

Science with Passion



KNAUER IJM Technology

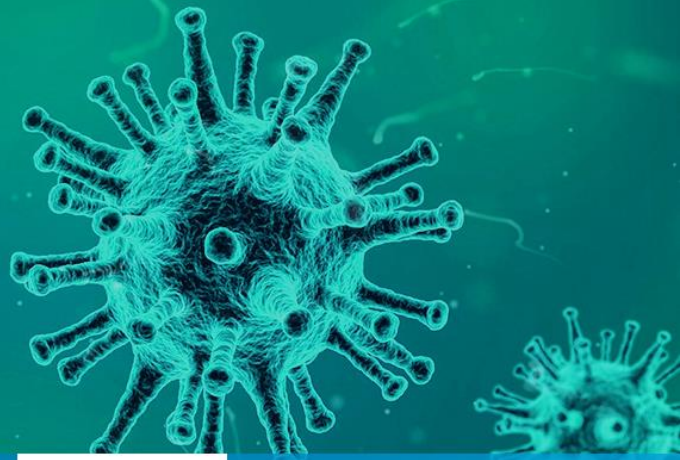
Customized Solutions @KNAUER

Are you researching on a vaccine against COVID19 ?

We support your efforts with LC technology.

For protein purification, RNA purification, analysis of active agents and more.

[Learn more](#)



Lipid nanoparticles

KNAUERforFuture

Training

ULDC Technology

SARS-CoV-2



Analytical HPLC



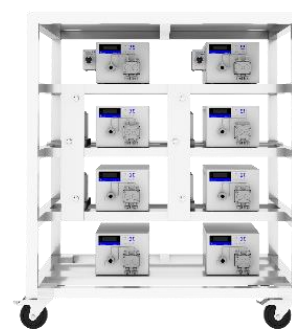
FPLC



Preparative LC



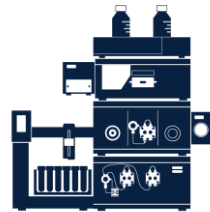
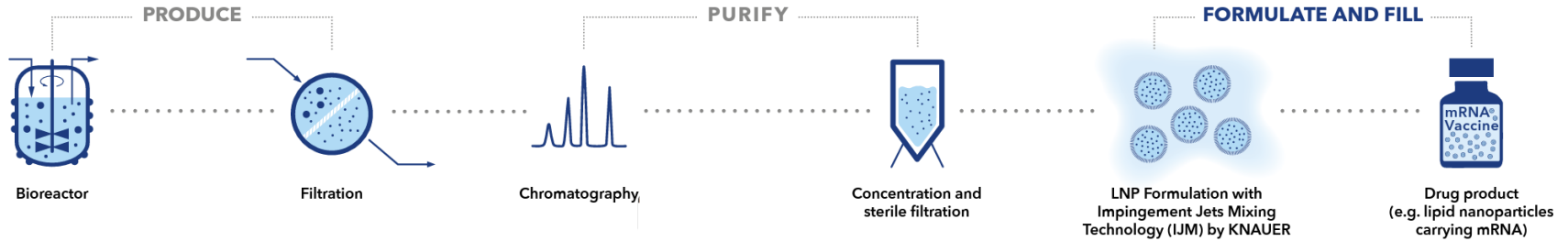
SMB



IJM - Skid

mRNA-LNP production flow

PROCESS OVERVIEW



AZURA FPLC



IJM Skid

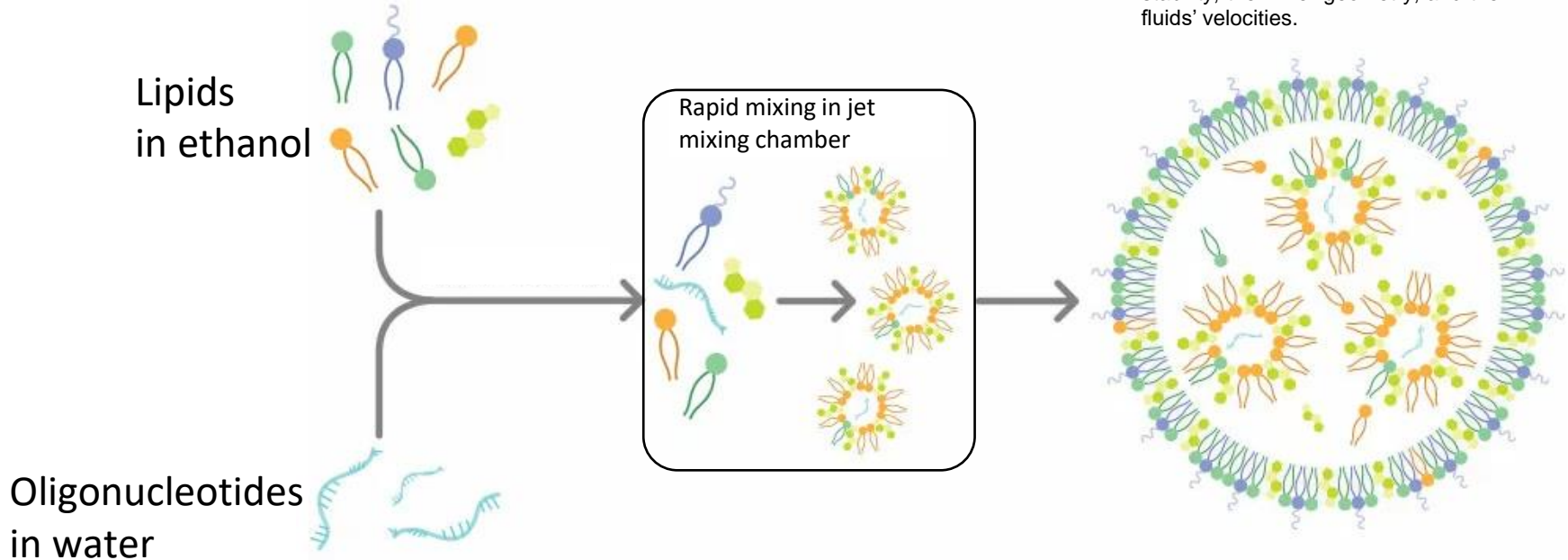
Impingement Jets Mixing (IJM) technology

- Lipid nanoparticles (LNPs) are a suitable delivery form for mRNA-based vaccines, as proven during the SARS-CoV-2 pandemic
- CoViD vaccines comprise the first large-scale use of mRNA in vaccination history
- LNPs encapsulate and protect the active pharmaceutical ingredient (API)
- KNAUER's impingement jets mixing (IJM) technology has demonstrated precise and consistent performance for small and large-scale production of LNPs
- KNAUER IJM skids are available for R&D and for production scale in the pharmaceutical industry

Impingement Jets Mixing (IJM) technology

Two liquid streams collide at high velocity in a jet mixing chamber; one of the streams contains the lipids in organic solvents, and the other stream contains the API in water.

Homogenous nanoparticles are formed. The quality of nanoparticles depends on the streams' flow stability, the mixer geometry, and the fluids' velocities.



