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GHENT UNIVERSITY

FACULTY OF PHARMACEUTICAL SCIENCES

LP PAT

CHAUVIN ARNOUX
INDATECH

In-line quantification of API encapsulated in LNPs using UV spectroscopy

Tryfon Digkas, Prof. Dr. Thomas De Beer

5th September 2024



PEMBROKE INSTRUMENTS, LLC
U.S. Product Information & Quotations
Manufactured by INDATECH | Chauvin Arnoux Group
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Drug-loaded lipid-based nanoparticles (LBNPs)

Topical Corticosteroid (TCs)

Lipid molecules

gel base for topical application

Advanced treatment of topical chronic and inflammatory skin conditions such as atopic dermatitis

↓

Enhanced cutaneous permeability
Efficient targeting potential
Reduced side effects

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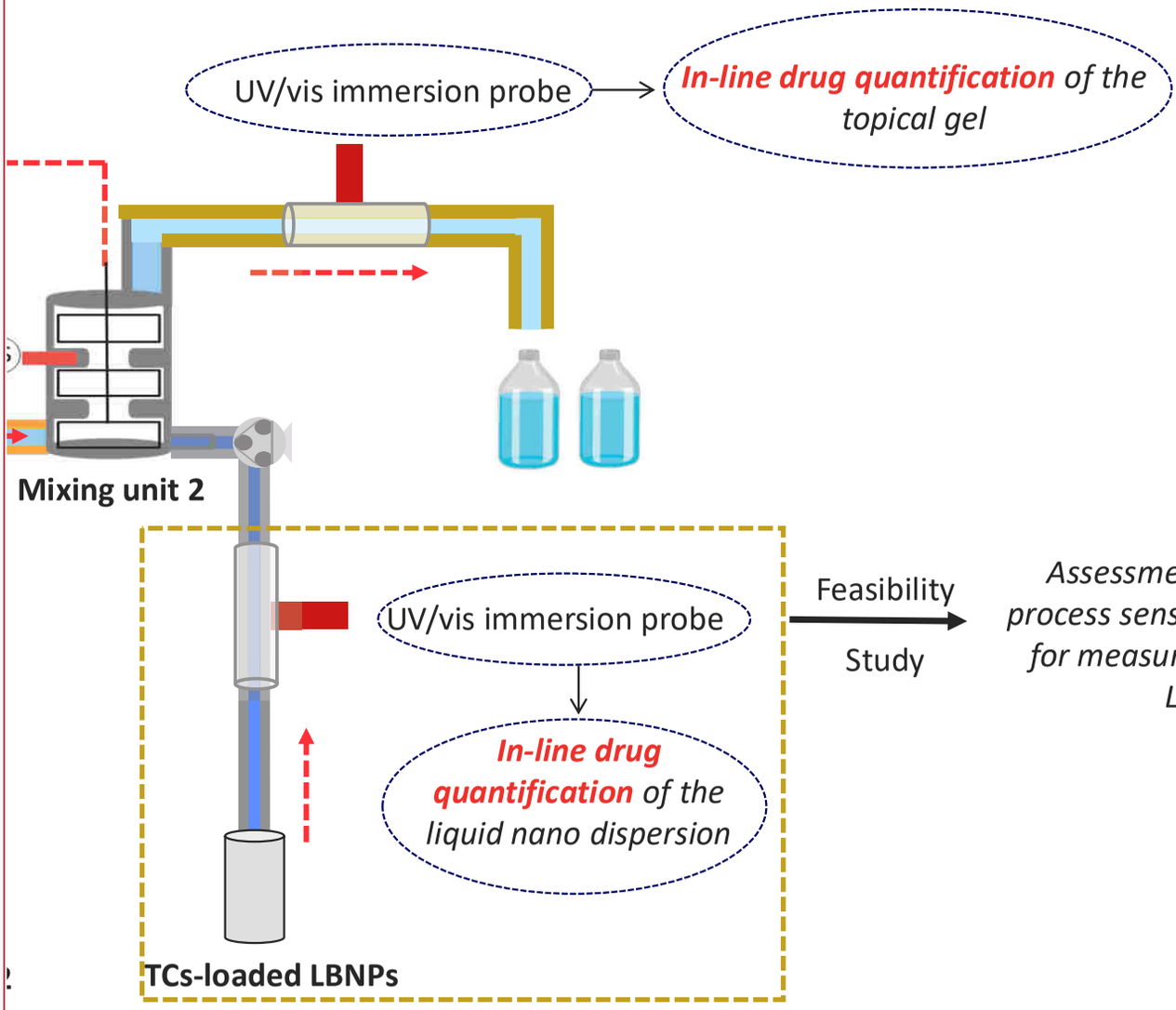

