



# Nanomi, Pushing the boundaries

Chiel Welink

*Analytical Chemist*

Thijs Duursma

*Process Development Engineer*

May 28th 2025



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A LUPIN GROUP COMPANY

# My background in a nutshell

**Chiel Welink**

*Analytical chemist*

2015 – 2019

BSc in Chemistry, at Saxion Enschede

2020 – now

Analytical Chemist , Nanomi

Nanomi, Pushing the boundaries



**Chiel Welink**  
Analytical Chemist

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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, Nanomi

Nanomi, Pushing the boundaries





# Nanomi – The Netherlands



Our facilities

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 **lead program** is a Generic in antipsychotics; a long-acting injectable, predominantly for the US market. Goal date for commercial launch July 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.





# The team

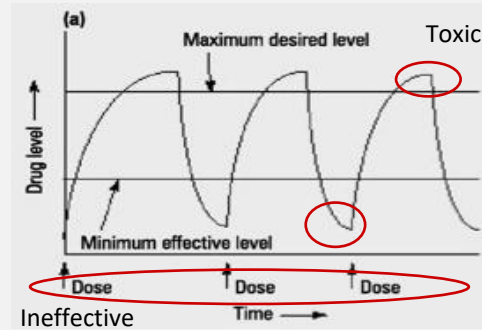
- We have an **enthusiastic team** with ambitious and talented people.
- We are a **dynamic, R&D-driven organization** with a constant focus on innovation and ground-breaking technologies. At Nanomi, initiative is valued, daring is rewarded, and we encourage you to explore and ‘push the boundaries!’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

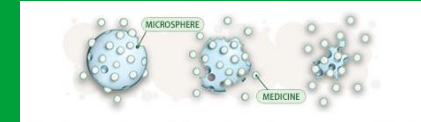
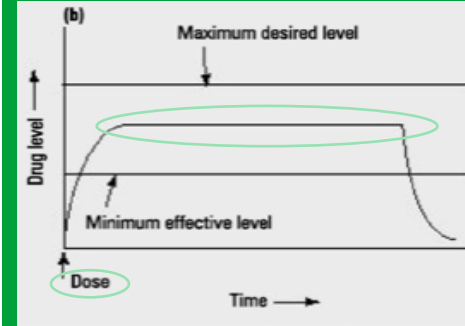
## Immediate release

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



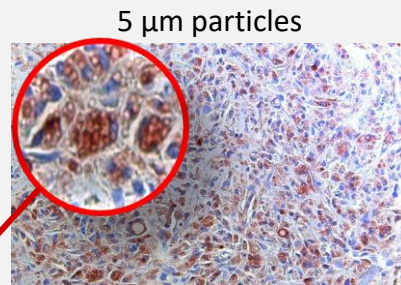
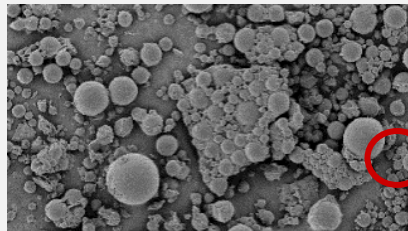
## Long-acting release particles

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



## Traditional long-acting release products

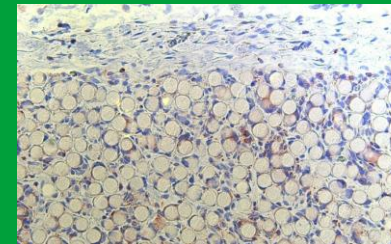
- Pain and swelling
- Poor injectability
- Large needles
- Burst



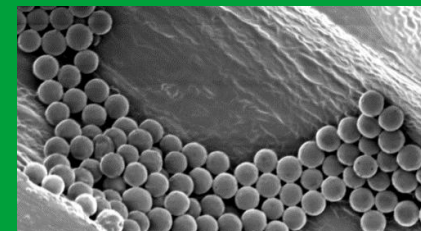
Phagocytosis by macrophages (red):  
Swelling and pain