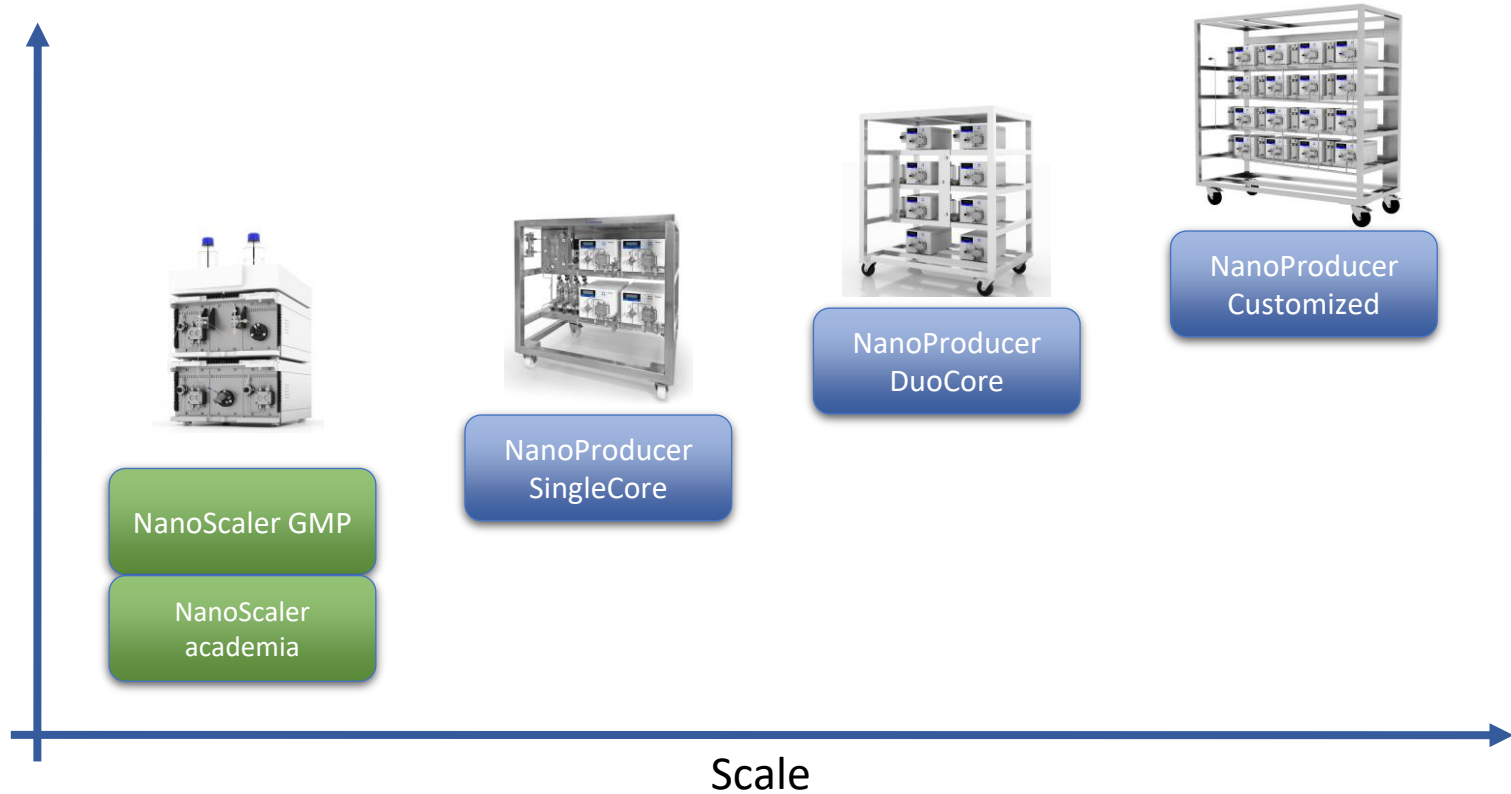
Science with Passion



KNAUER IJM units



KNAUER IJM units



Science with Passion



IJM NanoScaler



R&D and small scale production



IJM NanoScaler



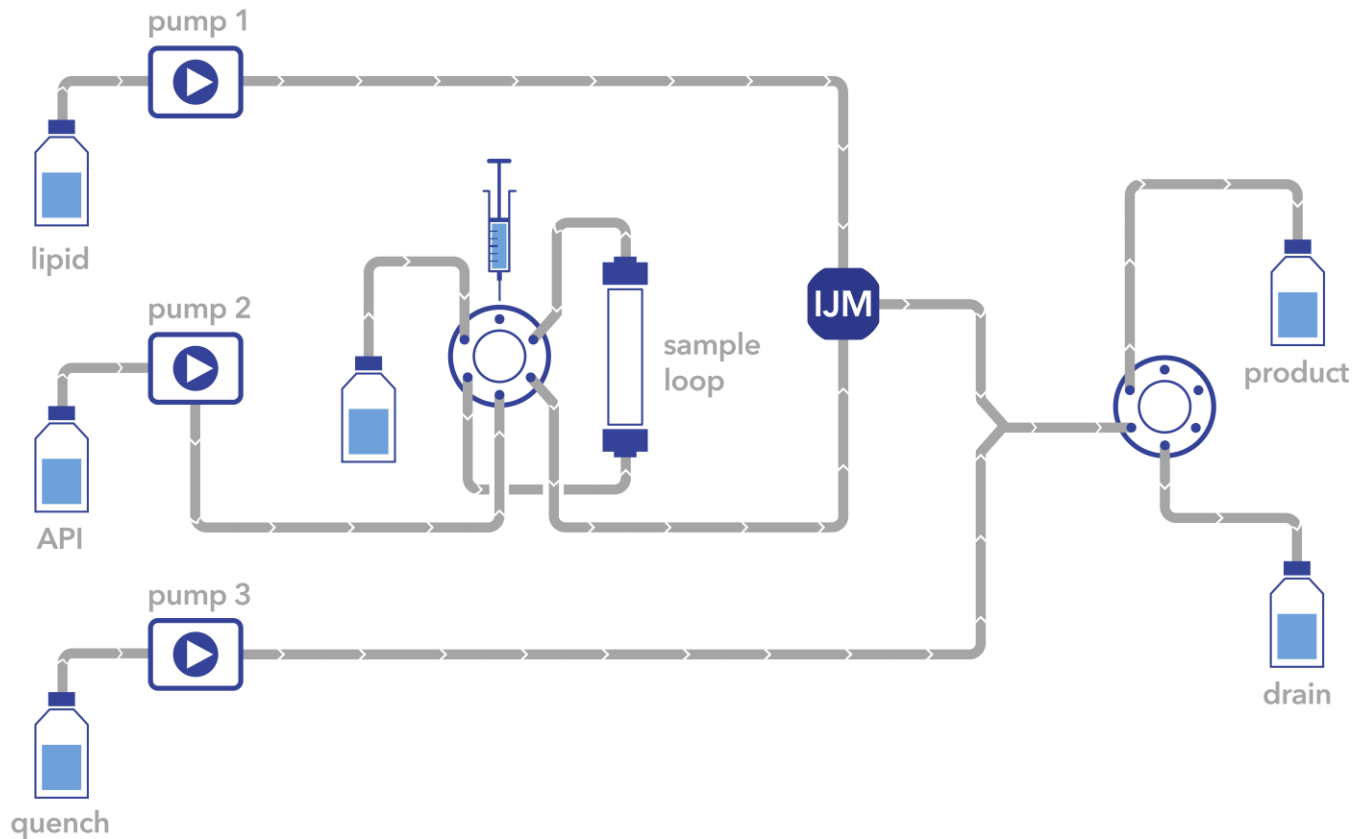
System description

The NanoScaler contains five different Impingement Jets Mixers (IJM), allowing researchers to determine the optimum encapsulation conditions before scaling up the process to run on a larger IJM NanoProducer unit.

