# Scheme Description

## Pharmaceutical and Dietary Supplements (PHARMASSURE) Proficiency Testing Scheme

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## RECORD OF ISSUE STATUS AND MODIFICATIONS

| Issue | Issue Date | Details | Authorised by |
|---|---|---|---|
| 16 | Sep 2020 | Removed fax number and hard copy report info | A McCarthy |
| 17 | Jun 2021 | Updated units for sample 12, and DP for 14.<br>Sample 6L removed.<br>Updated email address and UKAS logo<br>Updated sample name for sample 14.<br>Addition of new samples (17-21)<br>Density added to sample 12 | R. Connolly<br>A Collins<br>S Xystouris |
| 18 | Sept 2022 | Added applicable Chinese Pharmacopoeia (ChP) methods<br>Added unit information for sample 20 and two extra analytes in sample 12, change in naming of sample 12 | R. Connolly<br>S. Xystouris |
| 19 | Dec 2022 | Updated USP method to the correct number for sample 8A | S. Xystouri |
| 20 | Sept 2023 | Removed sample 17<br>Added sample 6M<br>Removed some analytes from 2E<br>Specified matrices/testing requirements for 2A, 6F, 7A<br>Renamed sample 14 (removed specification for ginseng)<br>Enumeration and Detection tests separated in microbiology tables. AV, Reporting Units and DP updated.<br>'Range' column updated to include units<br>'Units' changed to 'Reporting Units' to match PORTAL | R. Connolly<br>S. Xystouris<br><br>T.Ashcroft |
| 21 | Oct 2023 | Changed units for Cr and Se in sample 21<br>Updated cfu/vial ranges for samples 4A and 4B | R. Connolly<br>T.Ashcroft |
| 22 | July 2024 | Changed the sample name and analytes for Sample 15<br>Added a new sample 22 for NDMA<br>Added a new sample 23 for e-liquid<br>Samples 13,18 & 19 removed<br>Units clarified for sample 20<br>Removed sample PT-PH-10<br>Added samples PT-PH-24 Total count, S.aureus and indicators in medicinal herbs, PT-PH-25 Pseudomonas, yeast and mould in medicinal herbs and PH-PH-26 Salmonella testing of medicinal herbs. | S. Xystouris<br>T.Ashcroft |
| 23 | Apr 2025 | Updated decimal places for 8B from 0 to 1. Unit updated for nicotine in sample 12 | R. Connolly<br>W. Gaunt |
| 24 | July 2025 | 1C: Titre changed to "for info only"<br>Updated SDPA for 8A, measurements in 7B<br>Added method for 6M<br>Added new analyte to sample 12<br>Supplied as updated for sample 12 | R. Connolly |

Notes: Where this document has been translated, the English version shall remain the definitive version

## SCHEME INFORMATION

### Scheme Aims and Organisation

The primary aim of the Pharmaceutical Proficiency Testing Scheme (PHARMASSURE) is to enable laboratories performing the analysis of pharmaceutical products to monitor their performance and compare it with that of their peers. PHARMASSURE also aims to provide information to participants on technical issues and methodologies relating to testing of pharmaceutical products.

The PHARMASSURE scheme year operates from January to December. Further information about this scheme, including test material availability, round despatch dates and reporting deadlines, are available on the current PHARMASSURE application form.

The PHARMASSURE scheme operates an advisory group made up of participants and industry experts. A list of advisory group members is available from LGC Standards on request. The advisory group meets twice a year and is concerned with all aspects of scheme development, operation and participant performance.

### Test Materials

Details of test materials available in the PHARMASSURE scheme are given in the 'samples Available' section. The test parameters are continually reviewed to ensure they meet the needs of current laboratory testing and regulatory requirements.

Test material batches are tested for homogeneity for at least one test parameter where deemed appropriate. Details of homogeneity tests performed and results are given in the PHARMASSURE Scheme Reports.

Some aspects of the scheme, such as test material production, homogeneity testing and stability assessment, can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and LGC is responsible for this work. The planning of the scheme, the evaluation of performance and the authorisation of the final report will never be subcontracted

### Statistical Analysis

Information on the statistics used in PHARMASSURE can be found in the General Protocol and in the Scheme Report. Methods for determining assigned values and the values for SDPA used for individual samples are given in the 'Samples Available' section.

