

Date

Reference

2024-12-29

2023/2580

Scope of accreditation

Testing according to SS-EN ISO/IEC 17025:2018

NBAB, Nordic BioAnalysis AB

Södertälje

Accreditation number

10483

A014500-001

Chemical analysis

<i>Technical area</i>	<i>Parameter</i>	<i>Method</i>	<i>Technique</i>	<i>Measure</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>
Drug analysis	Glycogen	Inhouse method; 10688	ELISA	0,4-2,0 µg/well	Medical devices	Yes	2
	Lactic acid	Inhouse method; 10689	HPLC	100-700 µg/ml	Medical devices	Yes	2
	pH	Ph. Eur. 11th Ed. 2.2.3	Electrode	3-10	Medical devices	Yes	2
	Water content	Ph. Eur. 11th Ed. 2.5.32	Karl Fischer	0,01-6%	Drugs	Yes	2
Water analysis	Conductivity	Ph Eur 11th, Monograph; 0008, 0169, 1927	Electrode	>0,05 µS/cm	Water	Yes	2
	Total organic carbon, TOC	Ph. Eur. 11th Ed. 2.2.44	Combustion	0,05-1 mg/l	Water	Yes	2

Microbiological analysis

<i>Technical area</i>	<i>Parameter</i>	<i>Method</i>	<i>Technique</i>	<i>Measure</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>
Drug analysis	Candida albicans	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	Yes	2
	Clostridium sporogenes	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	Yes	2

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Microbiological analysis

<i>Technical area</i>	<i>Parameter</i>	<i>Method</i>	<i>Technique</i>	<i>Measure</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	
Drug analysis	Escherichia coli	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	Yes	2	
	Pseudomonas aeruginosa	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	Yes	2	
	Salmonella	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	Yes	2	
	Staphylococcus aureus	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	Yes	2	
	Total viable aerobic count, quantitative, membrane filtration		Ph. Eur. 11th Ed. 2.6.12 Microbiological examination of non-sterile products			Medical devices	Yes	2
						Water	Yes	2
	Total viable aerobic count, quantitative, pour plate		Ph. Eur. 11th Ed. 2.6.12 Microbiological examination of non-sterile products			Medical devices	Yes	2
Total viable aerobic count, quantitative, surface spread		Ph. Eur. 11th Ed. 2.6.12 Microbiological examination of non-sterile products			Medical devices	Yes	2	

Changes in the scope of accreditation are in bold.