Nelson Labs
A Sotera Health company

Certifications:

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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

BELAC BELAC BELAC

BELAC 6-319 R0-2020

Organisme belge d'Accréditation
Belgische Accreditatieinstelling
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Belgian Accreditation Body

EA MLA Signatory

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	16
Geldigheidsperiode / Validité / Validity / Gültigkeitsdauer	2024-03-01 - 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

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> Ph.Eur. 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> Ph.Eur. 2.6.12 Microbial enumeriation/Microbial Limit test
SOP 3.1.2.26 / SOP0236	FPP	Detection of Specified Micro-organisms	USP <62> Ph.Eur. 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> Ph.Eur. 2.6.1 Sterility Testing by: Direct contact Membrane filtration
SOP0472 (soiling, cleaning and extraction) SOP0336	MD	Hemoglobin	AAMI TIR 12, AAMI ST 98 ISO 17664-1 ISO 17664-2 ISO 15883-5 ASTM F3208 UV/VIS

SOP0472 (soiling, cleaning and extraction) SOP0242	MD	Carbohydrate	AAMI TIR 12, AAMI ST 98 ISO 17664-1 ISO 17664-2 ISO 15883-5 ASTM F3208 UV/VIS
SOP0472 (soiling, cleaning and extraction) SOP0471 (BCA Assay)	MD	Protein	AAMI TIR 12, AAMI ST 98 ISO 17664-1 ISO 17664-2 ISO 15883-5 ASTM F3208 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 17664-1 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**			
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,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
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> Ph.Eur. 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> Ph.Eur. 2.2.28 Gas Chromatography / Mass spectrometry (GC/MS)

SOP 3.2.39 / SOP0251 SOP 3.2.76 / SOP0264 (APCI) SOP0268 (ESI) SOP0633 (ESI) SOP0634 (APCI)	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 SOP0253	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
SOP0262	MD/ FPP	Subvisible particles	USP <787>, USP<788>, USP<789> Ph.Eur. 2.9.19 Light obscuration
SOP0273	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)

Flex scope			
II. **Chemistry**			
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> Ph.Eur. 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> Ph.Eur. 2.2.28 Gas Chromatography / Mass spectrometry (GC/MS)
Instrument procedures: - SOP 2.2.3.35 / SOP0293, SOP 2.2.3.49 / SOP0304 (LC/UV) - 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> Ph.Eur. 2.2.29 Liquid Chromatography (LC/UV) or Liquid Chromatography/ Mass Spectrometry (LC/MS)
Instrument procedures: SOP0299	Solvent extracts of FFP (*)	Specific Quantitative Methods for the detection of Silicon oil through elemental analysis of atomized Silicon (Si) (*).	USP <852> Graphite Furnace Atomic Absorption Spectrometry (GF-AAS)

(*) 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.

Drug Establishments Current Registration Site

New Search

Search Results for **Nelson Labs**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Nelson Labs NV	3005742674	766951479	ANALYSIS;	Romeinsestraat 12, Leuven, B-3001, Belgium (BEL)	12/31/2024

Showing 1 to 1 of 1 entries

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Data Current through: Sunday, Dec 10, 2023

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2022/052***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***Nelson Labs***
Site address: ***Romeinse Straat 12, Leuven, 3001, Belgium***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012241*** / ***LOC-100020445***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1844 H*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-24***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2022-08-23

Name and signature of the authorised person of the Competent Authority of Belgium

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Confidential
Federal Agency for Medicines and Health Products
Tel:***Confidential***
Fax:***Confidential***

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2022/054***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 63 of Regulation (EU) 536/2014

The competent authority of Belgium confirms the following:
The manufacturer: ***Nelson Labs***
Site address: ***Romeinse Straat 12, Leuven, 3001, Belgium***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012241*** / ***LOC-100020445***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1844 IMP*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-24***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2022-08-23

Name and signature of the authorised person of the Competent Authority of Belgium

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Confidential
Federal Agency for Medicines and Health Products
Tel:***Confidential***
Fax:***Confidential***

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2022/053***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 94(1) of Regulation (EU) 2019/6 as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***Nelson Labs***
Site address: ***Romeinse Straat 12, Leuven, 3001, Belgium***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012241*** / ***LOC-100020445***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1844 V*** in accordance with Art. 88 of Regulation (EU) 2019/6.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-24***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
	2.1.4 Biological

2022-08-23

Name and signature of the authorised person of the Competent Authority of Belgium

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Confidential
Federal Agency for Medicines and Health Products
Tel: ***Confidential***
Fax: ***Confidential***

sciensano

GOOD LABORATORY PRACTICES

STATEMENT OF COMPLIANCE IN ACCORDANCE WITH DIRECTIVE 2004/9/EC

Date of inspection: 19/09/2023 **to:** 20/09/2023

According to the criteria specified in the article 5, § 8 of the Royal Decree of March 6, 2002 the General Director of the Sciensano, endorses on the advice of the GLP Monitorate, that the Test Facility,

Nelson LABS nv
Romeinsestraat 12
3001 Leuven
T02

has carried out GLP studies in the area(s) of expertise **In Vitro Toxicology, Microbiology & Healthcare Reprocessing** with respect to the OECD and the EU principles of Good Laboratory Practices between 16/03/2021 and 20/09/2023.

The Test Facility is regularly inspected within a cycle of 2 to 3 years.

Brussels, Thursday, 23 November 2023
Prof. C. Léonard
Managing director
Head BE GLP Monitoring Authority

Christian Léonard

Digitally signed by Christian Léonard
Date: 2023.11.27 20:27:48 +01'00'