



# PHARMASSURE – Pharmaceutical analysis proficiency scheme

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

Our PHARMASSURE scheme has been specifically designed to meet the needs of the pharmaceutical industry. The test materials cover

chemical and microbiological analysis and sterility testing.

Regular participation in a proficiency testing scheme offers a truly independent assessment of measurement quality, which enable laboratories to compare their analytical capabilities with their peers. Results obtained are recognised as a demonstration of laboratory quality and competency by a range of 'third parties', customers, regulators and accreditation bodies. 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.



## Scheme operation

Our PHARMASSURE scheme year operates from April to March and test materials are despatched four times per annum. Round despatch dates and reporting deadlines are available on our current PHARMASSURE application form, and further information can be found in our PHARMASSURE scheme description. These documents can be downloaded from our website [www.lgcstandards.com](http://www.lgcstandards.com)

Test material	Analytes
Varying forms in diverse formats.	Acid/base titration, Density, Melting point, Other basic titration (actual analytes dependant on test), pH, Refractive index.
Format will depend upon test type.	Advanced titration (potentiometric, non-aqueous), Flame spectroscopy, GC, IR/FTIR, LOD, Moisture by Karl Fischer, Polarimetry, TLC, UV, Viscosity (dynamic, kinetic).
Format varies from round to round.	HPLC analysis.
Powder material.	*Trace elements.
Tablet.	*Dissolution, *Physical measurements.
Solution.	*Low level conductivity, *Particulate determination.
Lyophilised test material of a single microorganism.	<b>Enumeration and/or Identification</b> Low level inoculum of a single microorganism.
Lyophilised test material of mixed microorganisms.	<b>Enumeration</b> Bile-tolerant Gram-negative bacteria, <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> , Total aerobic microbial count, Total bacterial count. <b>Detection</b> Bile-tolerant Gram-negative bacteria, <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> .
Lyophilised test material of mixed microorganisms.	<b>Enumeration</b> <i>Candida albicans</i> , Mould, Yeast, Total yeast and mould. <b>Detection</b> <i>Candida albicans</i> , <i>Pseudomonas aeruginosa</i> .
Lyophilised test material.	<b>Sterility testing and Identification</b> Five test materials which may or may not be sterile.

\*Not included in our scope of accreditation.

For further information contact LGC Standards:



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