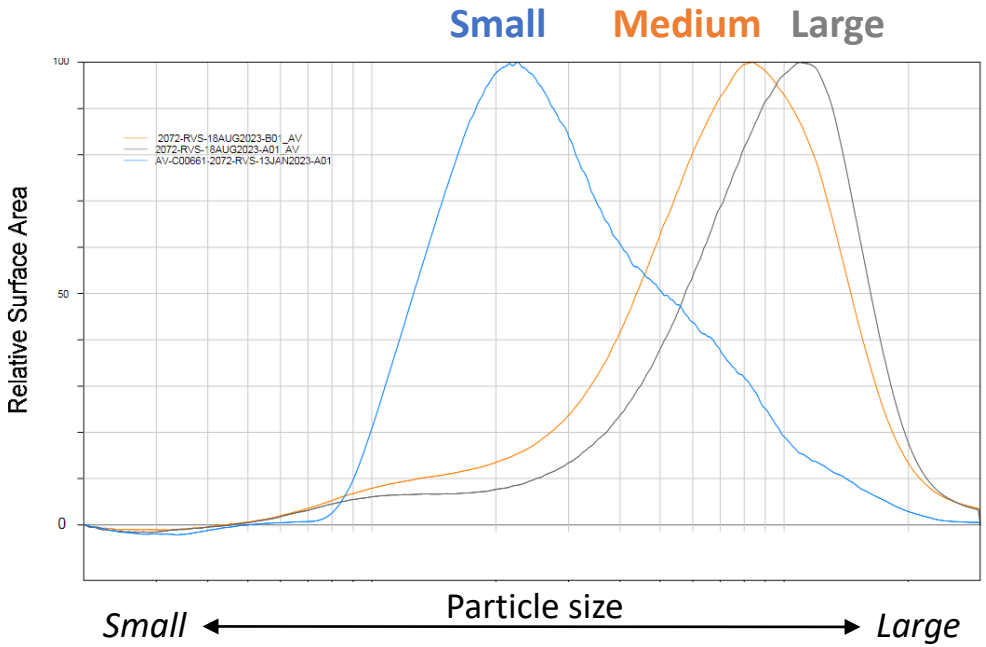
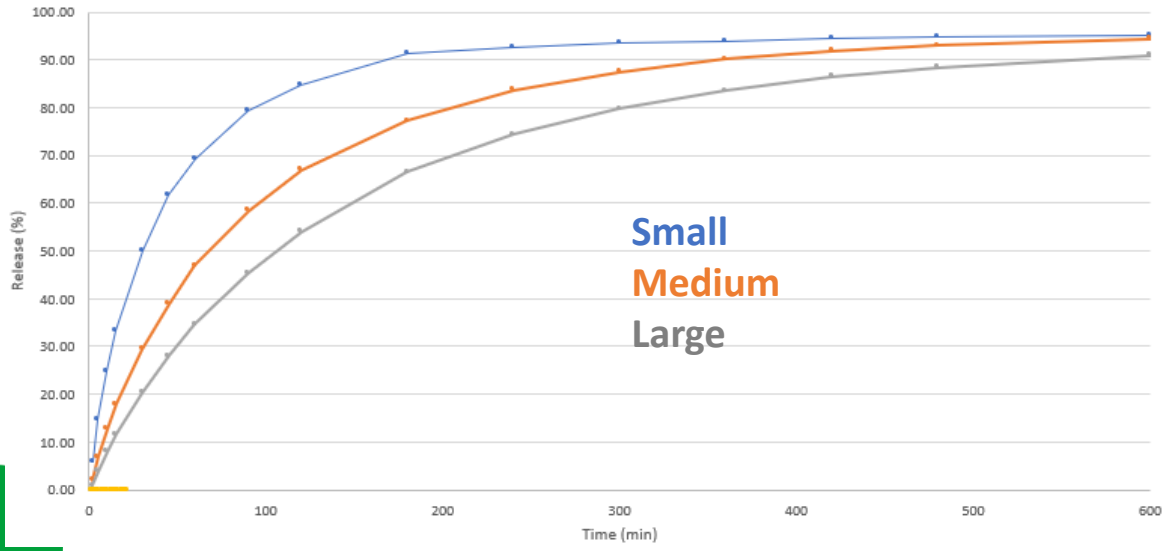
Particle size & dissolution

DCS (Differential Centrifugal Sedimentation)





Discriminate between particle sizes

Animal or clinical trial for in vivo data -> IVIVC

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Questions?

or visit our booth for more info

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