

Date

Reference

2021-08-09

2020/983

Scope of accreditation

Testing laboratory 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>Field</i>
Drug analysis	Glycogen	Inhouse method 10688, edition 2	ELISA	0,4-2,0 µg/well	Medical devices	No
	Lactic acid	Inhouse method 10689, edition 2	HPLC	100-700 µg/ml	Medical devices	No
	pH	Ph. Eur. 10th Ed. 2.2.3	Electrode	3-10	Medical devices	No
	Water content	Ph. Eur. 10th Ed. 2.5.32	Karl Fischer	0,01-6%	Drugs	No
Water analysis	Conductivity	Ph Eur 10, Monograph; 0008, 0169, 1927	Electrode	>0,05 µS/cm	Water	No
	Total organic carbon, TOC	Ph. Eur. 10th Ed. 2.2.44	Combustion	0,05-1 mg/l	Water	No

Microbiological analysis

<i>Technical area</i>	<i>Parameter</i>	<i>Method</i>	<i>Technique</i>	<i>Measure</i>	<i>Material</i>	<i>Field</i>
Drug analysis	Candida albicans	Ph. Eur. 10th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Clostridium sporogenes	Ph. Eur. 10th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Escherichia coli	Ph. Eur. 10th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No

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<i>Technical area</i>	<i>Parameter</i>	<i>Method</i>	<i>Technique</i>	<i>Measure</i>	<i>Material</i>	<i>Field</i>
Drug analysis	Pseudomonas aeruginosa	Ph. Eur. 10th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Salmonella	Ph. Eur. 10th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Staphylococcus aureus	Ph. Eur. 10th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Sterility, qualitative, Direct inoculation	Ph. Eur. 10th Ed. 2.6.1. Sterility			Medical devices	No
	Total viable aerobic count, quantitative, membrane filtration	Ph. Eur. 10th Ed. 2.6.12 Microbiological examination of non-sterile products			Medical devices	No
					Water	No
	Total viable aerobic count, quantitative, pour plate	Ph. Eur. 9th Ed. 2.6.12 Microbiological examination of non-sterile products			Medical devices	No
	Total viable aerobic count, quantitative, surface spread	Ph. Eur. 10th Ed. 2.6.12 Microbiological examination of non-sterile products			Medical devices	No