

Proficiency Testing



Consumer Safety

ISO/IEC 17043

PHARMASSURE Pharmaceutical

The LGC PHARMASSURE proficiency testing scheme has been specifically designed to meet the needs of the pharmaceutical industry. The test materials are provided for chemical and microbiological analysis including sterility testing.

The regulations surrounding the manufacture of pharmaceutical products and laboratories testing them are wide ranging, and compliance with GMP/GLP requirements is aimed at ensuring the safety and efficacy of all pharmaceutical preparations.

Regular participation in a LGC Proficiency Testing scheme offers a truly independent assessment of measurement quality, which enables participants to compare their analytical capabilities with peers. Managers are able to monitor trends in their laboratory's performance over time and enhance the training of individuals as they participate in frequent assessment.

Successful participation in PHARMASSURE is recognised as a demonstration of laboratory quality and competency by a range of third parties, customers, regulators and accreditation bodies.



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Chemistry***Analyte***

Format depends upon test type (oil, powder, solution)	Acid/base titration, Density, Melting point, Other basic titration (actual analytes dependant on test), pH, Refractive index.
Format depends upon test type (powder, solution)	Advanced titration (potentiometric, non-aqueous), Flame spectroscopy, GC, IR/FTIR, LOD, Moisture by Karl Fischer, Polarimetry, TLC, UV, Viscosity, NMR spectroscopy and X-ray Powder Diffraction (XRPD).
Powder or solution	HPLC analysis.
Powder	Arsenic, Cadmium, Chromium, Copper, Lead, Mercury, Zinc.
Tablets	Dissolution, Physical measurements.
Solutions	Low level conductivity, Particulate determination.

Microbiology***Analyte***

Lyophilised material (low-level for direct culture or filtration)	Enumeration and/or identification of a single microorganism.
Lyophilised material (Mixed microorganisms)	Enumeration of bile-tolerant Gram-negative bacteria, Candida albicans, Escherichia coli, Mould, Staphylococcus aureus, Total aerobic microbial count, Total bacterial count, Total yeast and mould, Yeast. Detection of bile-tolerant Gram-negative bacteria, Candida albicans, Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus.
Lyophilised material (5 vials for sterility testing)	Sterility testing and identification of isolated microorganisms.

* The full range and availability of test materials and analytes is determined on an annual basis and may be added or removed. For accredited and non-accredited status please see current application form/scheme description.



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