

Proficiency Testing Pharmaceutical (PHARMASSURE) 2023

APPLICATION FORM

Please complete all sections below and return to:
LGC Standards GmbH, Mercatorstr. 51, 46485 Wesel, Germany
Tel: +49 (0)281 9887 210, Fax: +49 (0)281 9887 699, E-Mail: axiopt.de@lgcgroup.com

YOUR ORDER

If you would like to renew your order as per your previous year's order, please tick this box:

RENEW ME AS LAST YEAR

☐

We will copy over the samples/rounds purchased by you in the previous year and send you an order confirmation for your review. If you would like to add any other samples to your order, please mark them accordingly on the subsequent pages.

If you would prefer to place a different/new order for this scheme year, please review the samples available on subsequent pages and indicate the number of samples required for each sample/round accordingly.

SCHEDULE OVERVIEW

Month	Round	Despatch Date	Reporting Deadline	Samples Available (PT-PH)
FEB	PH084	27 Feb	03 Apr	01, 2A, 2E, 4A, 4B, 05, 6J, 6K, 8B
JUN	PH085	26 Jun	31 Jul	01, 2B, 03, 05, 6A, 6B, 6C, 7A, 11, 12, 17, 19, 20
AUG	PH086	29 Aug	02 Oct	01, 2A, 2E, 4A, 4B, 05, 6D, 6E, 6F, 8A, 09, 10, 14, 16, 18, 21
NOV	PH087	27 Nov	08 Jan '24	01, 2B, 03, 05, 6G, 6H, 6I, 7B, 7C, 11, 13, 15

Please ensure that LGC receive your order as soon as possible in order to avoid stock shortages. Please note that orders received the week prior to the despatch date may be subject to a despatch delay.

The despatch date shown above is the date the sample will leave our site in the UK. Please note, this is not the date the samples will arrive at your laboratory. Delivery times vary based on country, if you require further information, please contact LGC.

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SAMPLE AVAILABILITY – Please see page 1 for specific despatch and reporting dates

Please indicate the number of samples required per round in the grid. If you require a sample in all available rounds, please complete the **ALL** column.

CHEMISTRY SAMPLES						Month and Rounds (PH)				
Sample	Pharmacopeia		Quantity	Supplied as	Target Analyte(s)	ALL	FEB 084	JUN 085	AUG 086	NOV 087
PT-PH-01	EUP	2.2.3 2.2.6 2.2.14 2.2.20 2.2.60	Varying volumes	6 samples 1A-1F	Acid/Base titration; Density; pH; Melting point; Refractive index Other titrations, for the determination of: Dipotassium hydrogen phosphate; Sodium bicarbonate; Magnesium; Sodium chloride					
		541 741 791 831								
	CHP	0601 0612 0622 0631 0701								
PT-PH-2A	EUP	2.2.29	Varying volumes**	1 sample and reference standard	HPLC Analysis					
	USP	621								
	CHP	0512								
PT-PH-2B*	EUP	-	5g sample; 1g matrix	Powder	Trace elements					
	USP	-								
	CHP	0411 0406 0412								
PT-PH-2E*	EUP	2.2.28 2.4.24	2g sample; 1ml spike	Powder and spiking solution	Residual solvents					
	USP	467								
	CHP	0861								
PT-PH-6A	EUP	2.2.28	Varying volumes**	Sample and reference standard **	Gas Chromatography (GC)					
	USP	621								
	CHP	0521								
PT-PH-6B	EUP	2.2.25	Varying volumes**	1 sample**	UV					
	USP	-								
	CHP	0401								

*Please note that these samples are not currently within the scope of LGC's UKAS accreditation; **Format depends upon type of test material.

