TERANGA GROUPE

QUALITY CONTROL (1/2)

CEBIPHAR – ACM Pharma : Entrust us with confidence your quality controls

Our set of techniques encompasses:

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 solvants
  - 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 & 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

A comprehensive & long lasting experience

Galenic, analytical, microbiological and regulatory expertise

More than 38 years servicing the pharmaceutical industry

Our equipments

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

Our commitment to quality

GMP compliant pharmaceutical site (ANSM & ANSES), FDA inspected

COFRAC accreditation (ACM Pharma)

CEBIPHAR

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TERANGA GROUPE

QUALITY CONTROL (2/2)

Experts in analytical chemistry and microbiology, our teams will assist you and meet your needs:

Routine analysis
- raw materials - according to Ph. Eur., USP, JP... or specific monographs
- human and veterinary medicines, medical devices, food supplements, cosmetic products
- imported medicines (from a third country with whom EC/EEA did not sign an Agreement on Mutual Recognition)
- post MA stability studies

Specific analysis
- residual solvants
- mineral elements (AAS, ICP)
- specific equipment

One-time analysis
- duplicate controls/counter tests
- occasional lack of resources
- unavailability of an equipment
- cleaning validation
- manufacturing process validation

Problem solving
- investigation of abnormal results
- method improvement
- management of non conformity : root cause analysis and action plan

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