## Nanomi long-acting release products

30 µm particles

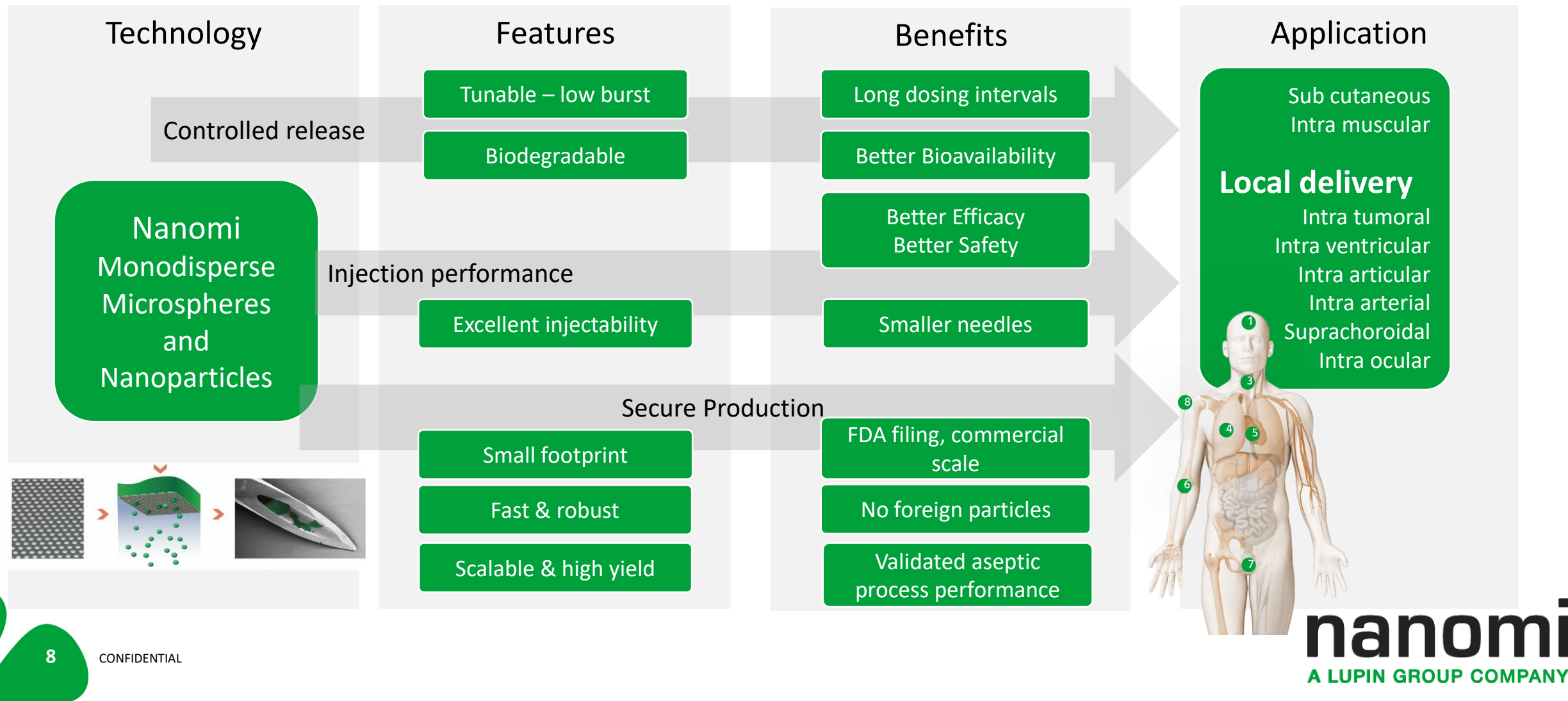


No phagocytosis of particles





# Developing enhanced applications with the benefits from Nanomi's platforms





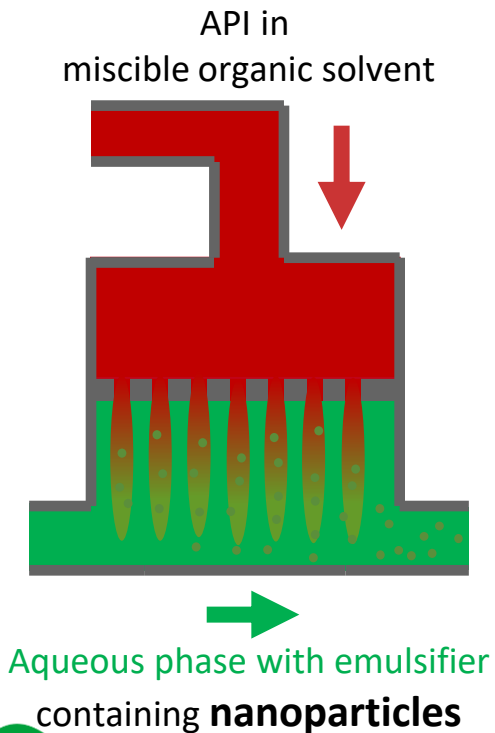
# The Nanomi technology is unique and patent-protected