Opportunities	*Challenges*
*:s **flow** & **easy scale-up***	*Development of sensor technologies (hard and soft sensors) for continuous process monitoring*
me-to-market	
ergy consumption	
non-destructive analysis	*Development of a quantitative model for the determination of encapsulated drug concentration in LBNPs*
***nitoring and control** during production*	
*ion of a **low-dose API***	

:ation of a UV spectroscopy as a Process Analytical Technology (PAT) tool for future in-
etermination of low-dosed active pharmaceutical ingredients (APIs) in a Continuous
1) process for pharmaceutical semi-solid (gel) and liquid (suspensions) formulations.

n off-line, non-destructive analytical method for the quantitative determination of a
Ps

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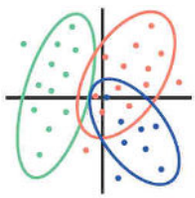
Diagnostic model (PCA)

[TCs concentration ug/mL]
[Y]

Calibration set
(Training set)

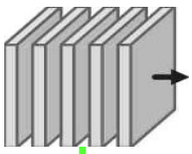


Review of data Fit
Visual data Interpretation

TCs EE % in LBNPs

sis of LBNPs

calibration set (Training set)



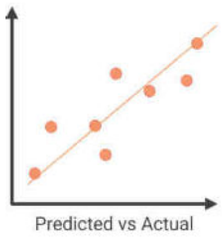
Evaluation of the raw data:
Outlier detection
Spectra pre-processing

UV Spectra - TCs
loaded LBNPs
[X]

Quantification model (PLS)

Calibration
set

Validation
set



Predict the encapsulated TCs concentration
in new samples (validation set)

rsion probe

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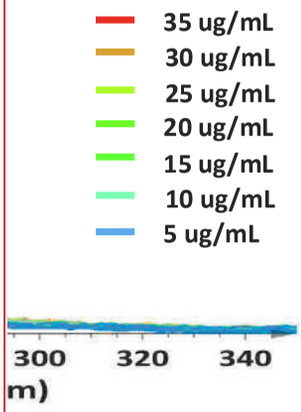
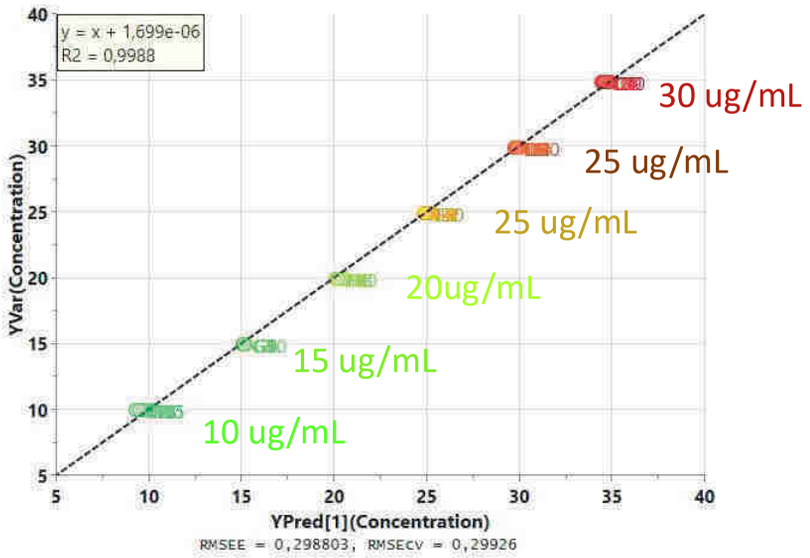
API + Excipients



ents

Observed values (YVar) vs predictive values (YPred)



Results:

- PLS components **1 #**
- High *Goodness of fit :* **$R^2X = 0.997$**
- Good predictive ability : **$Q^2 = 0.999$**
- Prediction errors estimated to **0.29% (RMSEcv)**

