



Lab Service

Particle size analysis & Micronisation

- Micronisation
- Sieving
- Grinding/Milling
- & Particle size analysis



www.lab-service.fr



9 INDEPENDENT UNITS, specifically designed thanks to our experiences. In relation with the production rooms, each entity includes:

- Staff airlock
- Finished product airlock
- Own HVAC system
- A separated facility with 2 units dedicated to the β -lactamines
- Raw material airlock
- Laundry
- Own compressed air system

QUALITY ASSURANCE

- Ensures the respect of the current GMP Part II by achieving regular internal audits, habilitation and training of each employee, and the plan follow-up of continuous improvement
- Records and deals with internal deviations, OOS, customers complaints and remarks observed during the different audits (internal and from our customers) or inspections (ANSM, FDA, PMDA)
- Ensures the follow-up of the preventive and corrective actions defined in the CAPA plan and timeliness
- Updates about new standards regulations that have to be applied to the company
- Ensures the respect of the VMP
- Releases each batch produced on the site.

QC LABORATORY

- Performs granulometric analyses on raw materials, In Process Controls and finished products using diffraction laser instruments: Beckman Coulter LS 13320, Beckman Counter Coulter Multisizer III and Malvern Morpho 4, Mastersizer 2000 and 3000. All the instruments are annually qualified
- Performs Infrared-Red spectra on raw materials
- Performs granulometric analyses on different type of powder upon clients 'request with a short time-frame
- Performs validation of micronisation/grinding process and validation of PSD method
- Controls the production rooms 'cleaning visually and by air, microbiologic samplings...
- Performs cleaning validation on worst case products by HPLC or UV spectrophotometry.




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