### Methods

Methods are listed PORTAL. Please select the most appropriate method from the list. If none of the methods are appropriate, then please report your method as 'Other' and record a brief description in the Comments Section in PORTAL.

### Results and Reports

PHARMASSURE results are returned through our electronic reporting software, PORTAL, full instructions for which are provided by email.

PHARMASSURE reports will be available on the website within 10 working days of round closure. Participants will be emailed a link to the report when it is available.

## DESCRIPTION OF ABBREVIATIONS USED

### Assigned Value (AV)

The assigned value may be derived in the following ways:

- From the robust mean (median) of participant results (RMean). This is the median of participant results after the removal of test results that are inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors. Generally, the assigned value will be set using results from all methods, unless the measurement is considered method-dependant, in which case the assigned value will be set by method as illustrated in the report tables.
  For some analytes, where there is a recognised reference method for that type of measurement, this may be used as the assigned value for a particular analyte i.e. it would be applied to results obtained by any method.

*Traceability: Assigned values which are derived from the participant results, or a sub-set of the results are not traceable to an international measurement standard. The uncertainty of assigned values derived in this way is estimated from the participant results, according to ISO 13528.*

- From a formulation value (Formulation). This denotes the use of an assigned value derived from sample preparation details, where known and exact quantities of analyte have been used to prepare the sample.

*Traceability: Assigned values calculated from the formulation of the test sample are traceable, via an unbroken metrological traceability chain, to an international measurement standard. The measurement uncertainty of the assigned value is calculated using the contributions from each calibration in the traceability chain.*

- From a qualitative formulation (Qual Form). This applies to qualitative tests where the assigned value is simply based on the presence/absence of the analyte in the test material.

*Traceability: Assigned values calculated from the qualitative formulation of the test sample are traceable to a certified reference standard or a microbiological reference strain.*

- From expert labs (Expert). The assigned value for the analyte is provided by an 'expert' laboratory.

*Traceability: Assigned values provided by an 'expert' laboratory may be traceable to an international measurement standard, according to the laboratory and the method used. The uncertainty of measurement for an assigned value produced in this way will be provided by the laboratory undertaking the analysis. Details of traceability and the associated uncertainty will be provided in the report for the scheme/round.*

### Range

This indicates the concentration range at which the analyte may be present in the test material.

### SDPA

SDPA represents the 'standard deviation for proficiency assessment' which is used to assess participant performance for the measurement of each analyte. This may be a fixed value (as stated), a percentage (%) of the assigned value or based on the robust standard deviation of the participant measurement results, either across all methods or by method depending on whether the measurement made is method dependent (see assigned value).

### Units

This indicates the units used for the assessment of data and in which participants should report their results. For some analytes in some schemes participants may have a choice of which units to report their results, however, the units stipulated in this scheme description are the default units to which any results reported using allowable alternative results will be converted to.

### DP

This indicates the number of decimal places to which participants should report their measurement results.

## SAMPLES AVAILABLE

## CHEMISTRY

**Sample PT-PH-01** **Basic testing**

**Chemical Testing**

**Sample PT-PH-01A** **pH**
Supplied as: 1 x 60mL buffer solution

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| pH (20˚C) | Ph. Eur. 2.2.3<br>USP 791<br>ChP 0631 | RMean | 4-10 | 0.05 | - | 2 |

**Sample PT-PH-01B** **Acid/Base Titration**
Supplied as: 1 x 60mL acid solution

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Acid/base titration | Phenolphthalein endpoint<br>Potentiometric endpoint<br>ChP 0701 | Formulation | 15-25 | 0.15 | mL | 2 |

**Sample PT-PH-01C** **Other Basic Titration**
Supplied as: 1 x 60mL or 125mL solution (sample format dependant on test type)

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Titre | Various | This analyte is to be reported for information only | | | | |
| Sodium bicarbonate | Various | Formulation | All | 0.10 | %(w/v) | 2 |
| Magnesium | Mordant black endpoint<br>Other endpoint | Formulation | All | 1% of AV | mg/L | 0 |
| Dipotassium hydrogen phosphate | Ph. Eur. 2.2.20<br>USP 541 | RMean | All | 2% of AV | % | 2 |
| Sodium chloride | Ph. Eur. 2.2.20<br>USP 541<br>Mohr<br>Volhard | Formulation | All | 1% of AV | g/L | 2 |

Samples for this test will vary by round.

