



Organisme belge d'Accréditation
Belgische Accreditatieinstelling
Belgische Akkreditierungsstelle
Belgian Accreditation Body

EA MLA Signatory

Accreditation Certificate No. 363-TEST

In compliance with the provisions of the Royal Decree of 31 January 2006 setting up BELAC, the Accreditation Board hereby declares to have granted accreditation conform the requirements of the standard EN ISO/IEC 17025:2017 to:

NELSON LABS bv
Romeinse straat 12
3001 Leuven
Enterprise number: 0442.395.719

The body demonstrated the competence to perform the activities in the activity sites, as described in the scope of accreditation 363-TEST which is an integral part of the present certificate.

The current version of the scope of accreditation is available at www.belac.be.

This certificate remains valid as long as the body continues to meet the accreditation conditions.

The Chair of the Accreditation Board BELAC,

Maureen LOGGHE

Version : 8

Validity period : 2026-07-23 - 2027-04-06

Original version of this certificate is in Dutch.



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Bijlage bij accreditatiecertificaat
Annexe au certificat d'accréditation
Annex to the accreditation certificate
Beilage zur Akkreditierungszertifikat

363-TEST

EN ISO/IEC 17025:2017

Versie / Version / Version / Fassung	19
Geldigheidsperiode / Validité / Validity / Gültigkeitsdauer	2026-07-23 - 2027-04-06

Maureen Logghe

Voorzitster van het Accreditatiebureau
La Présidente du Bureau d'Accréditation
Chair of the Accreditation Board
Vorsitzende des Akkreditierungsbüro

De accreditatie werd uitgereikt aan / L'accréditation est délivrée à /
The accreditation is granted to / Die akkreditierung wurde erteilt für:

NELSON LABS bv
Romeinse straat 12
3001 Leuven

Ondernemingsnummer / Numéro d'entreprise / Enterprise number / Unternehmensnummer:
0442.395.719

Abbreviations:

FPP	Final Pharmaceutical Products
MD	Medical devices
GP	General Plastics used in MD or packaging FPP
WFI	Water for injection

Test code	Product/ Matrix	Measured property/ parameter (type of test)	Reference to test method	Test or measurement principle/measurement technique
I. Biology (Microbiology and Toxicology)				
NEL-SOP-0234	MD FPP GP	Bacterial endotoxins	USP<85> USP<161> Ph.Eur. 2.6.14	Bacterial endotoxins by LAL Chromogenic or Turbidimetric
NEL-SOP-0228	MD GP	Cytotoxicity (qualitative and quantitative determination)	ISO 10993-5 ISO 10993-12 USP<87>	Cytotoxicity Test by MEM Elution
NEL-SOP-0514	MD	Irritants	ISO 10993-12 ISO 10993-23 In Vitro Irritation	In Vitro Irritation through optical density measurement
NEL-SOP-0231	MD GP	Total viable count	ISO 11737-1	Total Bioburden Test Membrane filtration

NEL-SOP-0235	FPP	Total Aerobic count	USP <61> Ph.Eur. 2.6.12	Microbial enumeration / Microbial Limit test
NEL-SOP-0236	FPP	Screening for possible/presumptive presence of Specified Micro-organisms (Bile-tolerant Gram-negative bacteria, <i>Escherichia coli</i> , <i>Salmonella spec.</i> , <i>Pseudomonas paraeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Clostridium spec.</i> , <i>Candida albicans</i>)	USP <62> Ph.Eur. 2.6.13 (without confirmation)	Membrane filtration, selective plating
NEL-SOP-0229	MD	Sterility (qualitative)	ISO 11737-2	Sterility Testing by: Direct contact Membrane filtration
NEL-SOP-0229	FPP	Sterility (qualitative)	USP <71> Ph.Eur. 2.6.1	Sterility Testing by: Direct contact Membrane filtration
NEL-SOP-0472 (soiling, cleaning and extraction) NEL-SOP-0336	MD	Hemoglobin	AAMI TIR 12, AAMI ST 98 ISO 17664-1 ISO 17664-2 ISO 15883-5 ASTM F3208 UV/VIS	Absorbance by UV/VIS

NEL-SOP-0472 (soiling, cleaning and extraction) NEL-SOP-0471 (BCA Assay)	MD	Protein	AAMI TIR 12, AAMI ST 98 ISO 17664-1 ISO 17664-2 ISO 15883-5 ASTM F3208	Absorbance by UV/VIS
NEL-SOP-0476 (Steam sterilization validation)	MD	Sterility	ISO 11737-1 ISO 11737-2 ISO 11138-7 AAMI ST79 AAMI ST77	Sterility Assurance Dry time validation temperature profiling
NEL-SOP-0477 (Disinfection validation)	MD	Total viable count A_0 Value	ISO 17664-1 ISO 17664-2 ISO 15883-1 ISO 15883-2 ISO 15883-5 AAMI TIR 12 AAMI ST 98	Total bioburden Test Membrane filtration A_0 method