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CHEMISTRY SAMPLES - continued						Month and Rounds (PH)				
Sample	Pharmacopeia		Quantity	Supplied as	Target Analyte(s)	ALL	FEB 084	JUN 085	AUG 086	NOV 087
PT-PH-6C	EUP	2.2.9 2.2.10	250mL	Liquid solution sample	Viscosity					
	USP	911 912								
	CHP	0633								
PT-PH-6D	EUP	2.2.32	Varying volumes**	1 sample**	Loss on Drying (LOD)					
	USP	731								
	CHP	0831								
PT-PH-6E	EUP	2.2.24	Varying volumes**	Sample and reference standard**	FTIR					
	USP	197								
	CHP	0402								
PT-PH-6F	EUP	2.5.12	Varying volumes**	1 sample**	Karl Fischer					
	USP	921								
	CHP	0832								
PT-PH-6G	EUP	2.2.27	Varying volumes**	Sample, reference standard and TLC plates**	TLC					
	USP	621								
	CHP	0502								
PT-PH-6H	EUP	2.2.22 2.2.23 2.2.57	60mL	Liquid solution sample	FLAA					
	USP	232 233								
	CHP	0407								
PT-PH-6I	EUP	2.2.7	Varying volumes**	1 sample**	Polarimetry					
	USP	781								
	CHP	0621								
PT-PH-6J	EUP	-	Varying volumes**	1 sample**	Advanced Titration					
	USP	-								
	CHP	0701 0702								
PT-PH-6K*	EUP	2.2.33	1g	1 sample**	Nuclear Magnetic Resonance (NMR) Spectrometry					
	USP	761								
	CHP	0441								
PT-PH-7A*	EUP	2.9.3	Varying volumes**	Sample and reference standard**	Dissolution testing					
	USP	711								
	CHP	0931								

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CHEMISTRY SAMPLES – continued						Month and Rounds (PH)				
Sample	Pharmacopeia		Quantity	Supplied as	Target Analyte(s)	ALL	FEB 084	JUN 085	AUG 086	NOV 087
PT-PH-7B*	EUP	2.9.1 2.9.5 2.9.7 2.9.8	-	1 sample	Tablet testing					
	USP	701 1216 1217								
	CHP	0101 0921 0923								
PT-PH-7C*	EUP	2.9.40	10	Dosage units and reference standard	Uniformity of dosage units					
	USP	905								
	CHP	0941								
PT-PH-8A*	EUP	2.2.338	125mL	1 sample	Low level conductivity (<50 µS/cm)					
	USP	1644								
	CHP	0681								
PT-PH-8B*	EUP	2.9.19 2.2.20	-	1 sample	Particulate determination					
	USP	788								
	CHP	0903								
PT-PH-11*	EUP	2.6.14	4mL	Solution	Endotoxins in solutions					
	USP	85								
	CHP	1143								

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CONSUMER SAFETY SAMPLES						Month and Rounds (PH)				
Sample	Pharmacopeia		Quantity	Supplied as	Target Analyte(s)	ALL	FEB 084	JUN 085	AUG 086	NOV 087
PT-PH-12	EUP	-	100mL	E-Liquid Solution	Nicotine; Propylene glycol; Glycerol; Density; NEW Refractive index; NEW pH					
	USP	-								
	CHP	-								

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DIETRY AND HERBAL SUPPLEMENTS					Month and Rounds (PH)				
Sample	Pharmacopeia	Quantity	Supplied as	Target Analyte(s)	ALL	FEB 084	JUN 085	AUG 086	NOV 087
PT-PH-13*	EUP	-	5g	Ginseng supplement	Ginsenoside-Rb1; Ginsenoside-Rb2; Total ginsenosides				
	USP	-							
	CHP	0512							
PT-PH-14*	EUP	-	10g	Ginseng supplement	Arsenic; Cadmium; Lead; Mercury				
	USP	-							
	CHP	2321							
PT-PH-15*	EUP	-	2 x 5g sample	Powdered supplement	Sildenafil				
	USP	-							
	CHP	-							
PT-PH-16*	EUP	-	10ml of oil or 5g of powdered material	Oil or Powdered material	Cannabidiol				
	USP	-							
	CHP	-							
PT-PH-17*	EUP	-	10g	Pollen supplement	Arsenic; Cadmium; Lead; Mercury				
	USP	-							
	CHP	2321							
PT-PH-18*	EUP	-	5g	Ginkgo biloba	Quercetin; Kaempferol; Total Aglycones; Total Terpene Lactones; Ginkgolide B				
	USP	-							
	CHP	0512							
PT-PH-19*	EUP	-	1g	Plant material or plant extract	Phytochemical identity confirmation				
	USP	-							
	CHP	-							
PT-PH-20*	EUP	-	30g	Multivitamin supplement	Vitamin B1; Vitamin B2; Vitamin B3; Vitamin B5; Vitamin B6; Folic acid; Biotin; Vitamin B12; Vitamin C				
	USP	-							
	CHP	-							
PT-PH-21*	EUP	-	15g	Multielement supplement	Calcium; Zinc; Magnesium; Copper; Manganese; Potassium; Iron; Total Chromium; Selenium; Compliance with labelling				
	USP	-							
	CHP	-							