## 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



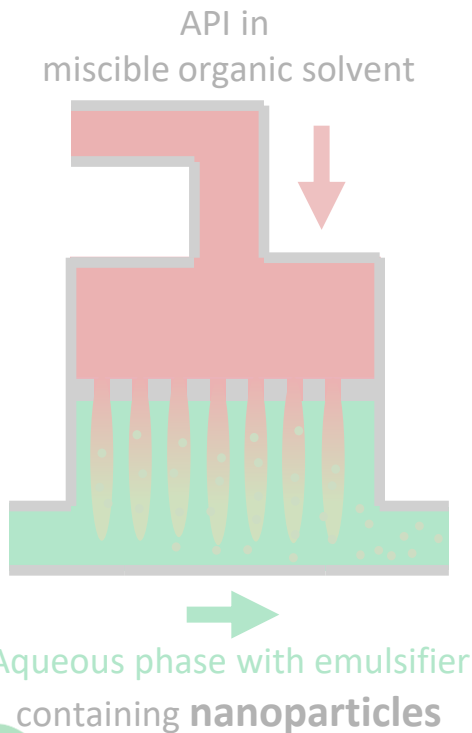
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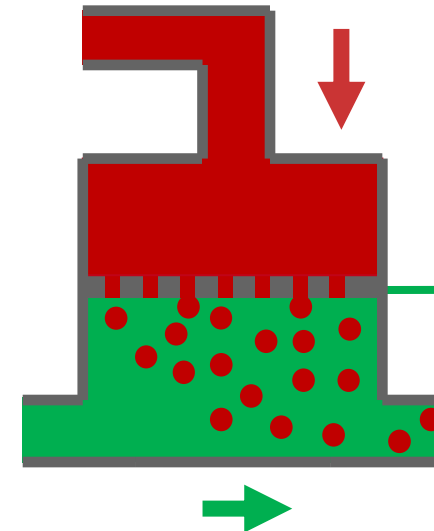


### 2. Immiscible solvents - microspheres

- 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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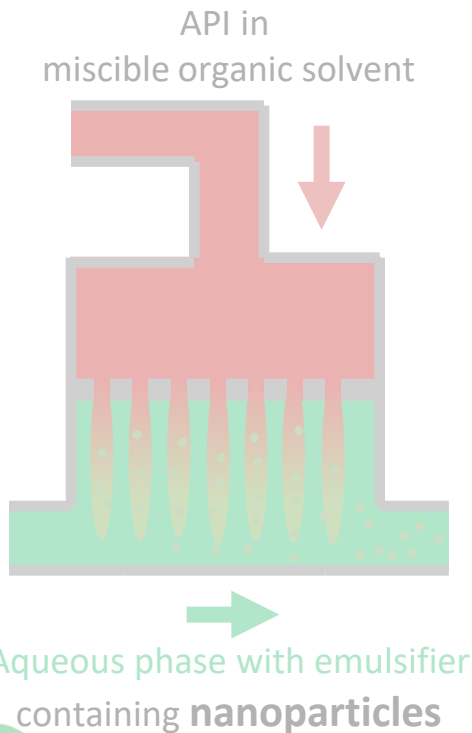
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## Two approaches, microspheres and nanoparticles:

### 1. Miscible solvents - nanoparticles

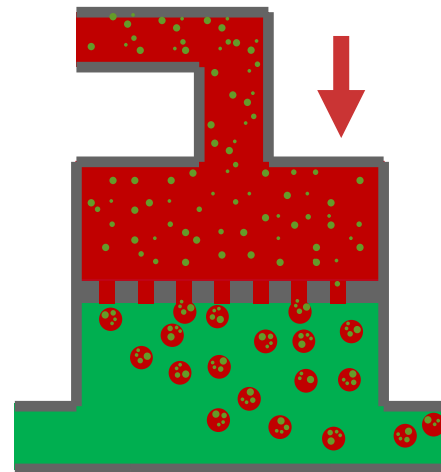
- 'Jetting' of API in a miscible organic solvent into aqueous phase: nanoprecipitation (eg., small molecules)