Each system contains three pumps. The API solution is transferred via a loop to be mixed with the organic phase to minimise the sample volume. Finally, the LNP mixture is quenched in a second mixer.

You can still use the API pump directly without the loop for larger volumes.

IJM NanoScaler schematic diagram



Technical Specifications

	IJM NanoScaler
Number of mixers	5, IJM 1 - 5
Number of pumps	3
Switching valves	2, injection and collection
Inlet connection	1/8"
Outlet connection	1/16"
Volume per minute outcome	50 ml/min
Dimensions (w x h x d)	441 x 416 x 603 mm
Weight (kg)	60
Site acceptance test (SAT)	YES, on request
Software PurityChrom 6.0 LNP	YES, on request



Science with Passion

 IJM NanoScaler

Replacement kits /spare parts

Article number

Maintenance kit for valves AVD26AE, AVJ26AE

ARV33

Replacement rotor seal for AVD26AE, AVJ26AE

A205145

Replacement stator for AVD26AE

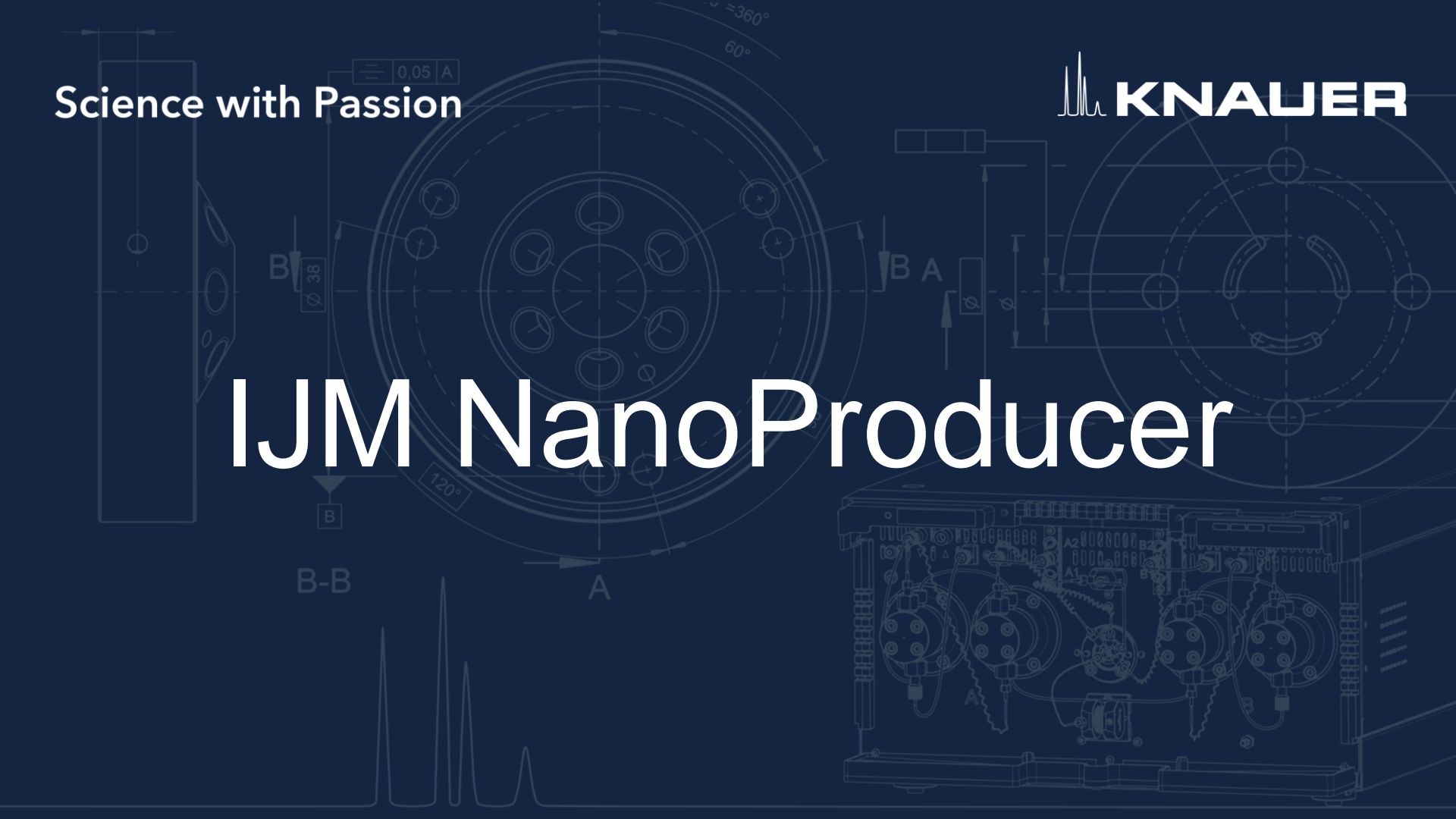
A205140



Science with Passion



IJM NanoProducer



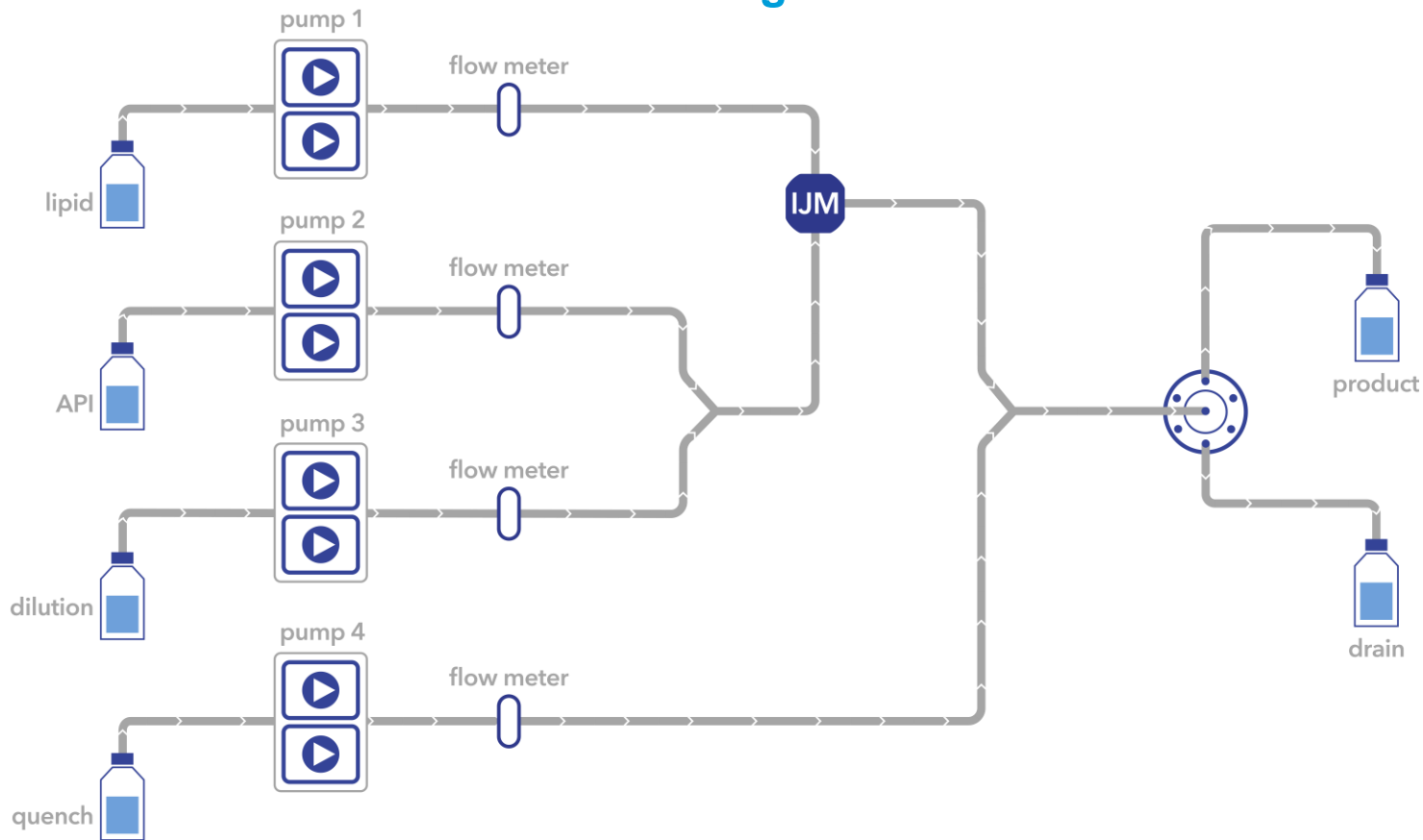


0.1 – 1.0 Liter / min
total output



0.1 – 2.0 Liter / min
total output

IJM SingleCore NanoProducer schematic diagram



 IJM SingleCore
NanoProducer

System description

The IJM SingleCore NanoProducer contains one mixing unit. The unit contains four pumps. Concentrated API solution is diluted first and then mixed with the organic phase. Finally, the mixture is quenched in a third mixer.

All skids are built in a stainless-steel frame on casters and are suitable for CIP cleaning procedure in pharmaceutical production.



0.1 – 1.0 Liter / min