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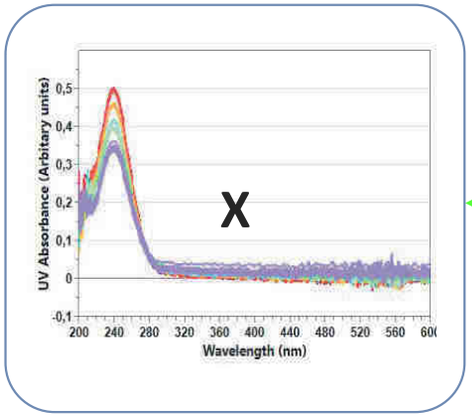
Asuryan UV spectroscopy analyzer & Multi angle cuvette holder





UV spectra

PLS

Y	
36	120 %
33	110 %
30	100 %
27	90 %
24	80 %

TCs conc. ug/ mL

Analytical settings

Sample temperature: 20 °C

No. of channels: 1

Cuvette 5mm path length

No. of spectra / sample : 10

Integration time: 25 ms

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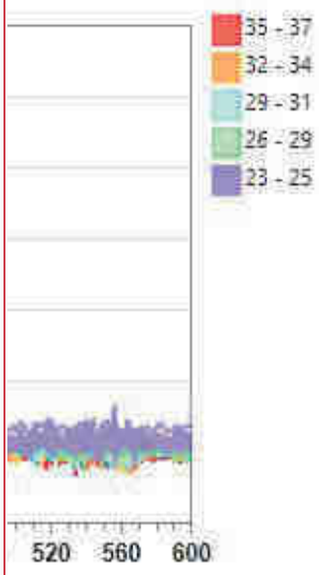
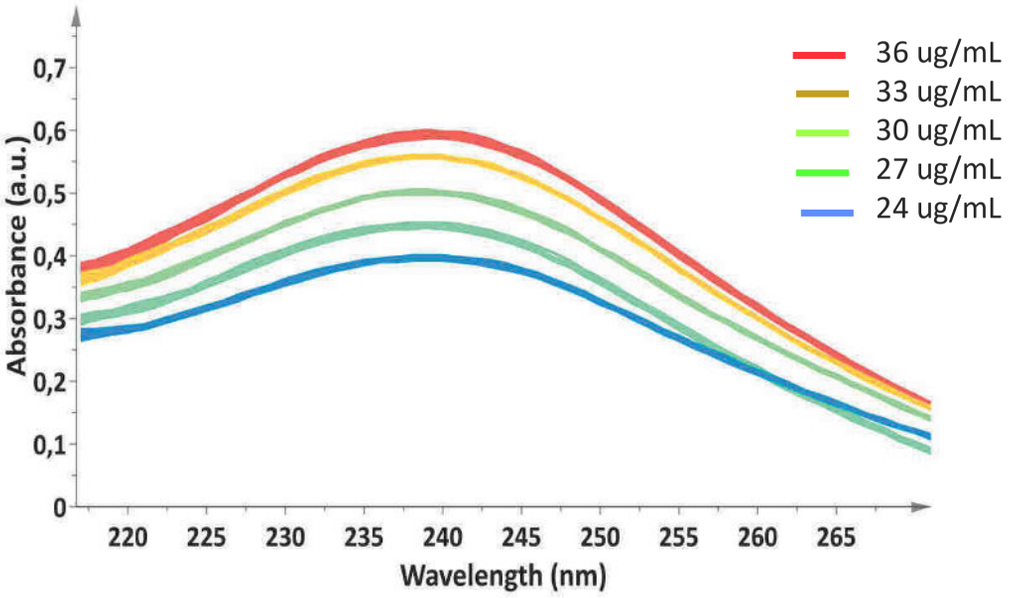
aded LBNPs



Calibration set of UV spectral data for the TCs-LBNPs



- Spectral region: 210nm – 280nm
- Preprocessing: Savitzky Golay , centering (ctr.) scale

