CONTRACT PARTICLE ANALYSIS

Analytical services for **Drug Substance & Drug Product** advanced characterization

GOOD MANUFACTURING PRACTICE
GMP
CERTIFIED
GOOD MANUFACTURING PRACTICE

NANOMOL
TECHNOLOGIES

Adding Value to your molecules

EXPERT ADVICE AND SERVICES

WHAT DO WE OFFER?

ROUTINE ANALYSIS AND R&D STUDIES

GMP services:

- PSD by Laser Diffraction
- Morphological and Particle Size Parameters by microsocopy
- NanoParticle Size and Concentration by MADLS
- Z-Potential by ELS
- Chemical composition by uHPLC

Complementary studies by:

- Thermal analysis - DSC & TGA
- Powder X-Ray Diffraction
- BET analysis
- Electron Microscopy - SEM / CRYO-TEM
- Density determination - True, Bulk & Tapped
- Stability determination - Turbiscan
- Rheological and Viscosity studies

VALUE ADDED CONSULTING SERVICES

- Development, validation and transfer of PSD methods
- Analytical investigation of out of specification batches
- Support in IP & regulatory procedures
- Support in API suppliers qualification
- Analytic studies in generic drug development and reverse engineering -test samples vs RLD
- Image analysis studies - Optical & Electron Microscopy
- Nanocharacterization studies

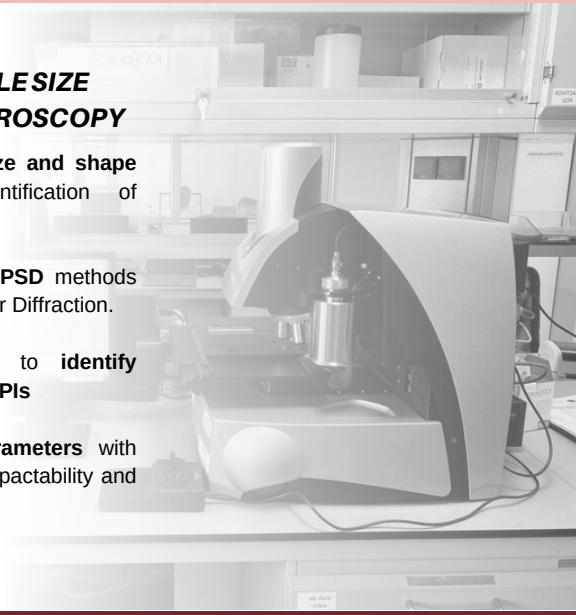
GMP SERVICES
PHYSICOCHEMICAL PARAMETERS

PARTICLE SIZE DISTRIBUTION (PSD) ANALYSIS BY LASER DIFFRACTION (LD)

- **We develop and optimize methodologies** to ensure the best performance in their implementation.
- PSD measurements of any type of products – APIs, pharmaceutical intermediates and final formulations.
- Analytical method **validation and transfer following Ph.Eur, USP and ISO**. Routine measurements according to validated **cGMP** methods.

MORPHOLOGY AND PARTICLE SIZE BY AUTOMATED OPTICAL MICROSCOPY

- **Statistical distribution of any particle size and shape** parameter by **image analysis**. Quantification of agglomerates
- **Verification and accuracy evaluation of PSD** methods and measurements already obtained by Laser Diffraction.
- **Comparison** of test/reference **samples** to **identify morphological differences in particulate APIs**
- **Correlation of particle morphology parameters** with pharmacological properties - flowability, compactability and others.



GMP SERVICES
PHYSICOCHEMICAL PARAMETERS

NANOPARTICLE SIZE, CONCENTRATION AND Z-POTENTIAL BY DYNAMIC LIGHT SCATTERING

- **Size and concentration of coloidal systems** containing nanoparticles by DLS and MADLS.
- **Determination of Z-Potential** by ELS technique, including pH titration studies (isoelectric point).
- **Characterization of biologicals and nanoconjugates** - protein aggregation, stability, globule size

CHEMICAL COMPOSITION STUDIES OF NANOFORMULATIONS BY UHPLC

- **Analytical Development** on nanoformulations and nanomedicines **by Ultra High Performance Liquid Chromatography**
- Determination of **active loading, encapsulation efficiency and release in nano-drug delivery systems**
- **Quantification of nanocarriers** components

COMPLEMENTARY STUDIES

Based on our knowledge & techniques

Differential Scanning Calorimetry & Thermogravimetric analysis

- Thermal analysis for solid form and polymorphism studies; Compatibility studies of API/excipients mixtures

Powder X-Ray Diffraction (PXRD)

- Evaluation of crystalline structure and polymorphism of solid and semi-solid samples in APIs and FDFs.