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MICROBIOLOGY						Month and Rounds (PH)				
Sample	Pharmacopeia		Quantity	Supplied as	Target Analyte(s)	ALL	FEB 084	JUN 085	AUG 086	NOV 087
PT-PH-03	EUP	2.6.12	10ml (final test quantity 100ml)	Vial representing pharmaceutical product	Low-level enumeration; Identification of microorganism (Intended for membrane filtration)					
	USP	-								
	CHP	1105								
PT-PH-4A	EUP	2.6.12 2.6.13	10ml (final test quantity 100ml)	Vial representing pharmaceutical product	Total aerobic microbial count; Total bacterial count Detection and/or Enumeration of Staphylococcus aureus; Escherichia coli; Bile-tolerant gram-negative bacteria					
	USP	-								
	CHP	1105 1106								
PT-PH-4B	EUP	2.6.13	10ml (final test quantity 100ml)	Vial representing pharmaceutical product	Detection of Pseudomonas aeruginosa; Burkholderia cepacia Enumeration of Yeast; Mould; Total yeast and mould, Enumeration and/or detection of Candida albicans					
	USP	-								
	CHP	1105 1106								
PT-PH-05	EUP	2.6.1	5 x 5ml (final test quantity 5 x 100ml)	Vial representing pharmaceutical product	Sterility; Identification of microorganism					
	USP	-								
	CHP	1101								
PT-PH-09	EUP	2.6.13	10ml (final test quantity 100ml)	Vial representing pharmaceutical product	Detection of Salmonella species					
	USP	-								
	CHP	1106								
PT-PH-10	EUP	-	10ml vial + 10g medicinal herb matrix (final test quantity 10g)	Medicinal herb	Total aerobic microbial count Detection and/or Enumeration of Staphylococcus aureus; Coliforms; Yeast; Mould; Yeast and Mould					
	USP	-								
	CHP	1105 1106 1108								

EUP, USP and CHP methods are indicated for information only.

Other methods can be used by the participants

For details on the full technical specification of the scheme, please refer to the LGC AXIO PT [PHARMASSURE Scheme Description](#).

YOUR DETAILS

Please complete your details below:

Send Test Materials to:	Send Invoices to:
Contact name:	Contact name:
Department:	Department:
Company:	Company:
Address:	Address:
Town/City:	Town/City:
Post/Zip Code:	Post/Zip Code:
Country:	Country:
Tel:	Tel:
Fax:	Fax:
Email:	Email:
Customer Number (optional):	VAT no:

Send Report Notifications to:	
Contact Name:	*An email will be sent to this address to notify when the report is available to download from PORTAL, the online reporting system
Email*:	
Returning customer Lab ID (optional):	Purchase order no. (optional):

Existing customers

If you would like to change your marketing preferences, please visit our [preference centre](https://www.lgcgroup.com/preference-centre) or contact axiopt.de@lgcgroup.com

New customers

LGC would like to contact you by email, phone or post about its products, services and related areas or research. LGC does not sell contact details to external parties. You may unsubscribe at any time.

- ☐ Yes, I am happy to be contacted about LGC's products, services and research
- ☐ No, I do not require marketing information about LGC's products and services at this time

By signing this application form, you are agreeing to comply by LGC's Standard Terms and Conditions for the Supply of Laboratory Quality Products and Services and are agreeing that you have read and agree to the 'General Notes' at the end of this document.

Name

Date

VOLUME QUANTITY DISCOUNT

Please note that any additional/duplicate samples ordered will not contribute to the calculation of volume discount, but will be charged at a lower rate (see Repeat/Additional samples section).