**Sample PT-PH-1D** **Density**
Supplied as: 1 x 60mL oil sample

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Density | Density meter<br>Pycnometer<br>ChP 0601 | RMean | All | 0.002 | $g/cm^3$ | 3 |

**Sample PT-PH-1E** **Refractive Index**
Supplied as: 1 x 60mL sugar solution

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Refractive Index | Ph. Eur. 2.2.6<br>USP 831<br>ChP 0622 | Formulation | All | 0.0010 | - | 4 |

**Sample PT-PH-1F** **Melting Point**
Supplied as: 1 x 2g sample

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Melting Point | Ph. Eur. 2.2.14<br>Ph. Eur. 2.2.60<br>USP 741<br>ChP 0612 | RMean | All | 1.0 | °C | 1 |

**Sample PT-PH-2A** **HPLC Analysis**
Supplied as: 1 x sample and reference standard for analysis by HPLC (Sample format will vary from round to round)

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| TBC*<br>One round as assay, one round as related substances test | Ph. Eur. 2.2.29<br>USP 621<br>ChP 0512 | RMean | All | 2.5% of AV | TBC* | 2 |

*Information regarding the format of the sample will be provided on the preparation instructions for each round. Samples will be formulated in such a way that the analysis will be applicable to the majority of laboratories performing HPLC analysis.

**Sample PT-PH-2B****
Supplied as:

**Trace elements**
1 x 5g sample for the determination of trace element impurities
1 x 1g of matrix

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Arsenic | ICP-MS<br>ICP-OES<br>AAS<br>ChP 0406<br>ChP 0411<br>ChP 0412 | RMean | 0.1-1.5 | Robust SD | µg/g | 2 |
| Cadmium | | RMean | 0.1-0.5 | Robust SD | µg/g | 2 |
| Lead | | RMean | 0.1-1.0 | Robust SD | µg/g | 2 |
| Mercury | | RMean | 0.1-1.5 | Robust SD | µg/g | 2 |
| Chromium | | RMean | 0.1 - 25 | Robust SD | µg/g | 2 |
| Copper | | RMean | 0.1 - 130 | Robust SD | µg/g | 2 |
| Zinc | | RMean | 0.1 - 1300 | Robust SD | µg/g | 2 |

**Sample PT-PH-2E*****
Supplied as:

**Residual solvents**
1 x 2g sample for the determination of residual solvents
1 x 1ml spiking solution

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Benzene | *Ph. Eur. 2.4.24*<br>*Ph. Eur. 2.2.28*<br>*USP 467*<br>*ChP 0861*<br>*GC-FID*<br>*GC-MS*<br>*GC-ECD*<br>*GC-PID*<br>*GC-TCD* | RMean | 0 - 2 | Robust SD | µg/g | 2 |
| Carbon tetrachloride | | RMean | 0 - 4 | Robust SD | µg/g | 2 |
| Chloroform | | RMean | 0 - 60 | Robust SD | µg/g | 1 |
| Hexane | | RMean | 0 - 290 | Robust SD | µg/g | 0 |
| Methanol | | RMean | 0 - 3000 | Robust SD | µg/g | 0 |
| Toluene | | RMean | 0 - 890 | Robust SD | µg/g | 0 |
| Acetone | | RMean | 0 - 5000 | Robust SD | µg/g | 0 |
| Ethanol | | RMean | 0 - 5000 | Robust SD | µg/g | 0 |

**Test material currently not included in LGC's UKAS Scope of Accreditation.

## Advanced Chemical Testing

### Sample PT-PH-6A — Gas Chromatography (GC)

Supplied as: Sample and reference standard (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| GC | Ph. Eur. 2.2.28<br>USP 621<br>ChP 0521 | Formulation or RMean | All | Robust SD | See instruction sheet | |

### Sample PT-PH-6B — UV

Supplied as: 1 x sample (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| UV | Ph. Eur. 2.2.25<br>ChP 0401 | RMean | All | Robust SD | See instruction sheet | |