Specific Surface Area by BET analysis

- Specific surface area, pore size, and overall porosity of solid samples.

Morphological characterization by Electron Microscopy (SEM/CRYO-TEM)

- High-resolution particle size and morphology characterization in nano and microscopic range; Elemental analysis by EDX.
- Analysis of colloidal systems by CRYO-TEM, including image analysis.

Density determination by He Pycnometry and Autotap

- True density measurement through Helium Pycnometer measuring the real volume of solid materials
- Bulk and tapped density measurements of powdered solids by Autotap equipment, enabling flowability studies.

Rheological and Viscosity studies

- Rheological characterization of dispersions, liquids and semisolid formulations.

TIME TO REPORT DELIVERY

Customized Studies

Contact us.

Express routine service

48h after receiving the samples.

Intermediate routine service

3/5 working days after receiving the samples.

Standard routine service

10 working days after receiving the samples.

SERVICES CREATING VALUE

Our value added particle characterization consultancy services are focused on your needs

Development, validation and transfer of methods for particle size analysis

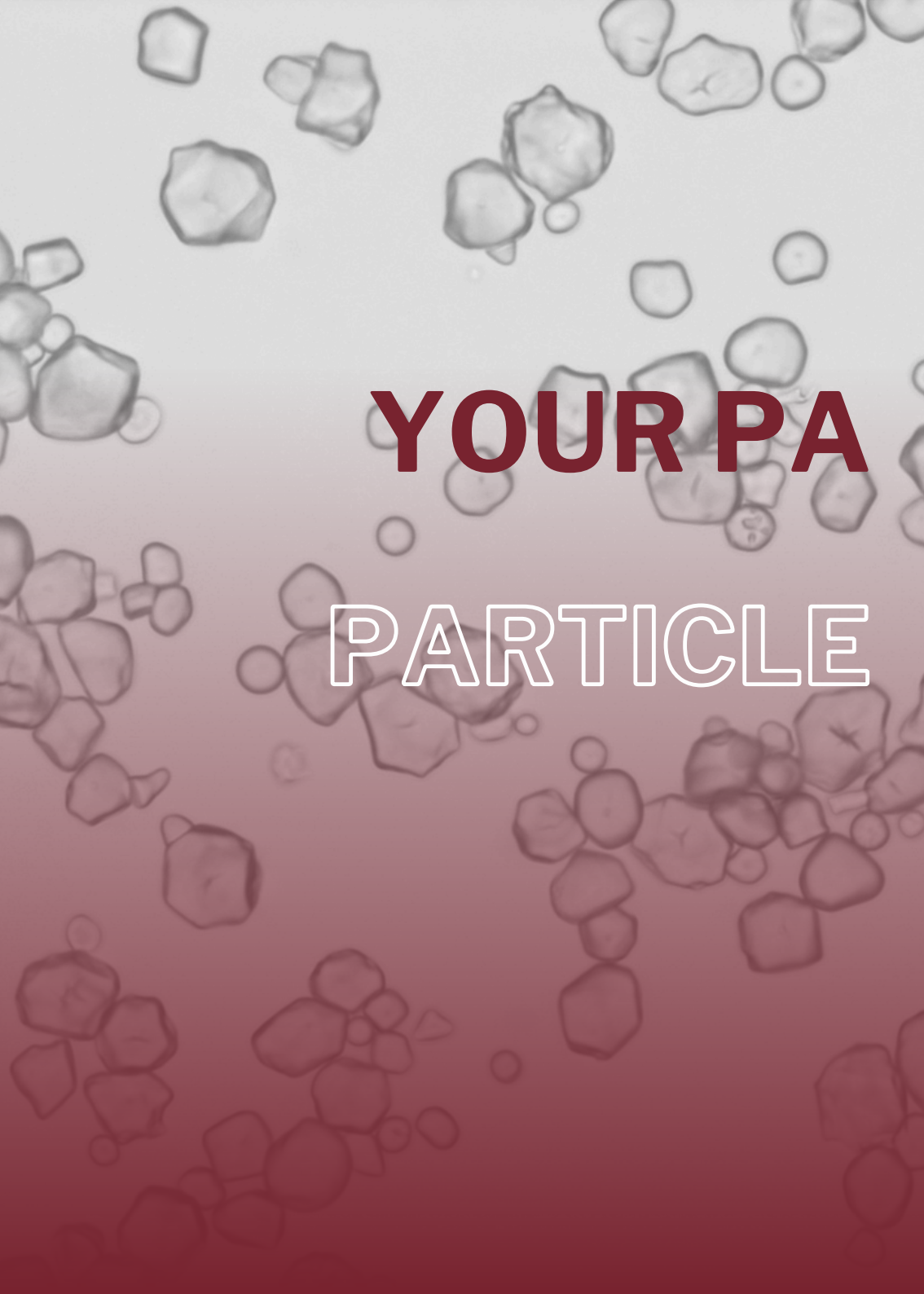
The suitability of methods with good performance to measure Particle Size Distribution (PSD) requires a deep understanding of the influence of sampling, measurement and instrument parameters

