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 nv
Romeinse straat 12
3001 Leuven

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 : **6**

Validity period : **2022-04-07 - 2027-04-06**

Original version of this certificate is in Dutch.

.be

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BELAC 6-319 R0-2020

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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	15
Geldigheidsperiode / Validité / Validity / Gültigkeitsdauer	2023-01-23 - 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 nv
Romeinse straat 12
3001 Leuven

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Abreviations:

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

Internal code	Test sample/ Product/ Matrix	Property determined/ Parameter determined/ Type of test	Standard specifications + Equipment or Techniques used
I. Biology (Microbiology and Toxicology)			
SOP 3.1.2.24 / SOP0234	MD FPP GP	Bacterial endotoxins	USP<85> USP<161> E.P. 2.6.14 Bacterial endotoxins by LAL Chromogenic
SOP 3.1.2.3 / SOP0228	MD GP	Cytotoxicity (qualitative and quantitative determination)	ISO 10993-5 ISO 10993-12 USP<87> Cytotoxicity Test by MEM Elution
SOP0514	MD	Irritants	ISO 10993-12 ISO 10993-23 In Vitro Irritation
SOP 3.1.2.8 / SOP0231	MD GP	Total viable count	ISO 11737-1 Total Bioburden Test Membrane filtration
SOP 3.1.2.25 / SOP0235	FPP	Total Aerobic count	USP <61> E.P. 2.6.12 Microbial enumeriation/Microbial Limit test
SOP 3.1.2.26 / SOP0236	FPP	Detection of Specified Micro-organisms	USP <62> E.P. 2.6.13 Membrane filtration, selective plating and identification
SOP 3.1.2.5 / SOP0229	MD	Sterility (qualitative)	ISO 11737-2 Sterility Testing by: Direct contact Membrane filtration
SOP 3.1.2.5 / SOP0229	FPP	Sterility (qualitative)	USP <71> E.P. 2.6.1 Sterility Testing by: Direct contact Membrane filtration

SOP0472 (soiling, cleaning and extraction) SOP0336	MD	Hemoglobin	AAMI TIR 12, 30 (AAMI ST 98) ISO17664 ISO15883-5 ASTF3208-17 UV/VIS
SOP0472 (soiling, cleaning and extraction) SOP0242	MD	Carbohydrate	AAMI TIR 12, 30 (AAMI ST 98) ISO17664 ISO 15883-5 ASTF3208-17 UV/VIS
SOP0472 (soiling, cleaning and extraction) SOP0471 (BCA Assay)	MD	Protein	AAMI TIR 12, 30 (AAMI ST 98) ISO17664 ISO 15883-5 ASTF3208-17 UV/VIS
SOP0476 (Steam sterilization validation)	MD	Sterility	ISO 11737-1 ISO 11737-2 ISO 11138-7 AAMI ST79 AAMI ST77 Steam sterilization
SOP0477 (Disinfection validation)	MD	Total viable count A_0 Value	ISO 17664 ISO 15883-1 ISO 15883-2 ISO 15883-5 ASTM E1837 AAMI TIR 12, 30 (AAMI ST 98) Total bioburden Test Membrane filtration A_0 method

II. Chemistry			
SOP 3.2.7 / SOP0244 SOP 3.2.83 / SOP0269	Acidified WFI extracts of GP Microwave-assisted digestion of GP FPP 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 and Zn	ISO 10993-18 (MD) USP <730> EP 2.2.57 EP 2.2.58 Inductive Coupled Plasma (ICP)- Optical emission or mass spectrometry
SOP 3.2.11 / SOP0247	WFI extracts of GP FPP MD	Quantification of Anions: chloride (Cl-), fluoride (F-), nitrite (NO2-), nitrate (NO3-), phosphate (PO43-), sulphate (SO42-), bromide (Br-) Acetate (CH3COO-) and Formate (HCOO-)	ISO 10993-18 (MD) USP <1065> Ion Chromatography (IC) employing conductivity detection
SOP 3.2.47 / SOP0254 SOP 3.2.92 / SOP0451	Neat material GP Solvent extracts of GP FFP MD	Identification of Volatile Organic Compounds	ISO 10993-18 (MD) USP<621> EP 2.2.28 Headspace Gas Chromatography / Mass spectrometry (HS-GC/MS)
SOP 3.2.8 / SOP0245 SOP0487 SOP 3.2.39 / SOP0251	Neat material GP Solvent extracts of GP FPP MD	Identification of Semi-Volatile Organic Compounds.	ISO 10993-12 (MD) ISO 10993-18 (MD) USP<621> EP 2.2.28 Gas Chromatography / Mass spectrometry (GC/MS)
SOP 3.2.39 / SOP0251 SOP 3.2.53 / SOP0255 (APCI) SOP 3.2.76 / SOP0264 (APCI)	Solvent extracts of GP FFP MD	Identification of Non-Volatile Organic Compounds	ISO 10993-12 (MD) ISO 10993-18 (MD) USP<621> EP 2.2.29 Liquid Chromatography/ Mass Spectrometry UV
SOP 3.2.44 SOP0253	WFI extracts of GP FPP Aqueous samples	Quantification of total organic carbon (TOC)	USP <643> EP 2.2.44 Total Organic Carbon by conductometric detection
SOP0262	MD/ FPP	Subvisible particles	USP <787>, USP<788>, USP<789> EP 2.9.19 Light obscuration

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SOP 2.2.3.66 /SOP0313 (instrument)	Neat material GP (*) Solvent extracts of GP (*) FFP (*) MD (*)	Specific Quantitative Methods in function of the product for Volatile Organic (target) Compounds.(*)	ISO 10993-18 (MD) USP<621> EP 2.2.28 Headspace Gas Chromatography / Mass spectrometry (HS-GC/MS)
Instrument procedures: - SOP 2.2.3.70 / SOP0317 (GC/MS) - SOP 2.2.3.56 / SOP0308 (GC/MS QQQ) - SOP 2.2.3.45 / SOP0301 (GC/FID)	Neat material GP (*) Solvent extracts of GP (*) FPP (*) MD (*)	Specific Quantitative Methods in function of the product for Semi-Volatile Organic (target) Compounds. (*)	ISO 10993-12 (MD) ISO 10993-18 (MD) USP<621> EP 2.2.28 Gas Chromatography / Mass spectrometry (GC/MS)
Instrument procedures: - SOP 2.2.3.24 / SOP0290, SOP 2.2.3.35 / SOP0293, SOP 2.2.3.49 / SOP0304 (LC/UV) - SOP 2.2.3.30 / SOP0291 (LC/MS) - SOP 2.2.3.39 / SOP0296 (LC/MS QQQ)	Solvent extracts of GP (*) FFP (*) MD (*)	Specific Quantitative Methods in function of the product for (target) Non Volatile Organic Compounds (*).	ISO 10993-12 (MD) ISO 10993-18 (MD) USP<621> EP 2.2.29 Liquid Chromatography/ Mass Spectrometry UV

(*) In the framework of its accreditation, the laboratory is authorized to determine the properties belonging to the group (of properties) mentioned in the third column, for all matrices belonging to the group (of matrices) mentioned in the second column. This authorization is given, provided that an appropriate validation is performed according to the general validation concept as set out in the laboratory's management system. The laboratory keeps a detailed list of the characteristics and products, belonging to the above mentioned groups, up-to-date for anyone involved.