Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

2505

Accredited to ISO/IEC 17025:2017

Stockport NHS Foundation Trust trading as Quality Control North West - Stockport

Issue No: 027 **Issue date:** 29 September 2021

Stepping Hill Hospital
Poplar Grove
Stockport
SK2 7JE

Contact: Ms Diane Rigge
Tel: +44 (0)161 419 5011
Fax: +44 (0)161 419 5394
E-Mail: diane.rigge@stockport.nhs.uk
Website: www.qcnw-stockport.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Stepping Hill Hospital Poplar Grove Stockport SK2 7JE **Local contact** Ms Diane Rigge	**Testing:** Chemical and Physical Microbiological Bacterial endotoxin test Customer site work	S

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Pharmaceutical manufacturing premises and associated clean rooms and workplace environments	Sampling of air, surfaces and water at clients premises Testing air quality for physical and microbiological quality at clients premises	Site

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
DRUGS, MEDICINES AND PHARMACEUTICALS	<u>Chemical and Physical Tests</u> As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph	Specifications and methods detailed in the British Pharmacopoeia (BP), the European Pharmacopoeia (PhEur), and/or the US Pharmacopoeia (USP), supplemented by Documented In-House methods and procedures where appropriate, using the following techniques and/or equipment:	
	Identification Tests Assay of active and non-active ingredients: Related substances tests Qualitative reactions and tests	a) Infra-red spectroscopy with reference to LSP479	S
		b) Ultra-violet and visible spectroscopy with reference to LSP478	S
		c) Thin layer Chromatography	S
		d) HPLC with UV detection with reference to LSP204	S
		e) Gas chromatography with FID or TCD detection with reference to LSP359	S
		f) Gravimetric techniques	S
		g) Volumetric techniques: Non-aqueous titration Potentiometric titration Complexometric titration Acid base titration Iodometric titration	S
	Colorimetric tests	Visual comparative technique as documented in Pharmacopoeial Monographs	S

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
DRUGS, MEDICINES AND PHARMACEUTICALS (cont'd)	<u>Chemical and Physical Tests</u> (cont'd)		
	Limit tests Excluding BP tests for Aluminium, Fluoride, Heavy metals - tests E, F and G, lead in sugars and Nickel in polyols Excluding USP tests for Calcium and dioxane, Mercury methods II a and b, Dimethylaniline, 4-epi-anhydrotetracycline, Lead and Selenium Excluding PhEur tests for Ethylene oxide and Dioxin	Visual comparative technique as documented in Pharmacopoeial Monographs	S
	Clarity of solution	Visual comparative technique as documented in Pharmacopoeial Monographs	S
	Colour of solution	Visual comparative technique as documented in Pharmacopoeial Monographs	S
	Density: Relative Density, Apparent Density and Weight per ml	LSP342 using automated densitometers	S
	Dissolution of tablets and capsules	Paddle method	S
	Loss on drying		S
	Melting point	a) LSP 21 using automated melting point apparatus	S
		b) BP Method III	S
	Optical rotation		S
	Particulate contamination	LSP482 Sub visible particle counting by light obscuration method	S

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
DRUGS, MEDICINES AND PHARMACEUTICALS (cont'd)	Chemical and Physical Tests (cont'd)		
	pH	LSP480 using pH meter	S
	Refractive index		S
	Residue on ignition		S
	Sulphated ash		S
	Uniformity of weight		
	Viscosity	a) Pharmacopoeial Capilliary methods	S
		b) Pharmacopoeial Rotational Viscometry using Brookfield RVT instrument	S
	Water content (Moisture)	BP Methods 1A and 1B using Karl Fischer automated titration apparatusa) Pharmacopoeial Capilliary methods	S
MEDICAL MATERIALS Containers	Chemical and Physical Tests As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph	Specifications and methods detailed in the British Pharmacopoeia (BP), the European Pharmacopoeia (PhEur), and/or the US Pharmacopoeia (USP) supplemented by documented procedures where appropriate, using the following techniques and/or equipment:	
	Light transmission	BP and PhEur tests only	S
	Surface hydrolytic resistance of glass containers	LSP - AM 23	S

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
DRUGS, MEDICINES, PHARMACEUTICALS, MEDICAL DEVICES, PHARMACEUTICAL AND PURIFIED WATER	<u>Microbiological Tests</u> As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph	Documented in-house methods based on specifications and procedures detailed in the British Pharmacopoeia (BP), the European Pharmacopoeia (PhEur) and/or the US Pharmacopoeia (USP):	
	Bacterial Endotoxins (Limit Test)	LSP73 using gel clot technique	S
	Bacterial Endotoxins (quantitative)	LSP358, kinetic turbidimetric method (Pyros Kinetix)	S
	Total viable aerobic colony count at 20-25°C and at 30-35°C	LSP341 using spread plate, with enrichment step in TSB for low level recovery, or membrane filtration techniques as appropriate for product type, followed by LSP515 to characterise any isolates	S
ENVIRONMENTAL SAMPLES Samples for hygiene monitoring purposes from controlled environments for pharmaceutical manufacturing:			
Contact plates from surfaces Finger imprint plates (finger plates) Plates or strips from active air samples Settle plates	Isolation, Enumeration presumptive Identification (to group, family or genus)	LSP341 supported by sample processing procedures and LSP515 to characterise any isolates	S

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
ENVIRONMENTAL SAMPLES (cont'd) Samples to monitor hygienic handling practices in controlled environments for pharmaceutical manufacturing:	<u>Microbiological Tests</u> (cont'd)	Documented In-House Methods:	
Universal Operator Validation Kits; Radiopharmacy generator eluates and kits; Broths for operator/ process validation	Confirmation of sterility	LSP178 for sample processing, subculture by streaking and assessment of results followed by LSP515 to characterise any isolates	S
Waters	Assessment of microbial loading/total viable count	a) LSP341 incubation of 1ml spread plate sample processing and LSP515 to characterise any isolates	S
		b) LSP341 aerobic colony count at 20-25°C and 30-35°C using membrane filtration	S
Working disinfectant solutions	Assessment of microbial loading/total viable count	LSP341 aerobic colony count at 20-25°C and 30-35°C using membrane filtration and DE neutralising agar	S
Taps/Wall gates in clean rooms/controlled environments	Water for assessment of microbial contamination	LSP516 using aseptic collection and spread plating onto TSA	Site
Clean Rooms and associated controlled environments	Air for microbial contamination	LSP516 supported by LSP406 for using MAS 100 air samplers	Site
	Surfaces for microbial contamination	LSP516 using contact plates or swab technique	Site

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
ENVIRONMENTAL SAMPLES (cont'd)	<u>Physical Tests</u>	Documented In-House Methods:	
Clean Rooms and associated controlled environments Cytotoxic cabinets LAF cabinets Safety cabinets	Particle counting for classification and monitoring of clean rooms (limited to existing customers only)	LSP516 based on EN ISO 14644-1:1999 (withdrawn) and the Orange Guide (Rules and Guidance for Pharmaceuticals Manufacturing and Distribution 2014) using laser particle counters	Site
END			