II. Chemistry				
NEL-SOP-0244 NEL-SOP-0269	Acidified WFI extracts of GP Microwave-assisted digestion of GP FFP MD	Quantification of Metals: Ag, Al, B, Ba, Bi, Ca, Cd, Co, Cr, Cu, Fe, Hg, In, K, Li, Mg, Mn, Na, Ni, Pb, Sr, S, Si, Sn, Ti, Tl, V, W, Zn, Ga, Hf, Pd, Zr, As, Be, Ge, Mo, Sb, Se, Pt, Au, Ir, Os, Rh, Ru, La	ISO 10993-18 (MD) USP <730> Ph.Eur. 2.2.57 Ph.Eur. 2.2.58	Inductive Coupled Plasma (ICP)- Optical emission or mass spectrometry
NEL-SOP-0247	WFI extracts of GP FFP MD	Quantification of Anions: chloride (Cl-), fluoride (F-), nitrite (NO ₂ -), nitrate (NO ₃ -), phosphate (PO ₄ 3-), sulphate (SO ₄ 2-), bromide (Br-) Acetate (CH ₃ COO-) and Formate (HCOO-)	ISO 10993-18 (MD) USP <1065>	Ion Chromatography (IC) employing conductivity detection
NEL-SOP-0254 NEL-SOP-0451	Neat material GP Solvent extracts of GP FFP MD	Identification of Volatile Organic Compounds	ISO 10993-18 (MD) USP<621> Ph.Eur. 2.2.28	Headspace Gas Chromatography / Mass spectrometry (HS-GC/MS)
NEL-SOP-0245 NEL-SOP-0487 NEL-SOP-0251	Neat material GP Solvent extracts of GP FFP MD	Identification of Semi-Volatile Organic Compounds.	ISO 10993-12 (MD) ISO 10993-18 (MD) USP<621> Ph.Eur. 2.2.28	Gas Chromatography / Mass spectrometry (GC/MS)

NEL-SOP-0251 APCI ionization: NEL-SOP-0264 NEL-SOP-0634 NEL-SOP-0852 ESI ionization: NEL-SOP-0268 NEL-SOP-0633	Solvent extracts of GP FFP MD	Identification of Non-Volatile Organic Compounds	ISO 10993-12 (MD) ISO 10993-18 (MD) USP<621> Ph.Eur. 2.2.29	Liquid Chromatography/ Mass Spectrometry
SOP 3.2.44 NEL-SOP-0253	WFI extracts of GP FPP Aqueous samples	Quantification of total organic carbon (TOC)	USP <643> Ph.Eur. 2.2.44	Total Organic Carbon by conductometric detection
NEL-SOP-0262	MD	Subvisible particles	USP <787>, USP<788>, USP<789> Ph.Eur. 2.9.19	Light obscuration
NEL-SOP-0273	Solvent extracts of MD Aqueous extracts of MD	Exhaustive extraction determination by differential analysis of Non Volatile Residue (gravimetric)	ISO 10993-12 (MD) ISO 10993-18 (MD)	Gravimetric analysis

General code (unique identifier for the group of activities)	Product/ Matrix	Measured property/ parameter (type of test)	Test or measurement principle/measurement technique
FLEXIBLE SCOPE			
FLEX-1	Neat material GP (*) Solvent extracts of GP (*) FFP (*) MD (*)	Specific Quantitative Methods in function of the product for Volatile Organic (target) Compounds.(*)	Headspace Gas Chromatography/Mass spectrometry (HS-GC/MS)
FLEX-2	Neat material GP (*) Solvent extracts of GP (*) FPP (*) MD (*)	Specific Quantitative Methods in function of the product for Semi-Volatile Organic (target) Compounds. (*)	Gas Chromatography/Mass spectrometry (GC/MS and GC/MS/MS) Gas Chromatography/Flame Ionization Detection (GC/FID)
FLEX-3	Solvent extracts of GP (*) FFP (*) MD (*)	Specific Quantitative Methods in function of the product for (target) Non Volatile Organic Compounds (*).	Liquid Chromatography/ Ultraviolet (LC/UV) Liquid Chromatography/Diode-Array Detection (LC/DAD) Liquid Chromatography/Mass Spectrometry (LC/MS/MS)

FLEX-4	Solvent extracts of FFP (*)	Specific Quantitative Methods for the detection of Silicon oil through elemental analysis of atomized Silicon (Si) (*)	Graphite Furnace Atomic Absorption Spectrometry (GF- AAS)
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(*) The laboratory is authorised to determine under accreditation the properties/parameters belonging to the mentioned group of measured properties/parameters for the products/matrices belonging to the mentioned group of products/matrices and this according to methods that use the mentioned test or measurement principle or the mentioned measurement technique. This authorisation is given on condition that an appropriate validation and/or verification has been carried out in accordance with the global validation and/or verification concept, as laid down in the laboratory's management system and the provisions of BELAC 2-002 and BELAC 2-101.

The laboratory shall make available to each applicant, an up-to-date and detailed list of the specific tests (in terms of specific measured properties/parameters belonging to the mentioned group of measured properties/parameters, specific products/matrices belonging to the mentioned group of products/matrices and specific test methods) that are executed under accreditation