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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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	17
Geldigheidsperiode / Validité / Validity / Gültigkeitsdauer	2025-06-17 - 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

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

BELAC BELAC BELAC

Test code (reference of the internal test procedure (if relevant) or other unique identifier for the activity)	Product/ Matrix	Measured property/ parameter (type of test)	Reference to test method (reference of the standardised method, reference of the kit, reference of the derived or in houde method)	*Column to be retained only if relevant :* Reference to product standard(s)
I. Biology (Microbiology and Toxicology)				
NEL-SOP-0234	MD FPP GP	Bacterial endotoxins	USP<85> USP<161> