

Date

Reference

2023-12-15

2022/2453

## 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>Field</i>
Drug analysis	Glycogen	Inhouse method 10688, edition 4	ELISA	0,4-2,0 µg/well	Medical devices	No
	Lactic acid	Inhouse method 10689, edition 3	HPLC	100-700 µg/ml	Medical devices	No
	pH	Ph. Eur. 11th Ed. 2.2.3	Electrode	3-10	Medical devices	No
	Water content	Ph. Eur. 11th Ed. 2.5.32	Karl Fischer	0,01-6%	Drugs	No
Water analysis	Conductivity	Ph Eur 11th, Monograph; 0008, 0169, 1927	Electrode	>0,05 µS/cm	Water	No
	Total organic carbon, TOC	Ph. Eur. 11th 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. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Clostridium sporogenes	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No
	Escherichia coli	Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products			Medical devices	No

<i>Technical area</i>	<i>Parameter</i>	<i>Method</i>	<i>Technique</i>	<i>Measure</i>	<i>Material</i>	<i>Field</i>
Drug analysis	<b>Pseudomonas aeruginosa</b>	<b>Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products</b>			Medical devices	No
	<b>Salmonella</b>	<b>Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products</b>			Medical devices	No
	<b>Staphylococcus aureus</b>	<b>Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products</b>			Medical devices	No
	<b>Sterility, qualitative, Direct inoculation</b>	<b>Ph. Eur. 11th Ed. 2.6.13. Microbiological examination of non-sterile products</b>			Medical devices	No
	<b>Total viable aerobic count, quantitative, membrane filtration</b>	<b>Ph. Eur. 11th Ed. 2.6.12 Microbiological examination of non-sterile products</b>			Medical devices	No
					Water	No
	<b>Total viable aerobic count, quantitative, pour plate</b>	<b>Ph. Eur. 11th Ed. 2.6.12 Microbiological examination of non-sterile products</b>			Medical devices	No
	<b>Total viable aerobic count, quantitative, surface spread</b>	<b>Ph. Eur. 11th Ed. 2.6.12 Microbiological examination of non-sterile products</b>			Medical devices	No

Changes in the scope of accreditation are in bold.