total output



IJM DuoCore
NanoProducer

System description

The IJM DuoCore NanoProducer contains two parallel mixing units. Each unit contains four pumps. Concentrated API solution is diluted first and then mixed with the organic phase. Finally, the mixture is quenched in a third mixer. Both units can be operated independently.

All skids are built in a stainless-steel frame on casters and are suitable for CIP cleaning procedure in pharmaceutical production.

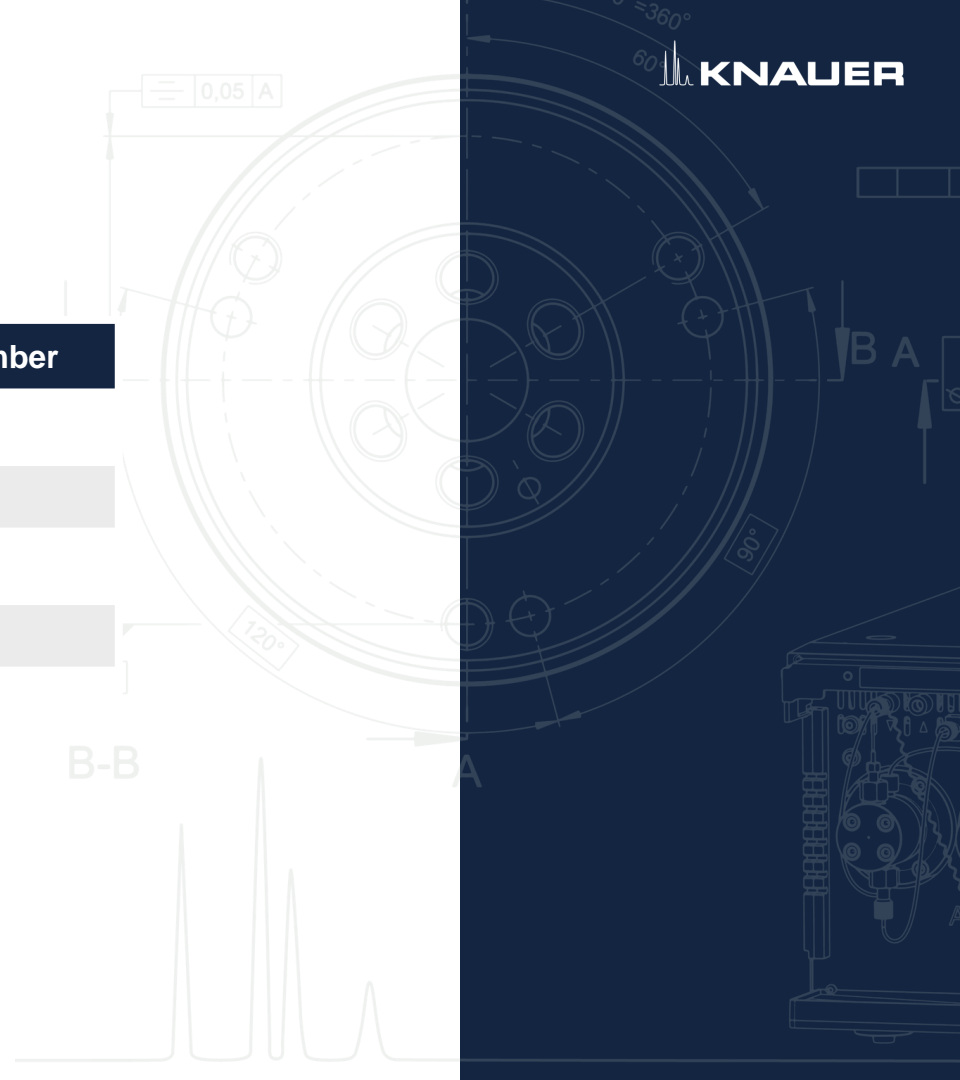


0.1 – 2.0 Liter / min
total output

Technical Specifications

	IJM SingleCore NanoProducer	IJM DuoCore NanoProducer
Number of mixers	1	2
Number of pumps	4	8
Number of flowmeters	4	8
Inlet connection	1/2" Tri-clamp	1/2" Tri-clamp
Outlet connection	1/2" Tri-clamp (1 outlet)	1/2" Tri-clamp (2 outlets)
Volume per minute	Up to 1 l/min	Up to 2 l/min
Dimensions (w x h x d)	900 x 915 x 700 mm	1000 x 1290 x 700 mm
GMP ready documentation	YES	YES
Factory acceptance test	YES	YES
Site acceptance test	YES	YES
Order number	5000 001	5000 002
Software Puritychrom 6 LNP	License; CFR 21 Part 11 and GAMP 5 compliant	License; CFR 21 Part 11 and GAMP 5 compliant
Software maintenance	Once per year	Once per year

Replacement kits /spare parts		Article number
Maintenance kit P2.1L 80P	100 ml pump head	A96425
Maintenance kit P2.1L 80P	250 ml pump head	A96426
Maintenance kit P2.1L 80P	500 ml pump head	A96427
Maintenance kit P2.1L 80P	1000 ml pump head	A96428
Maintenance kit for valves AVT84AH, AVT34AH		ARV42



Order and purchase conditions

Warranty

24 months from the date of invoice.

