PHARMASSURE

Pharmaceutical Proficiency Testing Scheme

Scheme Description

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Record of issue status and modifications

ISSUE	ISSUE DATE	DETAILS	AUTHORISED BY
7	Feb 2014	A new method added to sample 1F. Added new microbiological parameters: Candida albicans; identification of sterility. Statement on the traceability included in appendix A. Value of SDPA for sodium chloride in sample 1C updated. Inclusion of 2D Conductivity and Particulate determination in solutions trial sample. Micro method abbreviation codes added.	T. Noblett & M. Whetton
8	Dec 2014	Range for all parameters of sample 4 reduced. Inclusion of methods to samples 1C and 2. Additional information included for sample 2. Inclusion of subcontracting information in 'Test Materials' section.	T. Noblett & M. Whetton
9	Jan 2016	Inclusion of the USP methods for chemistry samples. Additional analytes for sample 2B. Inclusion of 2E Residual solvents. Additional analytes (microbiology). Samples re-numbered: 2 changed to 6A-6J; 2C changed to 7A and B; 2D changed to 8A and B; 4 changed to 4A and B. Removed Hard copy report information.	T. Noblett & M. Whetton A. McCarthy
10	May 2016	Kinematic viscosity split by calculated / measured. Additional analytes (Hexane and Acetone) added to sample 2E.	K. Baryla
11	Jan 2017	AAS method added to sample 2B. Analytes list updated for 2E Residual solvents. Inclusion of 6K NMR and 6L XPRD samples. Additional information added to sample 7B.	K. Baryla
12	Jun 2017	Methods added to sample 1D. Temperature added to 1A and 6C samples. Ranges included for 6C sample. Inclusion of sample 7C Uniformity of dosage units. Unit changed for sample 7A.	K. Baryla
13	Jul 2018	New Micro sample 9 added for Salmonella P/A New Micro sample 10 added for microbiological quality of medicinal herbs	R.Smith
14	Dec 2018	Amended units for sample 10 to cfu/g. Updated methods section for Micro samples Website information added to page 3	A.S.Eden/R.Smith A McCarthy
15	Nov 2019	Detection of *Burkholderia cepacia* added to micro 4B sample Added six chemistry samples: Endotoxins in solution (11), e-liquid chemical analysis (12), ginseng supplement analysis (13), elements in supplements (14), sildenafil in supplements (15) and cannabidiol in supplements (16) Units amended for Sample 9 Detection of Salmonella	R.Smith R. Connolly S. Xystouris A.S.Eden
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. Sample 6L removed. Updated email address and UKAS logo Updated sample name for sample 14. Addition of new samples (17-21) Density added to sample 12	R. Connolly A Collins S Xystouris
18	Sept 2022	Added applicable Chinese Pharmacopoeia (ChP) methods Added unit information for sample 20 and two extra analytes in sample 12, change in naming of sample 12	R. Connolly S. Xystouris

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

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 PHARMASSURE, including test material availability, round despatch dates and reporting deadlines, are available on the current PHARMASSURE application form and on the website www.lgcstandards.com.

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 PHARMASSURE are given in Appendix A. 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 Appendix A

Methods
Methods are listed in 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.
The time and temperature of incubation does not need to be reported.

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.

APPENDIX A - 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 and indicated 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 (Form). 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. These are the units 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.