### Sample PT-PH-6C — Viscosity

Supplied as: 1 x 250ml solution sample

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Dynamic viscosity (20˚C) | Ph. Eur. 2.2.9<br>Ph. Eur. 2.2.10<br>USP 911<br>USP 912<br>ChP 0633 | RMean | 10-300 | Robust SD | mPa·s | 0 |
| Kinematic viscosity - measured (20˚C) | Ph. Eur. 2.2.9<br>USP 911<br>ChP 0633 | RMean | 10-300 | Robust SD | mm2/s | 0 |
| Kinematic viscosity - calculated from dynamic viscosity (20˚C) | Ph. Eur. 2.2.9<br>Ph. Eur. 2.2.10<br>USP 911<br>USP 912<br>ChP 0633 | RMean | 10-300 | Robust SD | mm2/s | 0 |

### Sample PT-PH-6D — Loss on Drying (LOD)

Supplied as: 1 x sample (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Loss on drying (LOD) | Ph. Eur. 2.2.32<br>USP 731<br>ChP 0831 | RMean | All | 0.1 | %(w/w) | 2 |

**Sample PT-PH-6E** **FTIR**
Supplied as: Sample and reference standard (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| IR/FTIR | Ph. Eur. 2.2.24<br>USP 197<br>ChP 0402 | Qualitative Pharmaceutical Analysis | | | | |

**Sample PT-PH-6F** **Karl Fischer**
Supplied as: 1 x sample (Format depends upon type of test material); one round liquid, one round solid

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Moisture by Karl Fischer | Ph. Eur. 2.5.12<br>USP 921<br>ChP 0832 | RMean | All | Robust SD | %(w/w) | 2 |

**Sample PT-PH-6G** **TLC**
**Supplied as:** Sample, reference standard and TLC plates (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| TLC | Ph. Eur. 2.2.27<br>USP 621<br>ChP 0502 | Qualitative Pharmaceutical Analysis | | | | |

**Sample PT-PH-6H** **FLAA**
Supplied as: 1 x 60ml solution sample

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Flame spectroscopy | Ph. Eur. 2.2.22<br>Ph. Eur. 2.2.23<br>Ph. Eur. 2.2.57<br>USP 232<br>USP 233<br>ChP 0407 | Formulation | All | Robust SD | %(w/v) | 2 |

**Sample PT-PH-6I** **Polarimetry**
Supplied as: 1 x sample (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Polarimetry | Ph. Eur. 2.2.7<br>USP 781<br>ChP 0621 | RMean | All | Robust SD | ° | 2 |

**Sample PT-PH-6J** **Advanced Titration**
Supplied as: 1 x sample (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Advanced titration (potentiometric, non-aqueous) | Various | RMean | All | Robust SD | See instruction sheet | |

**Sample PT-PH-6K*** ** **Nuclear Magnetic Resonance (NMR) Spectrometry**
Supplied as: 1 x 1g sample

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Qualitative | Ph. Eur. 2.2.33 USP 761 ChP 0441 | Qualitative Pharmaceutical Analysis | | | | |
| Quantitative | | RMean | All | Robust SD | % | 2 |

**Sample PT-PH-6M*** ** **Residue on Ignition**
Supplied as: 1 x sample (Format depends upon type of test material)

| Technique | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Residue on Ignition | USP 281 Ph. Eur. 2.4.14 | RMean | All | Robust SD | See instruction sheet | |

**Sample PT-PH-7A** ** **Dissolution testing**
Supplied as: 1 x sample for dissolution testing and reference standard; one round analysis by HPLC, one round analysis by UV Spectrophotometry

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Dissolution | *Ph. Eur. 2.9.3 USP 711 ChP 0931* | RMean | All | Robust SD | % | 2 |

**Sample PT-PH-7B** ** **Tablet testing**
Supplied as: 1 x sample for tablet testing

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Diameter | Various | RMean | All | 0.05 | mm | 2 |
| Disintegration | Ph. Eur. 2.9.1 USP 701 ChP 0921 | Qual Form | All | N/A | N/A | N/A |
| Friability | Ph. Eur. 2.9.7 USP 1216 ChP 0923 | Qual Form | All | N/A | N/A | N/A |
| Resistance to crushing | Ph. Eur. 2.9.8 USP 1217 | RMean | All | 0.05 | N | 2 |
| Thickness | Various | RMean | All | 0.05 | mm | 2 |
| Uniformity of weight | Ph. Eur. 2.9.5 ChP 0101 | Qual Form | All | N/A | N/A | N/A |

**Test material currently not included in LGC's UKAS Scope of Accreditation.
***Analytes, assigned values, ranges and SDPAs are subject to alterations.

