Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

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Accredited to ISO/IEC 17025:2017

Swann-Morton Laboratory Services Limited

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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 Bradfield Works 710A Penistone Road Sheffield South Yorkshire S6 2DF **Local contact** Mr Darren Hall	**Testing:** Microbiological and physical Bacterial endotoxin test Client site work	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Medical Device and Pharmaceutical manufacturing and re-processing premises, associated clean rooms and workplace environments	Sampling of air and surfaces 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
MEDICAL DEVICES	Microbiological Tests	Documented In-house Methods	
	Bioburden (pre-sterilisation)	INS 8.4 based on the requirements of BS EN ISO 11737-1:2018 Amd 1:2021 using techniques as appropriate to the sample: INS 8.4.1 membrane filtration INS 8.4.2 pour plate INS 8.4.3 spread plate INS 8.4.4 impression plates INS 8.4.5 swabs INS 8.4.6 agar overlay	A
		Product validation recovery efficiency according to procedure INS 8.5	A
	Endotoxin detection	1) INS 8.7.12 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Endosafe-PTS/MCS cartridge system	A
		2) INS 8.7.12.1 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Biotek plate reader	A
		3) INS 8.7.12.2 using Biotek plate reader and Charles River Trillium recombinant cascade reagent (rCR)	A
		Product validation according to procedure INS 8.7.11/8.7.11.1 / 8.7.11.2	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
MEDICAL DEVICES (cont'd)	Microbiological Tests (cont'd)	Documented In-house Methods	
(not for routine product release or a test for sterility as defined by BS EN ISO 11737-2:2020)	Test of sterility	INS 8.9 based on the requirements of BS EN ISO 11737-2:2020 using direct immersion and membrane filtration techniques	A
	Test for sterility	INS 8.9 based on based on the requirements Appendix XVI of British Pharmacopoeia (current edition) Product inhibition validation according to procedure INS 8.9.1	A
WATER (process)	Endotoxin detection	1) INS 8.7.9 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Endosafe-PTS/MCS cartridge system	A
		2) INS 8.7.9.1 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Biotek plate reader	A
		3) INS 8.7.9.2 using Biotek plate reader and Charles River Trillium recombinant cascade reagent (rCR)	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
ENVIRONMENTAL SAMPLES	Microbiological Tests (cont'd)		
	Incubation and Enumeration of: Contact Plates Settle Plates Active Air Sampling Plates	INS 8.7.2 (settle plates), 8.7.3 (active air sampling), 8.7.4 (contact plates)	A
	Sampling for Contact Plates, Settle Plates, Active Air Sampling Plates	INS 8.7.2 (settle plates), 8.7.3 (active air sampling), 8.7.4 (contact plates) based on the requirements of BS EN 17141:2020	Site
	Physical Tests		
	Airborne Particle Concentration	INS 8.7.1 for the monitoring and classification of air cleanliness based on the requirements of BS EN ISO 14644-1:2015 and BS EN ISO 14644-2:2015	Site
END			