Commercial scale



Add-on

API in aqueous droplets  
in biodegradable polymer in immiscible  
organic solvent



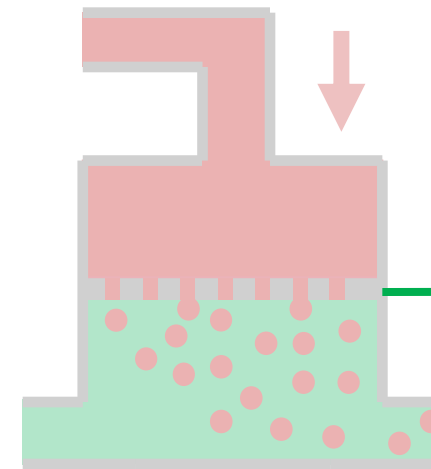
Aqueous phase with emulsifier containing **microdroplets**,  
hardening to **microspheres**, through solvent evaporation.

### 2. Immiscible solvents - microspheres

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

GMP Commercial scale

API and biodegradable polymer  
in immiscible organic solvent



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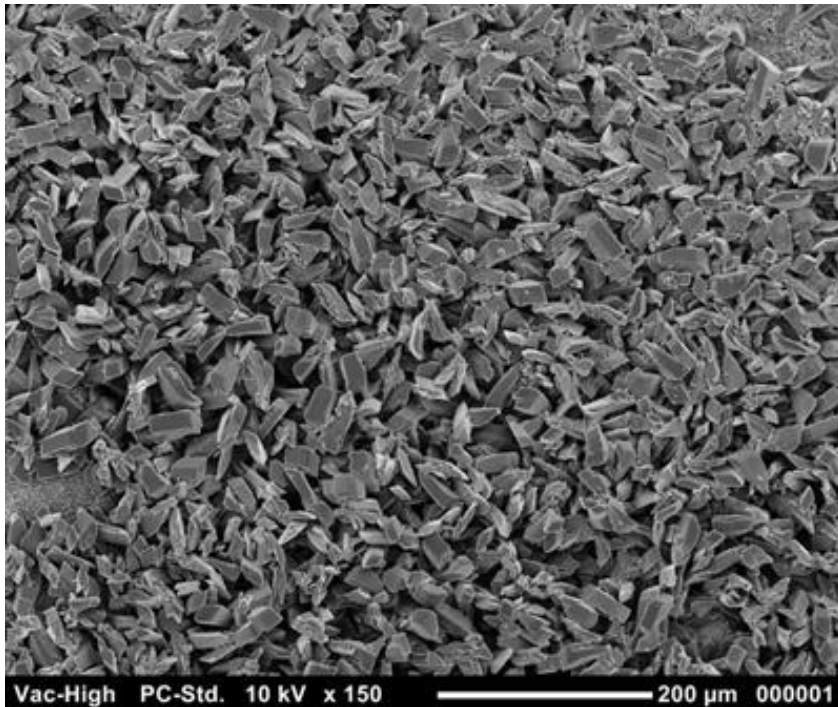


# The Nanomi technology is unique and patent-protected

Two approaches, microspheres and nanoparticles:

1. Miscible solvents - nanoparticles

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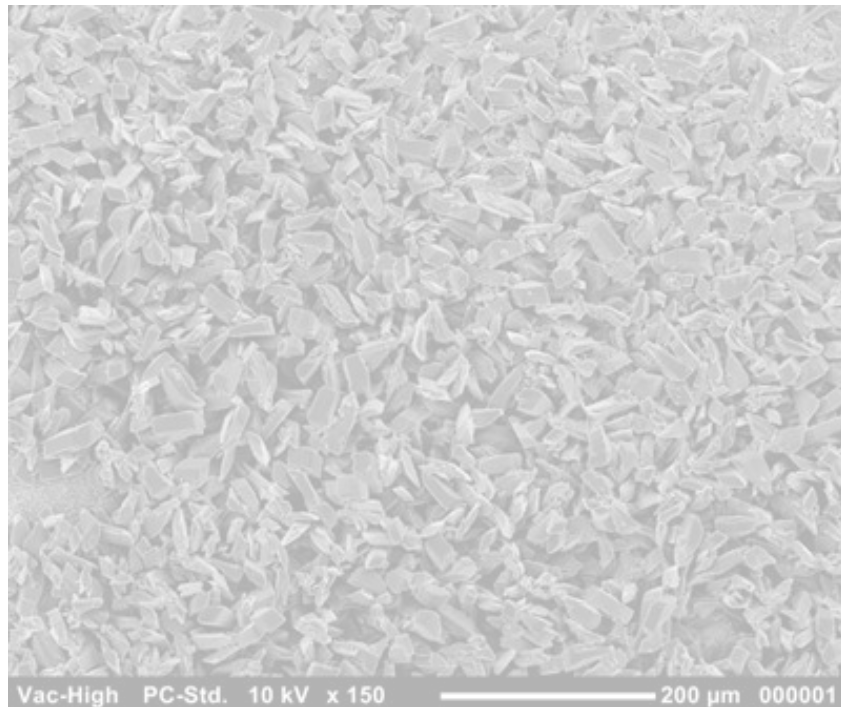