**Sample PT-PH-7C**** **Uniformity of dosage units**
Supplied as: 1 x 10 dosage units* and reference standard

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Uniformity of dosage units | *Ph. Eur. 2.9.40*<br>*USP 905*<br>*ChP 0941* | RMean | All | Robust SD | % | 2 |

*One of the following: tablets, capsules, powders or suspensions.

**Sample PT-PH-8A**** **Conductivity in solutions**
Supplied as: 1 x 125mL sample for conductivity in solutions

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Low level conductivity | *Ph. Eur. 2.2.38*<br>*USP 644*<br>*ChP 0681* | RMean | 1 - 50 | 5% | µS/cm | 2 |

**Sample PT-PH-8B**** **Particulate determination in solutions**
Supplied as: 1 x sample for particulate determination in solutions

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Particulate determination | Ph. Eur. 2.9.19<br>Ph. Eur. 2.9.20<br>USP 788<br>ChP 0903 | RMean | All | Robust SD | - | 1 |

**Sample PT-PH-11**** **Endotoxins in solutions**
Supplied as: 4mL of solution

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Endotoxins | Ph. Eur. 2.6.14<br>USP 85<br>ChP 1143 | RMean | >0.05 EU/ml | Robust SD | EU/ml | 3 |

**Sample PT-PH-12**** **E-liquid physical/chemical analysis**
Supplied as: 150mL of solution

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Nicotine | ISO 20714:2019 GC | RMean | All | Robust SD | mg/g | 2 |
| Propylene glycol | ISO 20714:2019 GC | RMean | All | Robust SD | % w/w | 1 |
| Glycerol | ISO 20714:2019 GC | RMean | All | Robust SD | % w/w | 1 |
| Density | Density Meter Pycnometer | RMean | All | Robust SD | $g/cm^3$ | 3 |
| Refractive index | Refractometer | RMean | All | Robust SD | - | 4 |
| pH | pH meter | RMean | All | Robust SD | - | 3 |
| Viscosity | Viscometer | RMean | All | Robust SD | cP | 3 |

**Test material currently not included in LGC's UKAS Scope of Accreditation.

**Sample PT-PH-14**** **Elemental contamination in supplements**
Supplied as: 10g of supplement

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Arsenic | ICP-MS<br>ICP-OES<br>AAS<br>ChP 2321 | RMean | All | Robust SD | µg/g | 3 |
| Cadmium | | RMean | All | Robust SD | µg/g | 3 |
| Lead | | RMean | All | Robust SD | µg/g | 3 |
| Mercury | | RMean | All | Robust SD | µg/g | 3 |

**Sample PT-PH-15**** **Adulterants in sexual enhancement supplements**
Supplied as: 2 x 5g of powdered supplement

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Qualitative | Various | Qualitative Pharmaceutical Analysis | | | | |
| Quantitative | | RMean | All | Robust SD | mg/g | 2 |

**Sample PT-PH-16**** **Cannabidiol in supplements**
Supplied as: 10ml of oil or 5g of powdered material

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Cannabidiol | Various | RMean | All | Robust SD | % w/v or % w/w | 2 |

**Sample PT-PH-20**** **Potency of multivitamin supplements**
Supplied as: 30g of multivitamin supplement (information on the material will be provided in the Instruction Sheet)

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Vitamin B1 *(Thiamine)* | LC-MS<br>LC MS/MS<br>HPLC<br>LC-ICP/MS | RMean | All | Robust SD | mg/g as thiamine mononitrate | 2 |
| Vitamin B2 *(Riboflavin)* | | RMean | All | Robust SD | mg/g | 2 |
| Vitamin B3 *(Niacin)* | | RMean | All | Robust SD | mg/g as niacin equivalents | 2 |
| Vitamin B5 *(Pantothenic acid)* | | RMean | All | Robust SD | mg/g as pantothenic acid | 2 |
| Vitamin B6 | | RMean | All | Robust SD | mg/g as pyridoxine HCl | 2 |
| Folic acid | | RMean | All | Robust SD | mg/g | 2 |
| Biotin | | RMean | All | Robust SD | mg/g | 2 |
| Vitamin B12 | | RMean | All | Robust SD | mg/g as cyanocobalamin | 2 |
| Vitamin C | HPLC Titration | RMean | All | Robust SD | mg/g as ascorbic acid | 2 |

The presence of the analytes is material dependent
**Test material currently not included in LGC's UKAS Scope of Accreditation.