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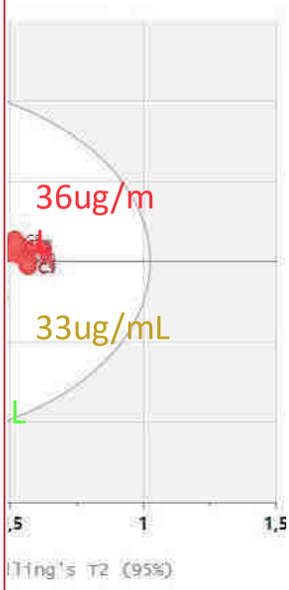
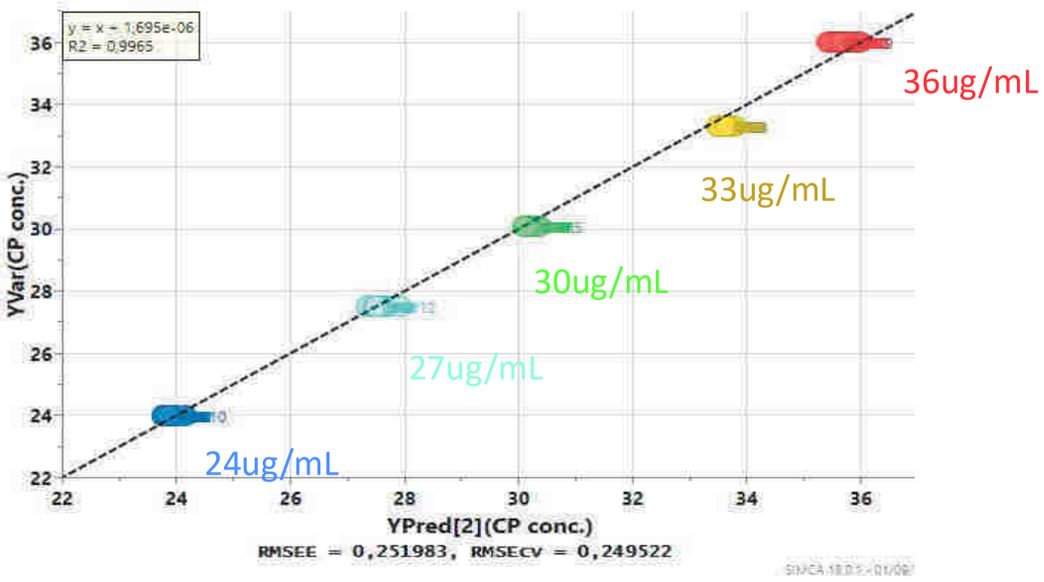
d LBNPs



with varying concentration

Observed vs predicted plot



- PLS with **2 #** Principal components
- High *Goodness of fit :* **R^2X = 0.999**
- Good predictive ability : **Q^2 = 0.997**
- Prediction errors estimated to **0.25 % (RMSEcv)**

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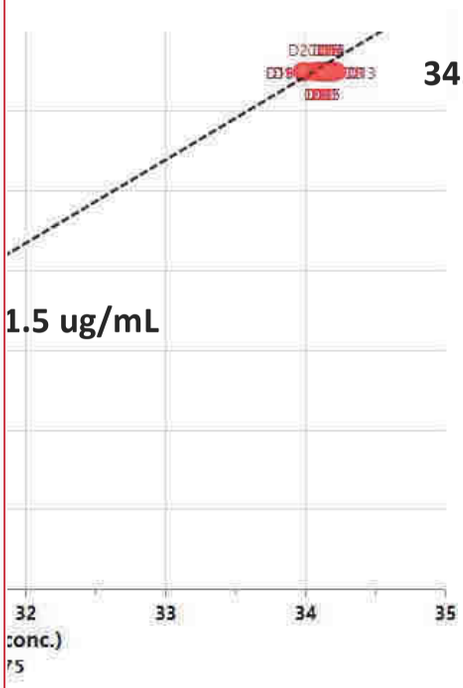
es for the validation set



predictive vs observed values
f the PLS model
0.35 %

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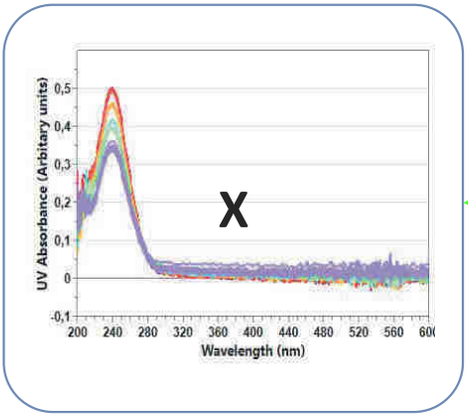
UVS-DIP immersion probe

Asuryan UV spectroscopy analyzer





UV spectra

PLS

Y	
36	120 %
33	110 %
30	100 %
27	90 %
24	80 %

TCs conc. ug/ mL

Analytical settings

- Sample temperature: 20 °C
- Continuous stirring: 300 rpm
- No. of channels: 1
- Patch length: 5mm
- Nr. of spectra / sample : 10
- Nr. of scans / spectra: 10
- Integration time: 37 to 41 ms