Sample Reference	% Discount for taking all available rounds
05	10

REPEAT/ADDITIONAL SAMPLES PRICES

Repeat and duplicate samples will be charged at 50% of the main sample cost. Please contact LGC for a quotation.

CARRIAGE CHARGES

Participants will pay an additional fee to cover courier charges. Please contact LGC AXIO Proficiency Testing for up-to-date charges.

CHANGES AND OTHER SCHEMES/SAMPLES OF INTEREST

CHANGES

We have added a number of new analytes as follows:

- Refractive index and pH to sample PT-PH-12 (E-liquid physical/chemical analysis).

GENERAL NOTES

Please note: Due to the German Protection Against Infection Act (IfSG) from 2000, your order cannot be processed until we receive the completed customer declaration form concerning the confirmation of compliance with the applicable laws of your country.

Please note:

- All prices stated are exclusive of VAT and carriage charges.
- VAT (charged at the prevailing rate) is payable by all participants based in the European Union if a VAT Registration Number is not provided.
- Participants will pay an additional fee to cover courier charges. Please contact LGC AXIO Proficiency Testing for up-to-date charges (where not specified previously in the application form).
- All courier charges set by LGC AXIO Proficiency Testing do not include local import charges, taxes (etc.), which will be covered by the participant.
- Do not send remittance with this form, you will be invoiced subsequently after the despatch of each round.
- No refunds will be given for failure to take part in any round of the PT scheme.
- LGC AXIO Proficiency Testing reserves the right to not send samples or the report for previous samples to any participant that has not paid their subscriptions within the terms stated on the invoice.
- LGC AXIO Proficiency Testing cannot guarantee the number of participants that will return results for any particular parameter in each round.
- The prices stated are for reporting results and receiving reports electronically via PORTAL (internet reporting).
- Surplus PT samples (Quality Control Material) are available; please contact LGC AXIO Proficiency Testing for further information.
- By signing this application form, you are agreeing to comply by LGC's Standard Terms and Conditions for the Supply of Laboratory Quality Products and Services.

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FOR INTERNAL USE ONLY

Name	
Customer	
Site	
Currency	
Delivery address	
PO no	
Carriage	

Renew ALY	
Year for PY	
Dt	
Doc Text	
Quotation	
Other	
Additional	

Form
"Customer Declaration
(Infectious Materials)"

LGC Standards GmbH

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Germany

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1. Customers in Germany

Any work or contact with pathogenic micro-organisms, or with substances containing pathogenic microorganisms, is regulated by the German Protection Against Infection Act (Infektionsschutzgesetz - IfSG).

According to § 52 of this law, disease causing organisms, as well as substances containing disease causing organisms, may only be supplied to such persons who have a permit according to § 44 of the IfSG; who work under supervision of somebody in possession of a permit; or who do not require a permit according to § 45, sections 1, 2, 3 of the IfSG. This regulation does not apply to state owned medical or veterinary institutions.

Microbiological materials distributed by LGC Standards might contain microorganisms with a biosafety level (BSL) of 1 or 2. These materials contain microorganisms in natural concentrations only.

All customers who order products with the biosafety levels 1 or 2 are therefore formally requested to submit a copy of their permit to work with disease causing organisms according to § 44 of the IfSG, or send us a written statement confirming that they do not need a permit according to § 45 of the IfSG.

- ☐ Copy of the permit to work with disease causing organisms according to §44 of the IfSG enclosed.
- ☐ This permit not required according to § 45 of the IfSG.

Name in print:.....

Company:.....

Signature:.....

Date.....

2. Customers abroad

With this customer declaration, all customers confirm that in using the materials belonging to the biosafety levels 1 and/or 2, they are complying with applicable laws and regulations.

- ☐ Confirmation of compliance with the applicable laws of

Country:

Name in print:.....

Company:.....

Signature:.....

Date:.....

Note: The person signing the form should be identical to the person possessing the permit.

3. Further information

Please visit <http://www.bmg.bund.de> for further information.

<http://www.gesetze-im-internet.de/bundesrecht/ifsg/gesamt.pdf>