**Sample PT-PH-21**** **Potency of multielement supplements**
Supplied as: 15g of multielement supplement

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| Calcium | ICP/MS<br>ICP-OES<br>AAS<br>XRF | RMean | All | Robust SD | mg/g | 2 |
| Zinc | | RMean | All | Robust SD | mg/g | 2 |
| Magnesium | | RMean | All | Robust SD | mg/g | 2 |
| Copper | | RMean | All | Robust SD | mg/g | 2 |
| Manganese | | RMean | All | Robust SD | mg/g | 2 |
| Potassium | | RMean | All | Robust SD | mg/g | 2 |
| Iron | | RMean | All | Robust SD | mg/g | 2 |
| Chromium (total) | | RMean | All | Robust SD | ug/g | 2 |
| Selenium | | RMean | All | Robust SD | ug/g | 2 |
| Compliance with labelling | | Qualitative Analysis | | | | |

The presence of the analytes is material dependent

**Sample PT-PH-22**** **Nitrosamines (NDMA) in pharmaceuticals**
Supplied as: 2g of powdered drug substances

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| N-nitrosodimethylamine (NDMA) | USP 1469 | RMean | 0.5-1 | Robust SD | mg/kg | 3 |
| N-nitrosodiethylamine (NDEA) | USP 1469 | RMean | 0.5-1 | Robust SD | mg/kg | 3 |

**Sample PT-PH-23**** **Additives in e-liquid**
Supplied as: 100mL of e-liquid

| Analyte | Method | AV | Range | SDPA | Units | DP |
|---|---|---|---|---|---|---|
| D-Glucose | R-Biopharm Sucrose/D-Glucose/D-Fructose, Spetrophotometer, HPLC | RMean | 10-50 | Robust SD | µg/ml | 2 |
| D-Fructose | R-Biopharm Sucrose/D-Glucose/D-Fructose, Spectrophotometer, HPLC | RMean | 10-50 | Robust SD | µg/ml | 2 |
| Caffeine | HPLC, Other (please specify) | RMean | 10-50 | Robust SD | µg/ml | 2 |
| Taurine | HPLC, Other (please specify) | RMean | 10-50 | Robust SD | µg/ml | 2 |
| Vitamin E acetate | HPLC, Other (please specify) | RMean | 5-200 | Robust SD | µg/ml | 2 |

**Test material currently not included in LGC's UKAS Scope of Accreditation.
Further details for Advanced Chemical Testing, for example analytes and reporting format, will be published on the preparation instructions supplied with the samples.

## MICROBIOLOGY

**Sample PT-PH-03** — **Low-level Enumeration and Identification (intended for membrane filtration)**

Supplied as: 1 x 10ml glass sealed vial containing a single culture of lyophilised microorganism. Final sample volume 1mL (for identification only) or 100mL (identification & enumeration).

| Analyte | Method | AV | Range cfu/vial | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Low-level enumeration | All | RMean | <500 | $\log_{10}$ 0.35 | cfu/100ml | 0 |
| Identification of microorganism | All | Qual Form | <500 | NA | NA | NA |

**Sample PT-PH-4A** — **Enumeration of TAMC and indicator organisms**

Supplied as: 1 x 10ml glass sealed vial containing a mixed culture of lyophilised microorganism(s). Final sample volume 100mL (neat).

| Analyte | Method | AV | Range cfu/vial | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Total aerobic microbial count | All | RMean | <500,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Total bacterial count | All | RMean | <500,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Detection of *Staphylococcus aureus* | All | Qual Form | <100,000 | NA | Detected/Not Detected 100ml | NA |
| Enumeration of *Staphylococcus aureus* | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Detection of *Escherichia coli* | All | Qual Form | <100,000 | NA | Detected/Not Detected 100ml | NA |
| Enumeration of *Escherichia coli* | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Detection of bile-tolerant gram-negative bacteria | All | Qual Form | <100,000 | NA | Detected/Not Detected 100ml | NA |
| Enumeration of bile-tolerant gram-negative bacteria | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |