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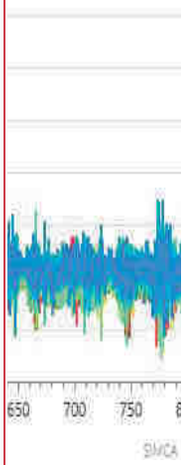
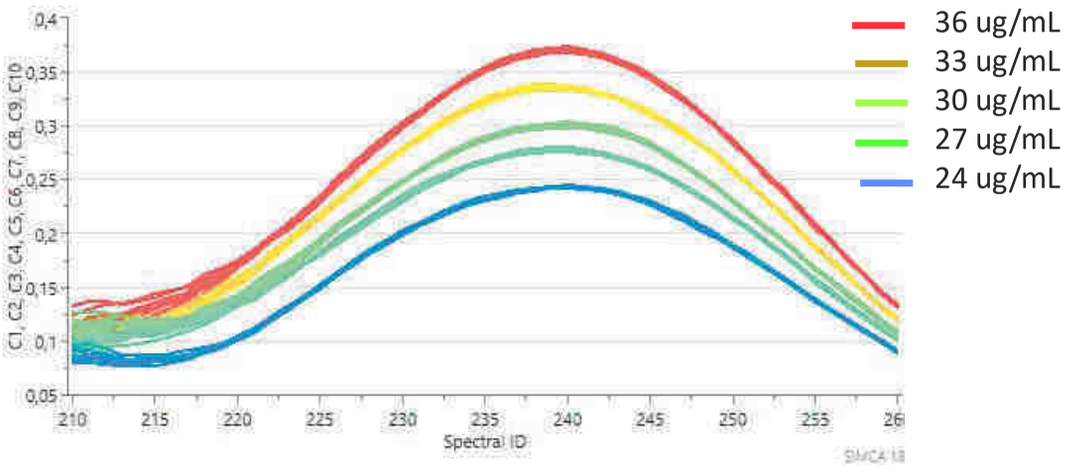
loaded LNPs



Calibration set of UV spectral data for the drug loaded LNPs



- Spectral region: 210nm – 260nm
- Preprocessing:
  - Savitzky Golay
  - Row centering
  - centering (ctr) scale

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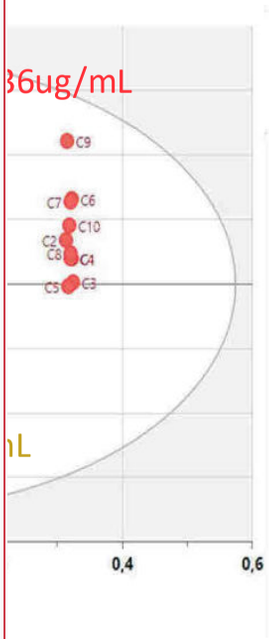
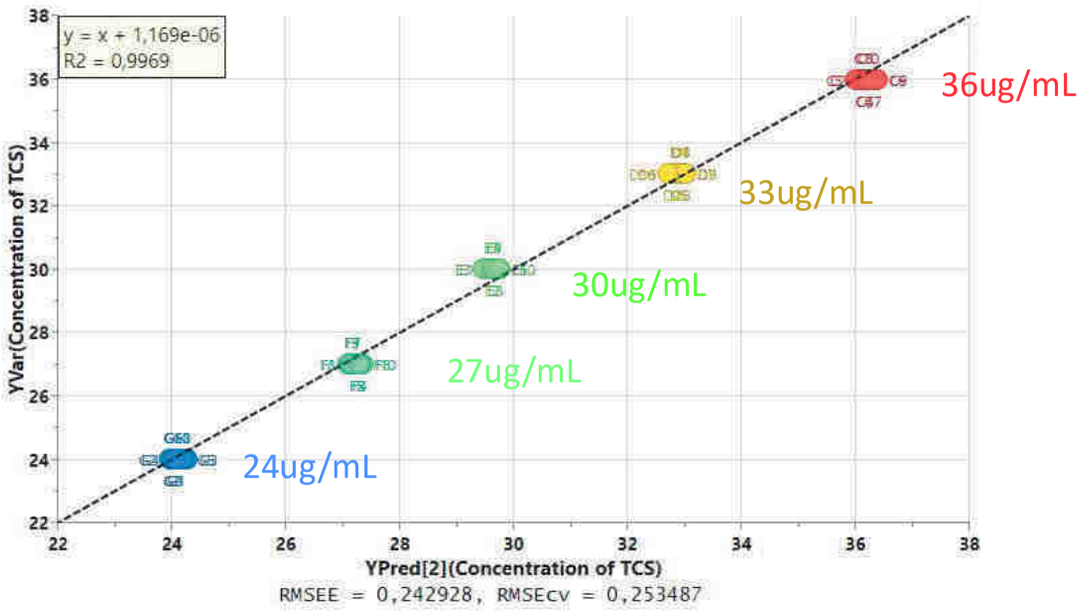
ded LBNPs