General terms and conditions

In case a license is required for the production process, the buyer is responsible for implementation and authorization of use by herself/himself. The patent rights should be considered.

Payment conditions

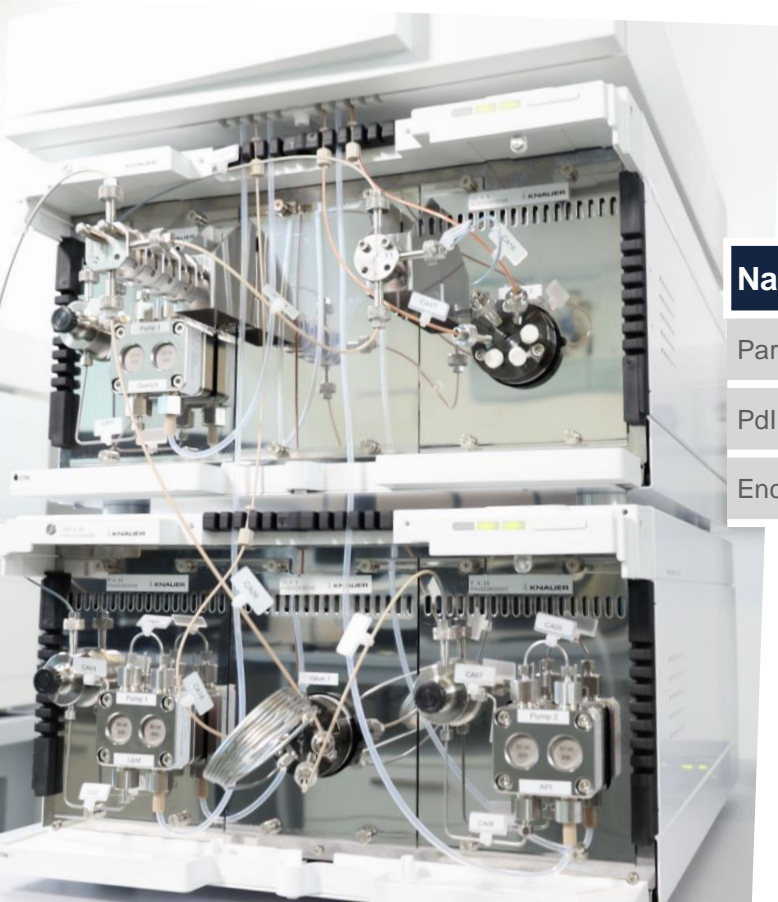
30 % prepayment
50 % before shipment
20 % after delivery/installation or successful SAT (Site Acceptance Test)

Purchase lead time

Single Mixing Unit: Four (4) months from the date of order confirmation.
Double Mixing Unit: Five (5) months from the date of order confirmation.
NanoScaler Unit: Three (3) months from the date of the order confirmation.

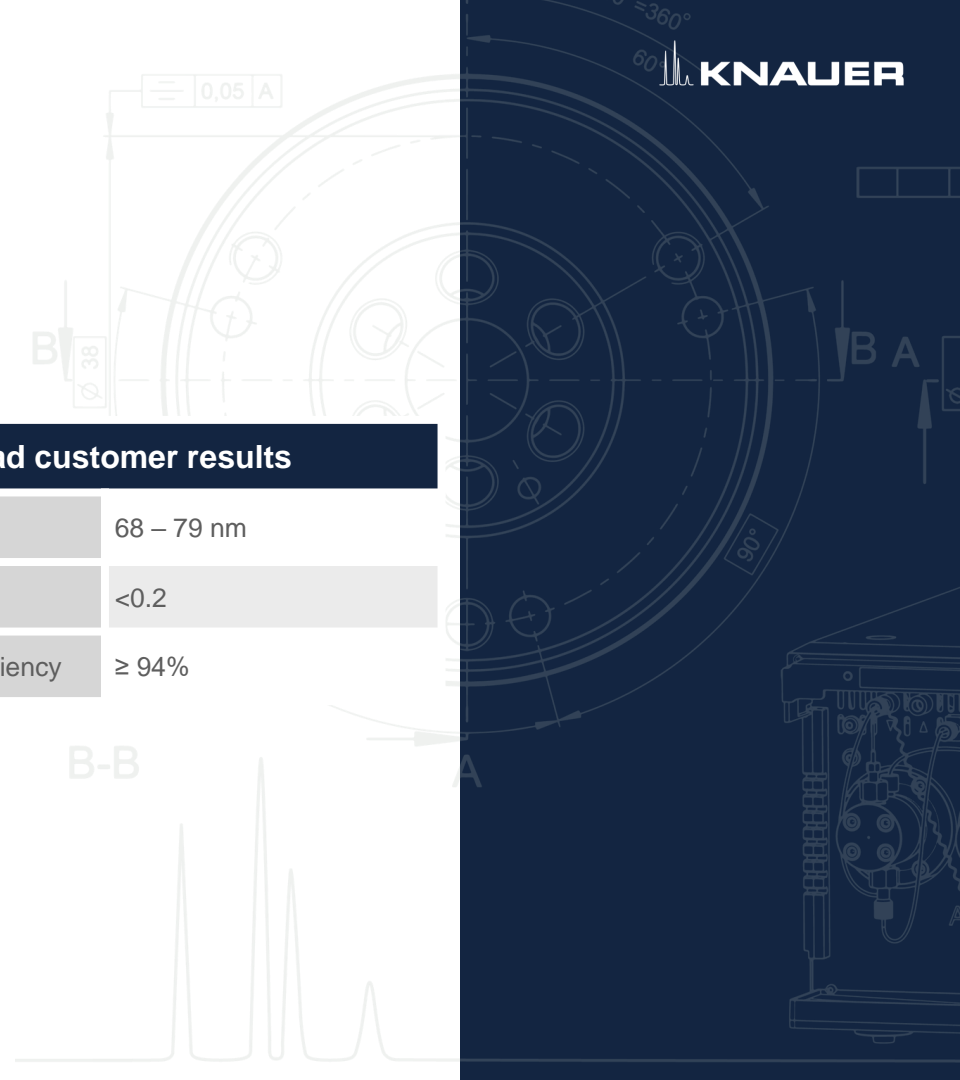
Quote validity

Three (3) months from the date of quote.



