



Coriolis Pharma

Biopharmaceutical Research and Development Service

cGMP – analytical service for
sub-visible aggregates and particles



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cGMP – analytical service for sub-visible aggregates and particles

Key techniques offered under cGMP

- Micro-Flow Imaging (MFI)
- Light Obscuration
- Asymmetrical Flow Field Flow Fractionation (AF4)
- Hollow Fiber Flow Field Flow Fractionation (HF5)
- other techniques can be implemented upon request

Our service – all under cGMP

- method development and validation
- method transfer
- quality control analysis
- analysis of stability samples
- support of formulation and process development

Micro-Flow Imaging (MFI)

- quantification, characterization and visualization of particles $\geq 1 \mu\text{m}$
- particle images and shape analysis
- differentiation of particles from different source (protein, silicone oil droplets, filter shedding, etc.)
- high sensitivity for transparent (protein) particles
- regularly referenced by regulatory agencies as requested orthogonal method to light obscuration

Light Obscuration

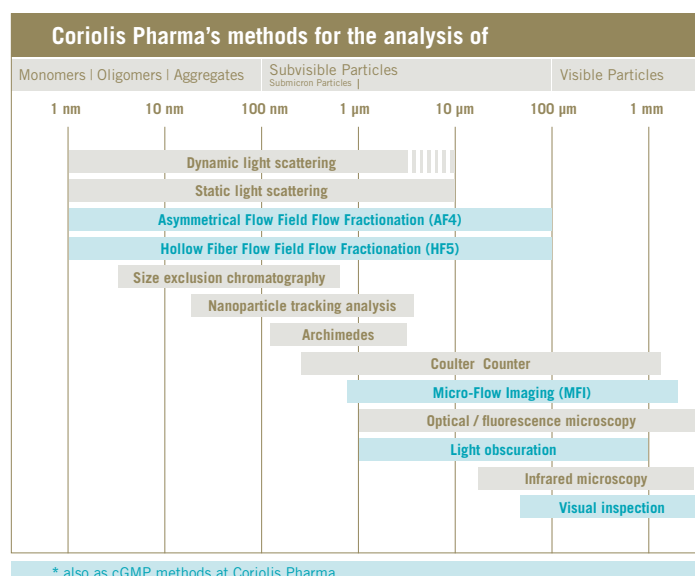
- quantification of particles $\geq 1 \mu\text{m}$
- pharmacopoeia method for determination of sub-visible particles $\geq 10 \mu\text{m}$ and $\geq 25 \mu\text{m}$ (USP, Ph. Eur.)
- low volume method established (max. 1.5 ml per sample)

Asymmetrical Flow Field Flow Fractionation (AF4) / Hollow Fiber Flow Field Flow Fractionation (HF5)

- quantification of monomer content, aggregation and fragmentation
- orthogonal method to HP-SEC
- higher separation range than HP-SEC
- high flexibility with respect to mobile phase
- combined with various detection systems (UV, RI, MALLS)

Orthogonal analysis of sub-visible aggregates and particles

Protein aggregates can be very heterogeneous in their size, ranging from few nanometers up to visible particles of $> 100 \mu\text{m}$. As obvious from the figure each size class requires dedicated analytical techniques for a proper characterization. At Coriolis Pharma we understand that an orthogonal approach for analyzing aggregates is crucial to assure the optimum stability of a formulation. We offer the best techniques for each size range, with selected methods (AF4, MFI, light obscuration and visual inspection) also under cGMP.



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