



Quality control

Miltenyi Bioprocess offers the following QC tests for finished drugs, medical products and their raw materials, as well as packaging.

General analytical tests

- assays for identity, concentration and purity (e.g., HPLC, AAS, FTIR, DC).
- particle contaminations
- total organic carbon (TOC)
- heavy metals
- pH value
- specific density
- osmometry
- refraction index

Electrochemical tests

- polarography
- potentiometric titration (pH, ion-selective)
- conductivity

Microbiological testing according to Ph.Eur.

- bioburden
- identification of microorganisms
- testing for Mycoplasma (culturing method)
- sterility (membrane filtering and direct inoculation)
- test for bacterial endotoxins (chromogenic kinetic method and chromogenic end-point method)

Monitoring: process media, clean room monitoring, hygienic controls (for quality assurance, qualification/ validation)

- process-attendant monitoring (e.g., WFI systems)
- surface checks (stereotyping procedures/ swab probes)
- air-check in clean rooms (airborne microbial count, determination of airborne particles, climate measurements)
- laboratory staff hygiene (e.g., fingerprints)

Protein analytics (internal/external)

- protein concentration
- peptide mapping
- SDS-PAGE/ WB
- carbohydrate structure analysis
- isoelectric focusing
- SEC (oligomer, aggregates)
- N-, C-terminal sequencing
- ELISA
- host cell proteins
- DNA
- qPCR



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