NanoScaler lead customer results

Particle Size	68 – 79 nm
PdI	<0.2
Encapsulation efficiency	≥ 94%



Science with Passion



LNP formulation and application development

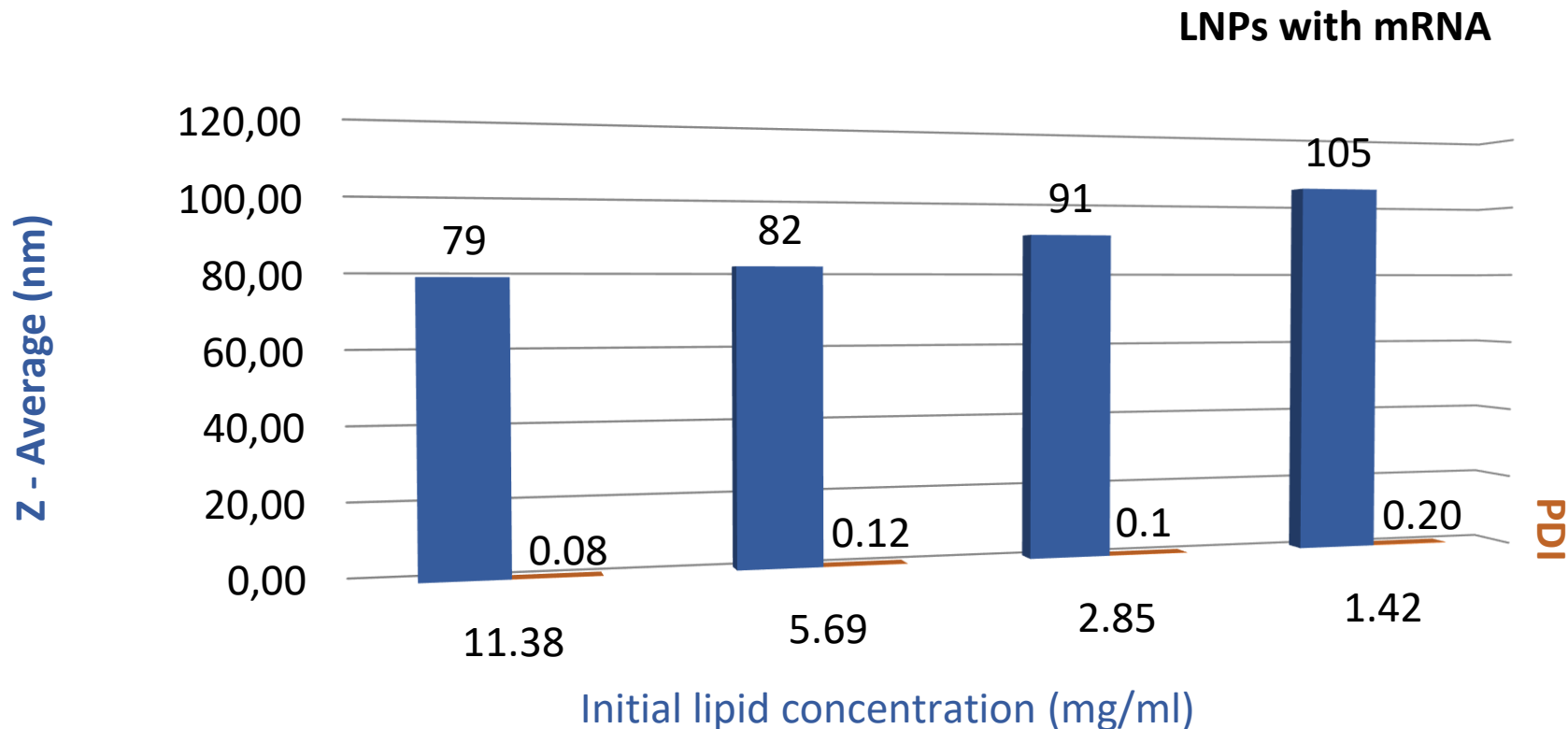
Cooperation partner PTS



PRECISION POLYMERS FOR DRUG DELIVERY

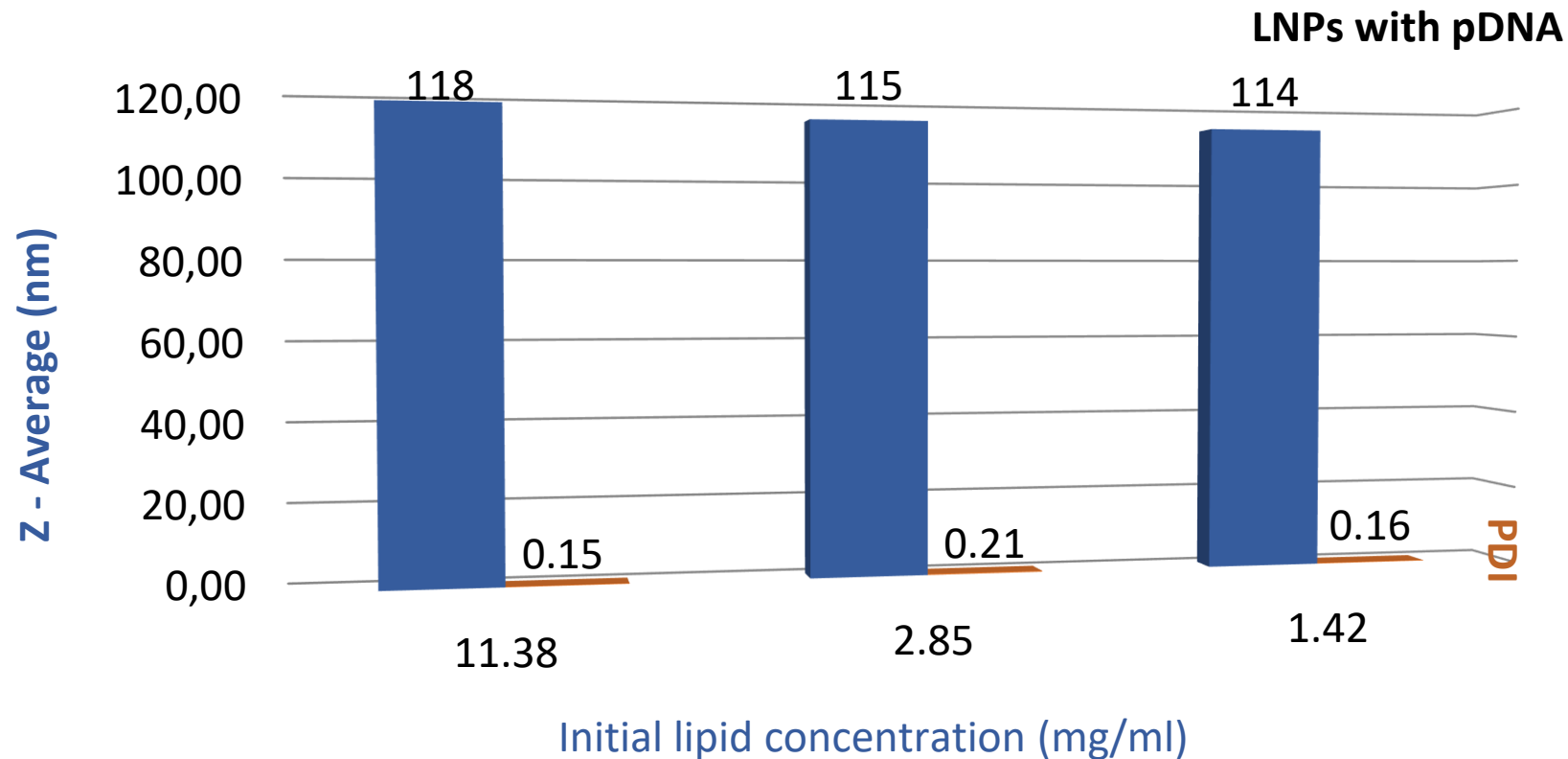
LNPs formulated with IJM technology

Values obtained with IJMixer #2



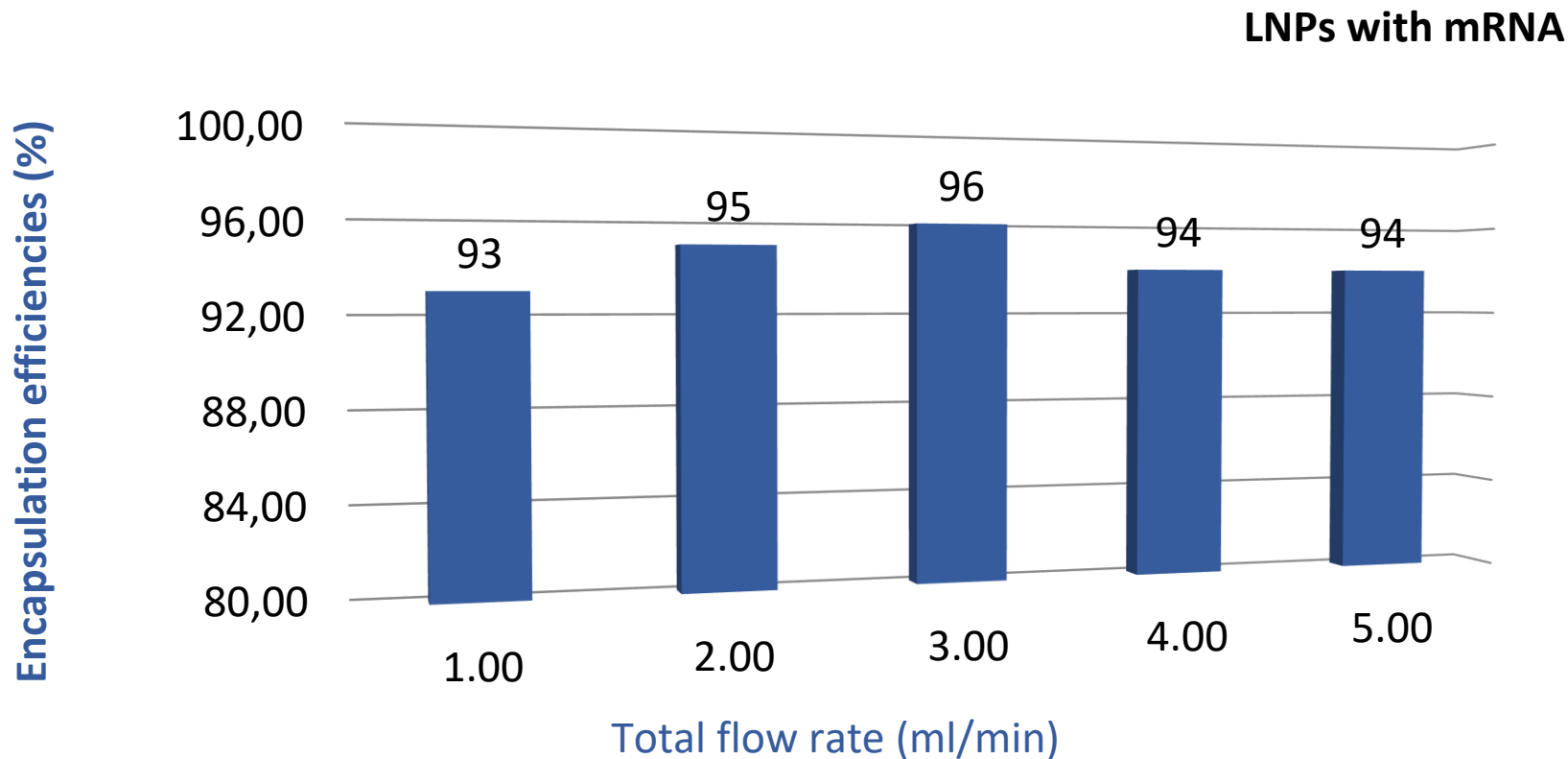
LNPs formulated with IJM technology