with varying concentration

Observed vs predicted plot for the calibration set



- PLS with **2 #** Principal components
- High *Goodness of fit :* **R^2X = 0.989**
- Good predictive ability : **Q^2 = 0.996**
- Prediction errors estimated to **0.25 % (RMSEcv)**

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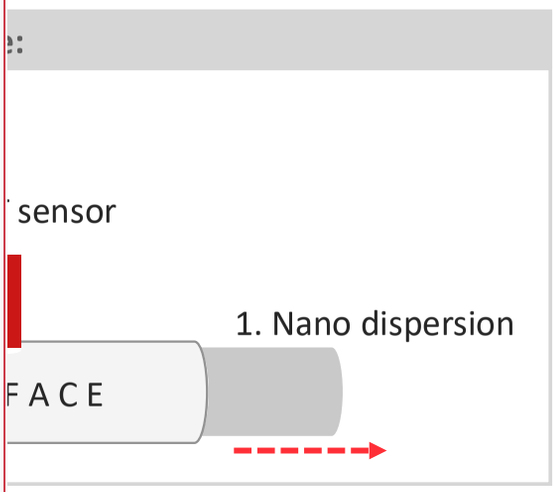
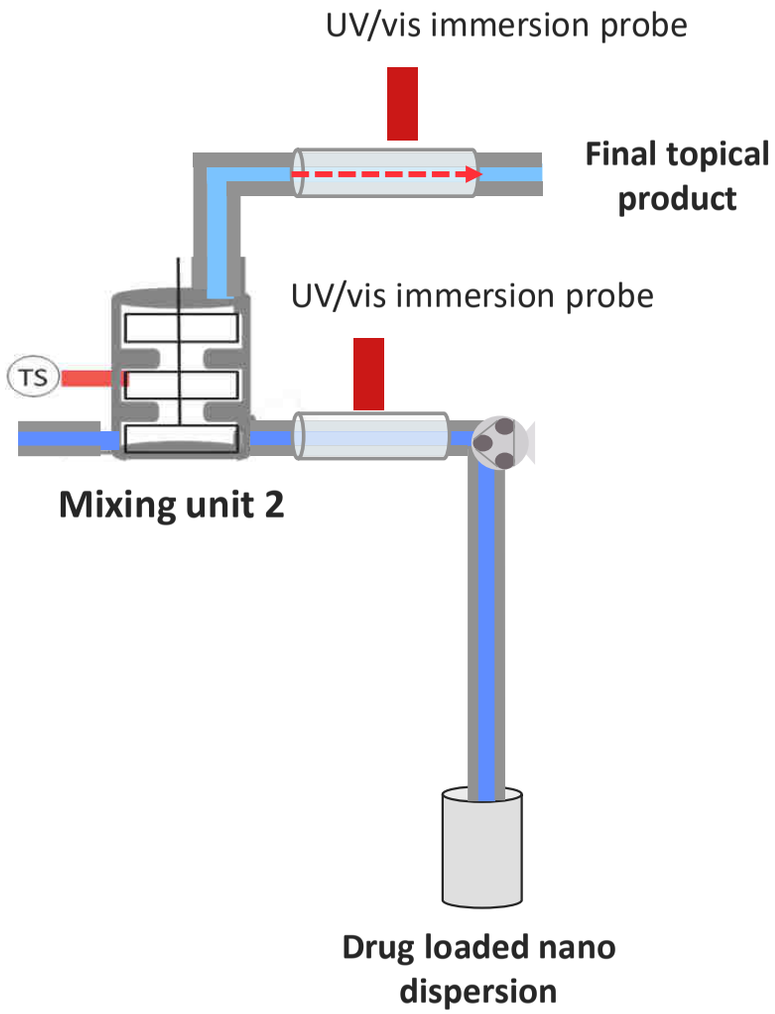
ectives

rated promising potential for e quantification method for the ed API in LBNPs.





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