# The Nanomi technology is unique and patent-protected

## Two approaches, microspheres and nanoparticles:

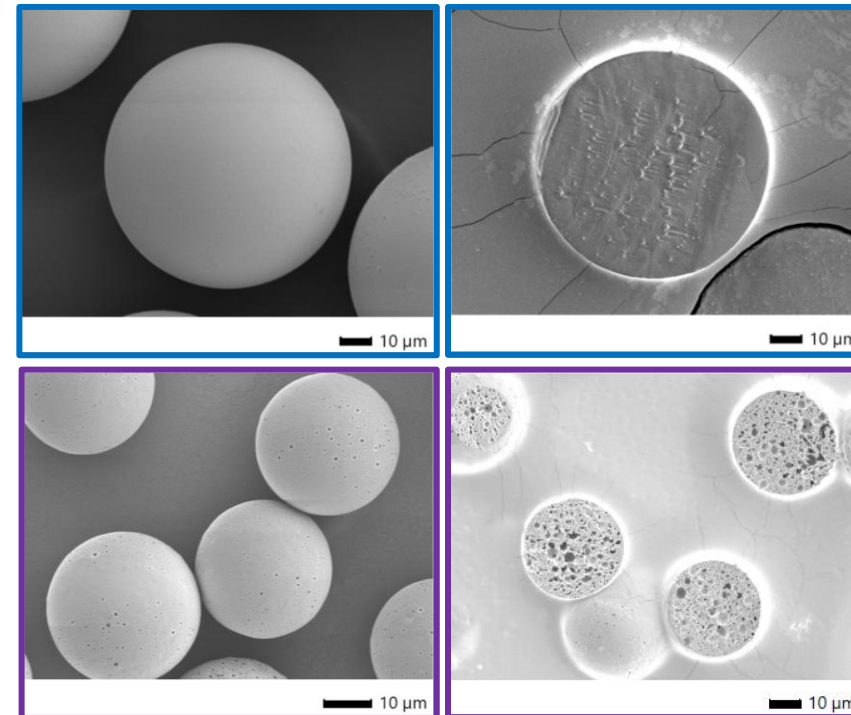
### 1. Miscible solvents - nanoparticles

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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)