Values obtained with IJMixer #2



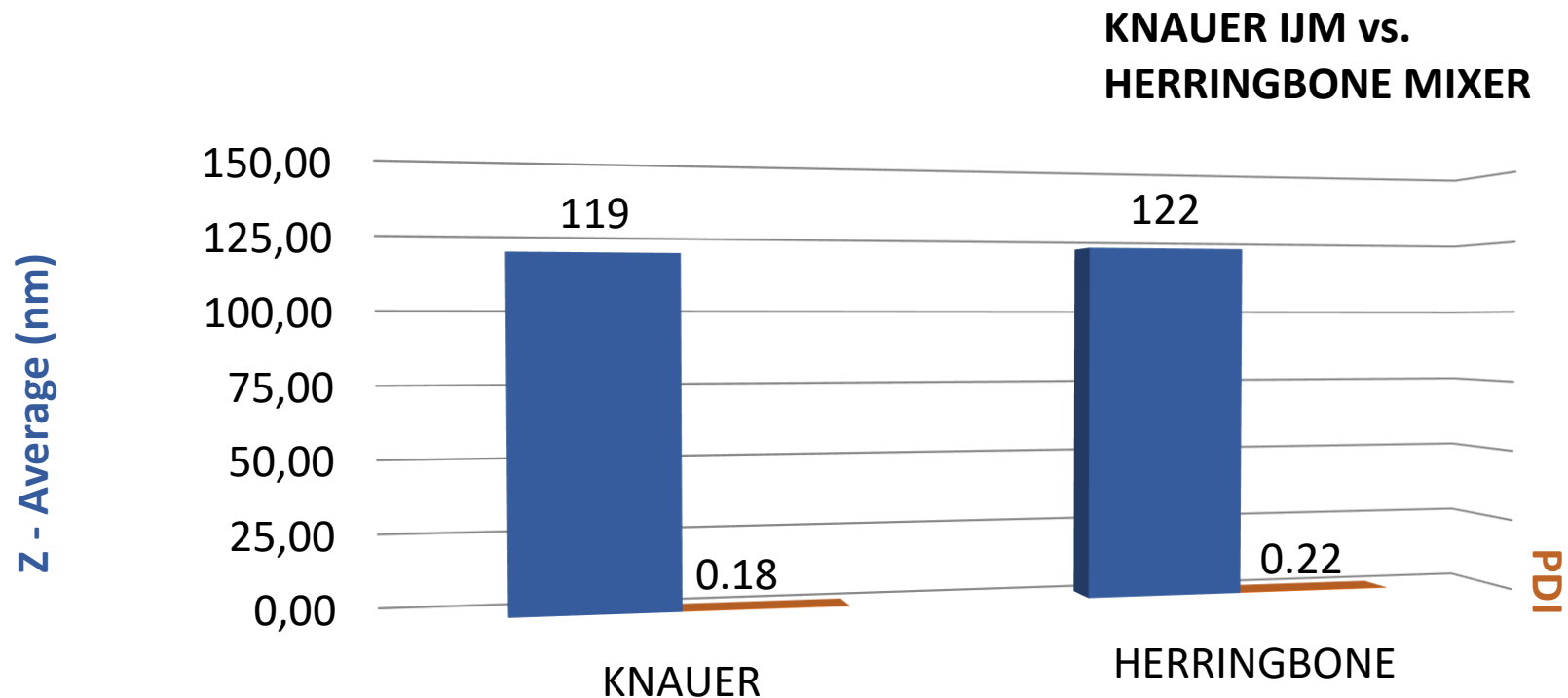
LNPs formulated with IJM technology

Values obtained with IJMixer #2



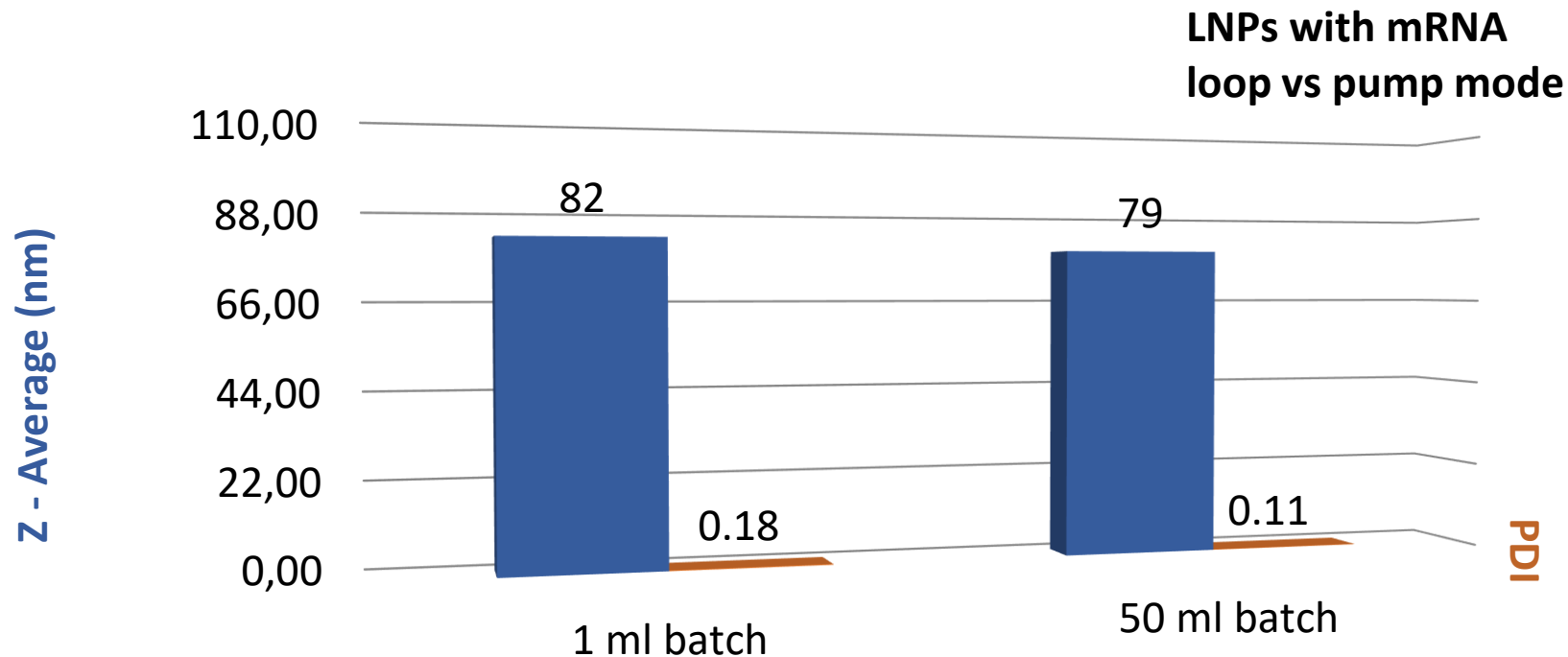
LNPs formulated with IJM technology

Values obtained with IJMixer #2



LNPs formulated with IJM technology

Values obtained with IJMixer #2



redo slide in Knauer style!!!

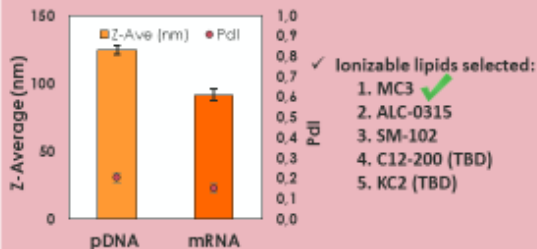


LNPs brochure

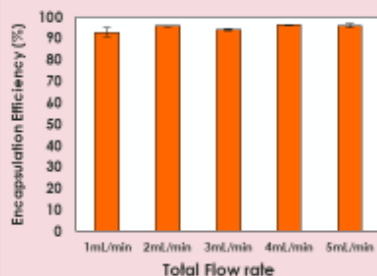
