

# Quality Control



**CEBIPHAR and ACM Pharma manage the Quality Control of raw materials\*, human and veterinary medicines, medical devices, food supplements, and cosmetic products.**

\* according to Ph. Eur., USP, JP... or specific monographs

## Physical and physico-chemical tests

- pH, osmolality, conductivity, polarimetry, density, melting point, Karl Fisher, coulometry,
- UV, IR, AAS, GC HS (FID & MS), HPLC (UV, DAD, RI, fluorimeter, MS), UHPLC, colorimeter, titrimeter, potentiometer, TLC, ICP-OES and ICP-MS (in partnership)
- Limit tests/assays :
  - assay of active ingredients, preservatives, impurities, degradation products
  - assay of mineral elements
  - identification and assay of residual solvents
  - identification of ions and functional groups
  - limit tests or assay of mineral impurities (in partnership)
  - limit tests : sulphuric ashes, heavy metals
  - fatty acids

## Pharmacotechnical tests

- Dissolution tests, rheology, viscosity, disintegration, friability, hardness, penetrometry, adhesiveness...
- Particulate contamination of injectables solutions (visible et non-visible)

## Microbiological tests

- Microbiological quality of sterile and non-sterile products
- Efficacy of antimicrobial preservation (challenge tests)
- Microbial identification
- Molecular sequencing
- Activity of biocides and preservatives
- Bacterial endotoxins
- Microbiological assays of antibiotics
- Equipments : Bact/Alert 3D®, VitekMS®Maldi TOF, MicroSeq®, Chemscan RDI®

## Our assets

### Our experience

More than 37 years servicing the pharmaceutical industry  
Working with major pharmaceutical companies worldwide

### Our expertise

Highly qualified analysts and microbiologists  
Technical & regulatory support  
Internal Pharmaceutical Expert

### Our equipments

State-of-the art qualified equipments  
Internal metrology IT systems validation department

### Our commitment to quality

GMP environment : certified sites by ANSM (& ANSES-Cebiphar), successfully inspected by FDA