Quality Control of Raw Materials and Finished Products

Eurofins has a long experience in quality control for medicinal products and raw materials. The laboratories' deep knowledge of manufacturing and packaging processes enables them to offer a wide range of assays according to pharmacopoeias (EP, BP, USP, JP, etc.) and/or customer specifications. Specific expertise is available for sterile products, radiopharmaceuticals and biotech and cell derived products.

The company's microbiology, toxicology and chemistry laboratories have highly qualified personnel and the most advanced instruments and equipment. All tests are performed according to excellent quality system procedures in compliance with GMP requirements. Prior to use, all methods are validated or transferred.

The range of tests includes:

- Chemical controls (identity and purity) of API and raw materials
- Chemical assays of API, preservatives, excipients in drug products
- Related substances and degradation products determination
- Residual solvents determination
- Limit tests (heavy metals, ashes, …)
- Physical and physico-chemical tests
- Tablets and capsules tests (dissolution, friability, hardness, disaggregation tests, etc.)
- Microbiological control of non sterile products
- Sterility testing
- Microbial identification (bacteria, yeast and mould)
- Subvisible particle counting
- LAL test
- Pyrogen test
- Toxicity testing
- Mycoplasma determination
- Bioassays
- Microbiological assays for antibiotics and vitamins
- Primary packaging testing

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