LNPs formulated with IJM skid technology

% Ionizable	% Helper	% Chol	% DMG-PEG	N/P
MC3 (50)	DSPC(10)	38,5	1,5	4

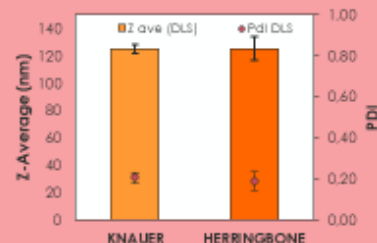
✓ Encapsulation of different nucleic acids (pDNA and mRNA) with formidable reproducibility



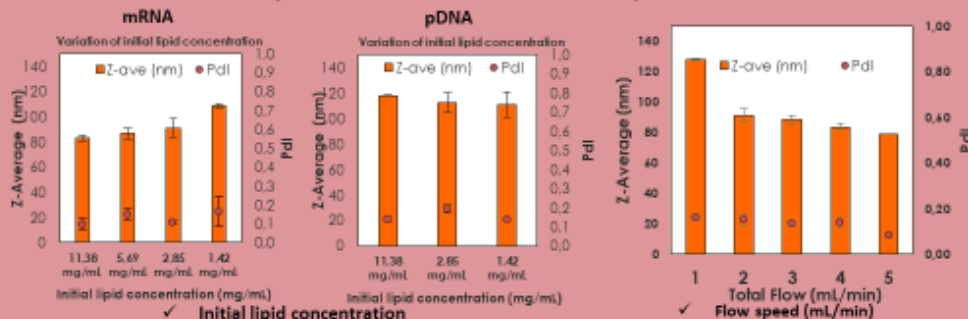
✓ High encapsulation efficiency



KNAUER vs HERRINGBONE



✓ Optimize size and Pdl with formulation parameters



✓ 1ml batch vs 50mL batch (50mL)