Our approach

- We offer our wide expertise in the development and optimization of particle analysis methods for:
  - 1. Method development from scratch.
  - 2. Adaptation of registered methods to new Laser Diffraction MS3000 equipment, when methods are coming from other instrument (brand or model).

- We perform the adjustment of critical parameters to obtain real/primary PSD measurements, supported by results and images obtained by Automated Optical Microscopy with coupled image analysis.

- We can carry out validation and transfer of PSD methods where the repeatability, intermediate precision, robustness, and accuracy of the methodology are fully evaluated.


YOUR PA
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ANALYSIS

Analytical investigation on out of specification samples

Searching the root-cause in an OOS investigation is a crucial point in order to fully resolve the deviation and take appropriate decisions.

Our approach

- We design and execute OOS investigations in order to assess the compliance of product quality attributes and specifications.
- We offer analytical support to give a reliable physicochemical characterisation of specific OOS samples and products, for example in relation to Particle Size Distribution (PSD) parameters.
- Investigations include evaluation of method suitability, comparative testing, accuracy measurements and revaluation of critical parameters concerning both sample preparation and measurement.

Analytical investigation to support IP and regulatory procedures

Regulatory agencies and Patent offices demand specific tests and studies concerning the characterization of drug substances and drug products following appropriate guidelines and state of the art technologies.

Our approach

- We offer consultancy services and expert advice for product document/dossier preparation and Intelectual Property issues.
- We can provide scientific advice and experimental studies to support discussions with Regulatory agencies, such as ECHA, EMA, FDA or EFSA, for example when quantifying particulate matter, nanoparticles and nanoforms contained in products under development or already on the market.

Analytical support into API suppliers qualification process

Particle size and shape characterization of APIs and powdered raw materials can be critical to evaluate an ingredient from a supplier, an must be supported on reliable methods and techniques

Our approach

- We put our knowledge at the service of the supplier qualification process in order to select the correct source of raw materials (API or excipient) and enable successful formulation and FDF manufacturing

- Appropriate characterisation of critical quality attributes and specifications is performed in our lab by comparison of samples coming from different suppliers or productive processes.

- Particle size and shape are relevant parameters to be characterised on the base of suitable techniques and methods. For that, we use the most relevant and complementary techniques, such as Laser Diffraction and Automated Optical Microscopy.

Characterization of test generic product vs RLD, and reverse engineering studies

A deep understanding of the physicochemical properties of Reference Listed Drug (RLD) product is crucial during the development of generic drugs

Our approach

- We offer similarity and sameness studies on drug products under development, by comparison to the RLD product properties
- We can characterize Particle/Globule Size Distribution in powders, tablets, gels and liquids for intravenous administration. Selective characterization of API contained in the final formulation can be achieved.
- The studies may include the use of advanced image analysis tools as well as statistical data analysis to identify or discard relevant differences

Image analysis studies from optical and electron microscopy

Appropriate combination of microscopy techniques, image processing software and the right expertise in image acquisition and processing, is required for advanced particle characterization challenges

Our approach

- Solid particles at the micron size range are fully characterized by Automated Optical Microscopy and an image analysis software to obtain statistical distributions of any morphological parameter: Circular equivalent and Feret diameter (Particle Size Distribution), circularity, aspect ratio, roughness, amongst others.

- Solid nanoparticles are analysed, after appropriate sample preparation, by Scanning Electron Microscopy (SEM), to obtain high-resolution images which can be further processed for quantitative analysis (*ImageJ*).

- Nanoparticles in colloidal formulations are visualized in their native state by Cryogenic transmission electron microscopy (cryo-TEM), and further analysed by image analysis software to lead to quantitative analysis of their morphological parameters.

OUR TEAM

WHY CHOOSE US

Nanomol Technologies provides **specialized physicochemical characterisation services** for the pharma and biotech industry. We are a team of experts in analysing **Critical Quality Attributes (CQA)** of particulate materials.

ABOUT US

We were born in 2010 with the purpose of **unlocking pharmaceutical R&D, by providing advanced solutions and technologies** for the development of next generation medicines.

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Particle Analysis Unit Manager

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