**Sample PT-PH-4B** — **Enumeration of yeast, mould and *Pseudomonas***

Supplied as: 1 x 10ml glass sealed vial containing a mixed culture of lyophilised microorganism(s). Final sample volume 100mL (neat).

| Analyte | Method | AV | Range cfu/vial | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Detection of *Pseudomonas aeruginosa* | All | Qual Form | <100,000 | NA | Detected/Not Detected 100ml | NA |

| Analyte | Method | AV | Range cfu/vial | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Detection of *Burkholderia cepacia* | All | Qual Form | <100,000 | NA | Detected/Not Detected 100ml | NA |
| Detection of *Candida albicans* | All | Qual Form | <100,000 | NA | Detected/Not Detected 100ml | NA |
| Enumeration of *Candida albicans* | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Enumeration of yeast | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Enumeration of mould | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |
| Total yeast and mould | All | RMean | <100,000 | $\log_{10}$ 0.35 | cfu/ml | 0 |

**Sample PT-PH-05** **Sterility and identification**
Supplied as: 5 x 5ml glass sealed vials which may or may not contain microorganisms at low levels (final sample volume up to 100mL)

| Analyte | Method | AV | Range cfu/vial | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Sterility | All | Qual Form | <100 | NA | Sterility Pass/Sterility Fail | NA |
| Identification of microorganism | All | Qual Form | <100 | NA | NA | NA |

**Sample PT-PH-09** ***Salmonella* presence/absence**
Supplied as: 1 x 10ml glass sealed vial which may or may not contain the target organism. Final sample volume 10ml (neat).

| Analyte | Method | AV | Range cfu/vial | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Detection of *Salmonella* spp | All | Qual Form | <100 | NA | Detected/Not Detected 10ml | NA |

**Sample PT-PH-24‡** **Total aerobic count, S.aureus and indicators in medicinal herbs**
Supplied as: 1 x 10ml glass sealed vial & 10g medicinal herb matrix

| Analyte | Method | AV | Range cfu/g | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Total aerobic microbial count | All | RMean | <5,000 | $\log_{10}$ 0.35 | cfu/g | 0 |
| Detection of *Staphylococcus aureus* | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of *Staphylococcus aureus* | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |

‡Accredited within the boundaries of LGC's flexible scope of UKAS accreditation

| Analyte | Method | AV | Range cfu/g | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Detection of Bile tolerant gram-negative organisms | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of Bile tolerant gram-negative organisms | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |
| Detection of *Escherichia coli* | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of *Escherichia coli* | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |

‡Accredited within the boundaries of LGC's flexible scope of UKAS accreditation

**Sample PT-PH-25**** **Yeast, Mould and Pseudomonas in medicinal herbs**
Supplied as: 1 x 10ml glass sealed vial & 10g medicinal herb matrix

| Analyte | Method | AV | Range cfu/g | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Detection of *Pseudomonas aeruginosa* | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of *Pseudomonas aeruginosa* | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |
| Detection of *Candida albicans* | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of *Candida albicans* | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |
| Detection of yeast | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of yeast | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |
| Detection of mould | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of mould | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |
| Detection of yeast and mould | All | Qual Form | <1,000 | NA | Detected/Not Detected 10g | NA |
| Enumeration of yeast and mould | All | RMean | <1,000 | $\log_{10}$ 0.35 | cfu/g | 0 |

**Test material currently not included in LGC's UKAS Scope of Accreditation.

**Sample PT-PH-26‡** **Salmonella in medicinal herbs**
Supplied as: 1 x 10ml glass sealed vial & 25g medicinal herb matrix

| Analyte | Method | AV | Range cfu/g | SDPA | Reporting Units | DP |
|---|---|---|---|---|---|---|
| Detection of Salmonella species | All | Qual Form | <1,000 | NA | Detected/Not Detected 25g | NA |

‡Accredited within the boundaries of LGC's flexible scope of UKAS accreditation