# Analytical chemistry

1. Microspheres
2. Nanosuspensions
3. Project phases

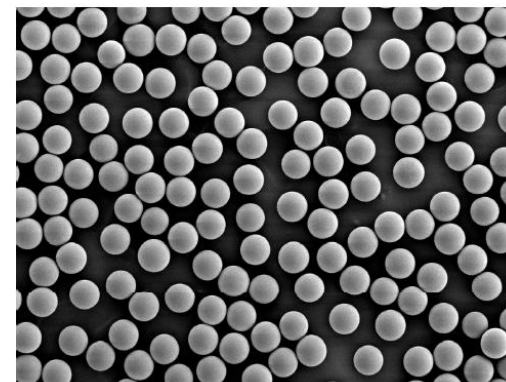




# Microspheres

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

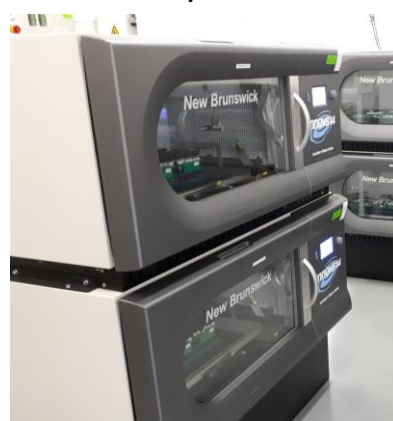
- Morphology -> SEM



Microspheres

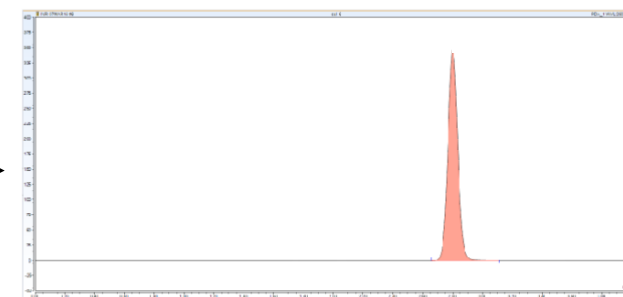


Weeks/months

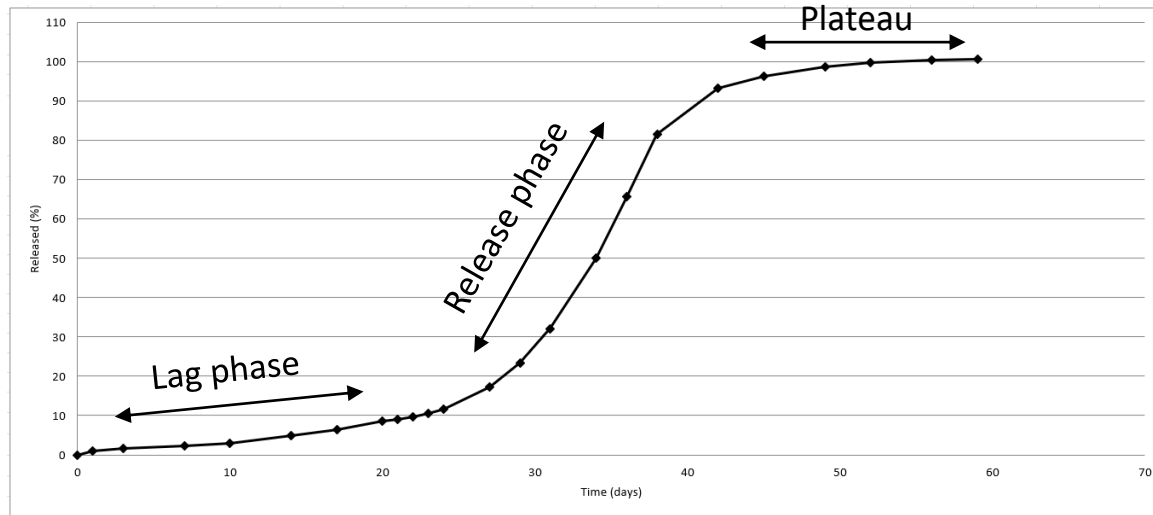


t0, t1 day, t1 week .....