Chemistry samples
Chemical Testing

Sample PT-PH-01 **Basic Chemical Testing**

Sample 1A **pH**
Supplied as: 1 x 60mL buffer solution

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

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

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

Sample PT-PH-1C **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	Formulation RMean	All	0.15	mL	2
Sodium bicarbonate	Various	Formulation	All	0.10	%(w/v)	2
Magnesium	Mordant black endpoint Other endpoint	Formulation	All	1% of AV	mg/L	0
Dipotassium hydrogen phosphate	Ph. Eur. 2.2.20 USP 541	RMean	All	2% of AV	%	2
Sodium chloride	Ph. Eur. 2.2.20 USP 541 Mohr 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 Pycnometer 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 USP 831 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 Ph. Eur. 2.2.60 USP 741 ChP 0612	RMean	All	1.0	^oC	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*	Ph. Eur. 2.2.29 USP 621 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** **Trace elements**
Supplied as: 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 ICP-OES AAS ChP 0406 ChP 0411 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*** **Residual solvents**
Supplied as: 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 Ph. Eur. 2.2.28 USP 467 ChP 0861 GC-FID GC-MS GC-ECD GC-PID GC-TCD	RMean	0 - 2	Robust SD	µg/g	2
Carbon tetrachloride		RMean	0 - 4	Robust SD	µg/g	2
1,2-Dichloroethane		RMean	0 - 5	Robust SD	µg/g	2
1,1- Dichloroethene		RMean	0 - 8	Robust SD	µg/g	2
1,1,1-Trichloroethane		RMean	0 - 1500	Robust SD	µg/g	0
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

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 USP 621 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 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 Ph. Eur. 2.2.10 USP 911 USP 912 ChP 0633	RMean	10-300	Robust SD	mPa·s	0
Kinematic viscosity - measured (20˚C)	Ph. Eur. 2.2.9 USP 911 ChP 0633	RMean	10-300	Robust SD	mm2/s	0
Kinematic viscosity - calculated from dynamic viscosity (20˚C)	Ph. Eur. 2.2.9 Ph. Eur. 2.2.10 USP 911 USP 912 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 USP 731 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 USP 197 ChP 0402	Qualitative Pharmaceutical Analysis				

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

Technique	Method	AV	Range	SDPA	Units	DP
Moisture by Karl Fischer	Ph. Eur. 2.5.12 USP 921 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 USP 621 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 Ph. Eur. 2.2.23 Ph. Eur. 2.2.57 USP 232 USP 233 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 USP 781 ChP 0621	RMean	All	Robust SD	º	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-7A** **Dissolution testing**
Supplied as: 1 x sample for dissolution testing and reference standard

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

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

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	Robust SD	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	Robust SD	N	2
Thickness	Various	RMean	All	Robust SD	mm	2
Uniformity of weight	Ph. Eur. 2.9.5 ChP 0101	Qual Form	All	N/A	N/A	N/A

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 USP 905 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 USP 1644 ChP 0681	RMean	1 - 50	Robust SD	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 Ph. Eur. 2.9.20 USP 788 ChP 0903	RMean	All	Robust SD	-	0

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

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 USP 85 ChP 1143	RMean	>0.05 EU/ml	Robust SD	EU/ml	3

Sample PT-PH-12** **E-liquid physical/chemical analysis**
Supplied as: 100mL of solution

Analyte	Method	AV	Range	SDPA	Units	DP
Nicotine	ISO 20714:2019 GC	RMean	All	Robust SD	mg/ml	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

Sample PT-PH-13** **Potency of Ginseng**
Supplied as: 5g of ginseng supplement

Analyte	Method	AV	Range	SDPA	Units	DP
Ginsenoside-Rb1	Various	RMean	All	Robust SD	mg/g	2
Ginsenoside-Rb2	Various	RMean	All	Robust SD	mg/g	2
Total ginsenosides	Various	RMean	All	Robust SD	mg/g	2

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

Sample PT-PH-14** **Elemental contamination in Ginseng**
Supplied as: 10g of ginseng

Analyte	Method	AV	Range	SDPA	Units	DP
Arsenic	ICP-MS ICP-OES AAS 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** **Sildenafil in 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-17** **Elemental contamination in Pollen supplement**
Supplied as: 10g of pollen supplement

Analyte	Method	AV	Range	SDPA	Units	DP
Arsenic	ICP-MS ICP-OES AAS 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-18** **Potency of *Gingko biloba***
Supplied as: 5g of *Gingko biloba*

