



# Quality Control Analysis

- API, Excipients, Finished Pharmaceutical Products
- Small Molecules and Biologics
- GMP certification
- EMA and FDA inspected laboratory



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## QUALITY CONTROL

KYMOS and PHARMAPROGRESS provide a wide experience offering analytical testing services for raw materials, APIs, utilities, intermediates, finished products, containers, manufacturing equipment and environment using the best practices and according to customer specifications or the relevant Pharmacopoeia (EP, USP, BP, JP).

When required, including non-compendial methods, we perform the method development and validation or the method transfer from the originator laboratory. In compendial methods we execute a method verification.

For Quality Control purposes, we work under approved Quality Agreements and we issue Certificates of Analysis signed by our QP and GMP certified.

### PHYSICO-CHEMICAL TESTING

- General identification test (IR, TLC, HPLC)
- Assay (UV/Vis, AAS, titration, HPLC with multiple detectors, UPLC, GC, GC/MS, LC/MS) and dosage uniformity
- Related substances identification and quantification (GC, HPLC, GC/MS, LC/MS)
- Physical determinations (pH, viscosity, density, polarimetry, refraction index, melting point, osmolality)
- Moisture (Karl Fisher, loss on drying)
- Limit tests (heavy metals, ash, anions)
- Residual solvents (volatile organic compounds, organic volatile impurities)
- Elemental impurities (AAS, ICP/MS)
- Solid oral dosage tests (disintegration, dissolution, hardness, friability)
- Particulate matter (visible and subvisible particles)
- Process environment analysis (cross-contamination, rinse water from cleaning process, swabbing surfaces)
- Analysis of orally inhaled and nasal drug products (OINDP)
- Enzymatic and chromogenic tests (heparins and others)
- In vitro release testing for semi-solids (vertical diffusion cells)

### MICROBIOLOGICAL TESTING

- Microbial counting: TAMC, TYMC
- Determination of pathogens
- Sterility testing
- Endotoxines
- Water analysis

### WHY US?

- FDA inspected laboratory in Europe
- Dedicated team and instrumentation for Quality Control
- Reduced delivery times

*\* For Quality Control of Biologics see our Biopharmaceutical testing brochure.*