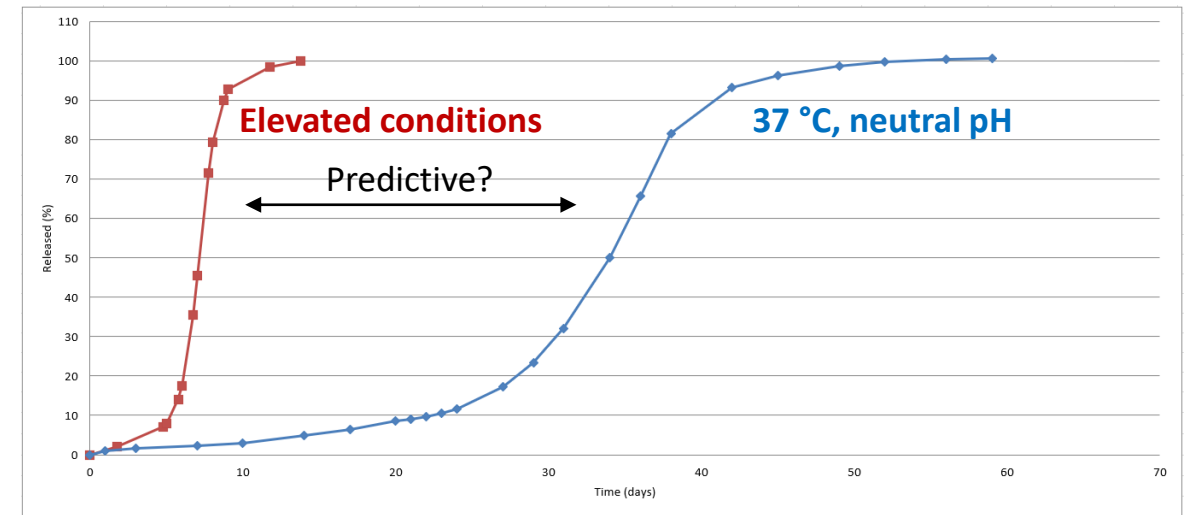
HPLC-UV



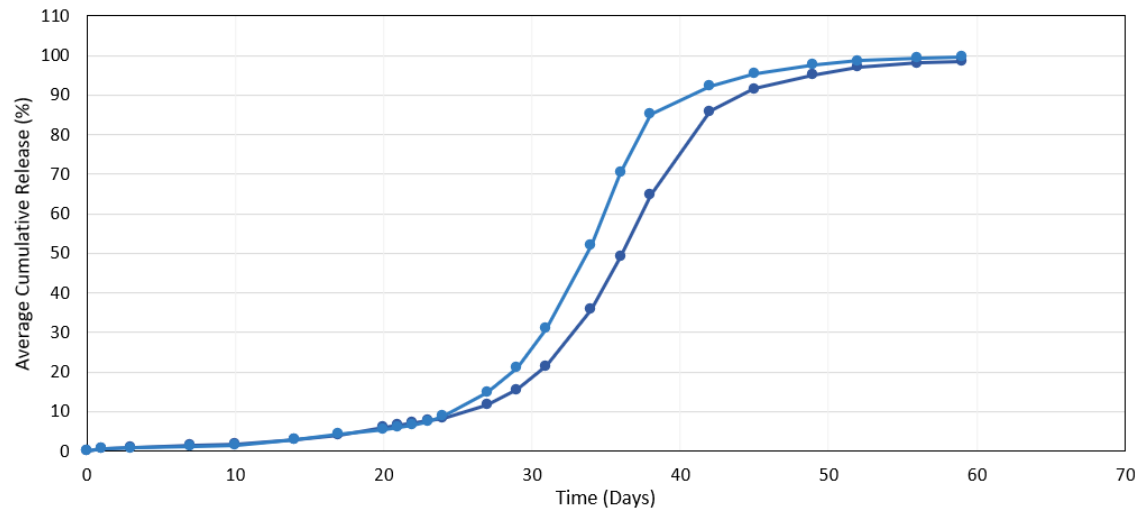
# In vitro release microspheres



*IVR curve*



*Accelerated vs normal*



*Different polymers, same conditions*

Discriminate between polymers

Animal or clinical trial for in vivo data -> IVIVC

# Nanosuspensions

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

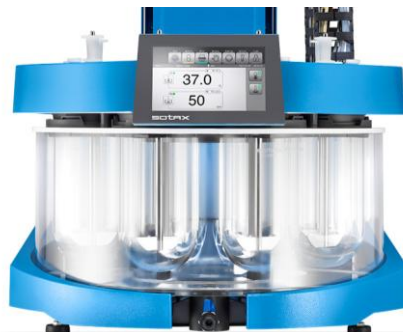
- Morphology -> SEM



Nanosuspension



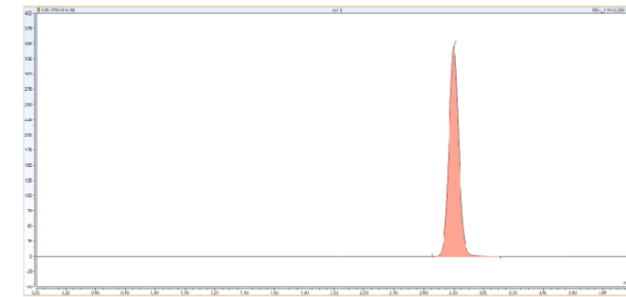
Hours/days



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



RP-HPLC

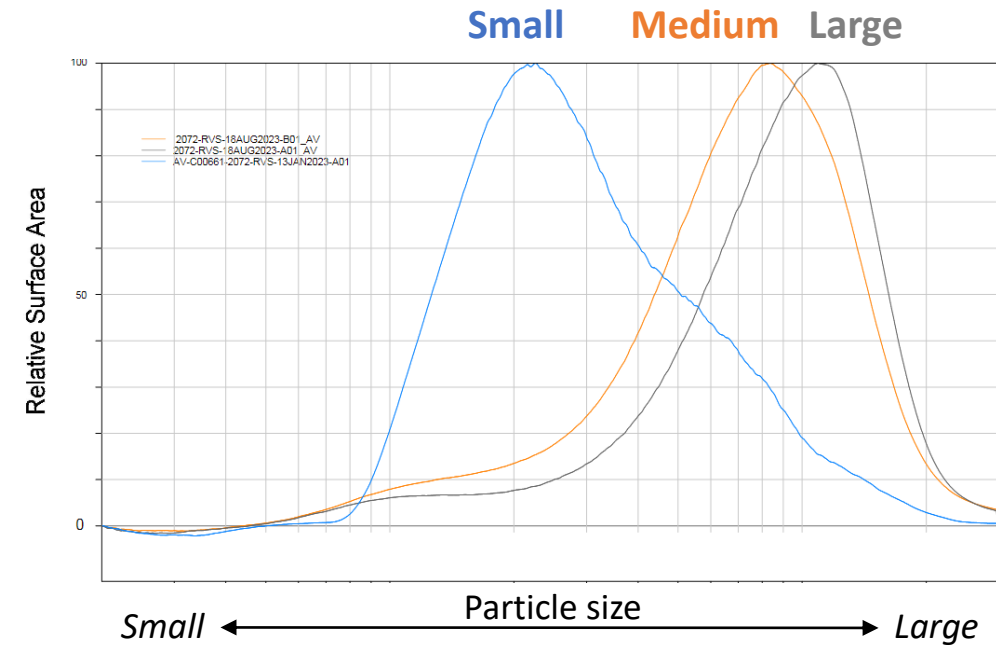
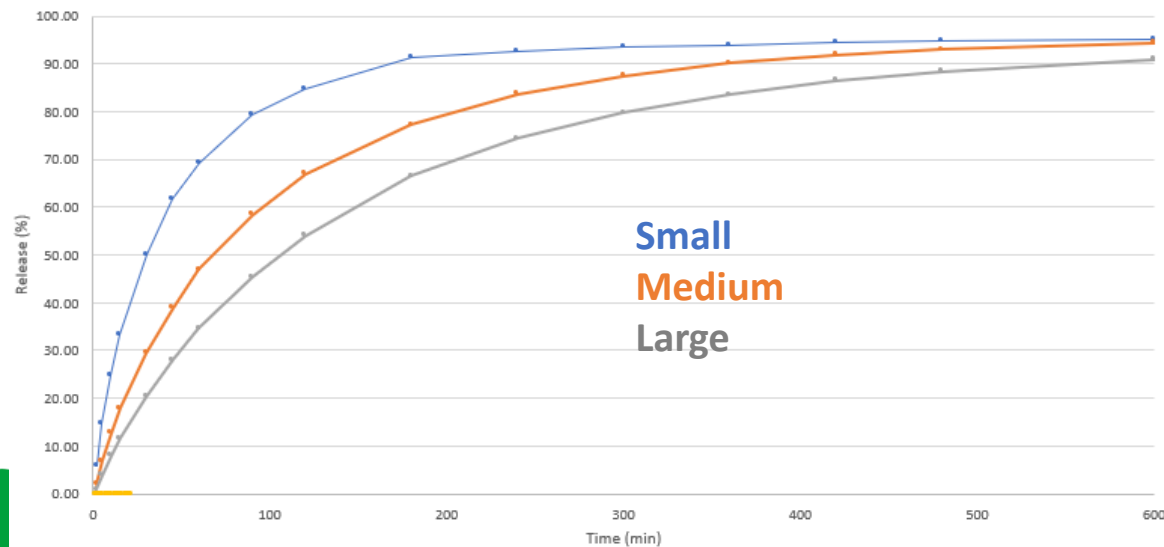


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# Particle size & dissolution

DCS (Differential Centrifugal Sedimentation)



Discriminate between particle sizes

Animal or clinical trial for in vivo data -> IVIVC

# Project phases



## **Formulation Lab**

Early-phase development



## **Cleanroom**

Proof-of-concept ATM



## **Process Lab**

Scale-up to commercial



## **GMP factory**

Clinical & commercial production

**'Scientific sound'**



**Validated**

- High throughput of API's
- Fit for purpose method development
- Limited stability studies

- Validated methods
- GMP
- Large stability studies





# Questions?

or visit our booth for more info

**Chiel Welink**

Analytical Chemist



**Thijs Duursma**

Process Development Engineer



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