Analyte	Method	AV	Range	SDPA	Units	DP
Quercetin	LC-UV LC-MS	RMean	All	Robust SD	mg/g	3
Kaempferol		RMean	All	Robust SD	mg/g	3

Analyte	Method	AV	Range	SDPA	Units	DP
Total Aglycones	Spectrophotometry ChP 0512	RMean	All	Robust SD	mg/g	3
Total Terpene Lactones		RMean	All	Robust SD	mg/g	2
Ginkgolide B		RMean	All	Robust SD	mg/g	3

Sample PT-PH-19** **Phytochemical Identity Confirmation**
Supplied as: 1g of plant material or plant extract (exact details to be confirmed)

Analyte	Method	AV	Range	SDPA	Units	DP
Phytochemical identity confirmation	All	Qualitative	All	N/A	N/A	N/A

Participants will be required to confirm, whether or not the sample provided is the given substance

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	LC-MS LC MS/MS HPLC LC-ICP/MS	RMean	All	Robust SD	mg/g as thiamine mononitrate	2
Vitamin B2		RMean	All	Robust SD	mg/g	2
Vitamin B3		RMean	All	Robust SD	mg/g as niacin equivalents	2
Vitamin B5		RMean	All	Robust SD	mg/g as pantothenic acid	2
Vitamin B6		RMean	All	Robust SD	mg/g as pyridoxine	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	2
Vitamin C	HPLC Titration	RMean	All	Robust SD	mg/g	2

The presence of the analytes is material dependent

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

Analyte	Method	AV	Range	SDPA	Units	DP
Calcium	ICP/MS ICP-OES AAS 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	mg/g	2
Selenium		RMean	All	Robust SD	mg/g	2
Compliance with labelling		Qualitative Analysis				

The presence of the analytes is material dependent

**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.

Microbiological samples

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	SDPA	Units	DP
Identification of microorganism	All	Qual Form	<500	N/A	N/A	N/A
Low-level enumeration	All	RMean	<500	0.35	cfu/100ml	0

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	SDPA	Units	DP
Total aerobic microbial count	All	RMean	<5,000	0.35	cfu/ml	0
Total bacterial count	All	RMean	<5,000	0.35	cfu/ml	0
Detection and/or enumeration of *Staphylococcus aureus*	All	RMean	<1,000	0.35	cfu/ml	0
Detection and/or enumeration of *Escherichia coli*	All	RMean	<1,000	0.35	cfu/ml	0
Detection and/or enumeration of bile-tolerant gram-negative bacteria	All	RMean	<1,000	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	SDPA	Units	DP
Detection of *Pseudomonas aeruginosa*	All	Qual Form	<1000	N/A	cfu/ml	N/A
Detection of *Burkholderia cepacia*	All	Qual Form	<1000	N/A	cfu/ml	N/A
Detection and/or enumeration of *Candida albicans*	All	RMean	<1,000	0.35	cfu/ml	0
Total yeast and mould count and/or enumeration of yeast, enumeration of mould	All	RMean	<2,000	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	SDPA	Units	DP
Sterility	All	Qual Form	<100	N/A	cfu/vial	N/A
Identification of microorganism	All	Qual Form	<100	N/A	cfu/vial	N/A

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

Analyte	Method	AV	Range	SDPA	Units	DP
Detection of *Salmonella* spp	All	Qual Form	<100	N/A	cfu/ml	N/A

Sample PT-PH-10 **Microbiological testing of medicinal herbs**
Supplied as: 1 x 10ml glass sealed vial & 10g medicinal herb matrix

Analyte	Method	AV	Range	SDPA	Units	DP
Total aerobic microbial count	All	RMean	<5,000	0.35	cfu/g	0
Detection and/or enumeration of *Staphylococcus aureus*	All	RMean	<1,000	0.35	cfu/g	0
Detection and/or enumeration of coliforms	All	RMean	<1,000	0.35	cfu/g	0
Detection and/or enumeration of yeast and/or mould	All	RMean	<1,000	0.35	cfu/g	0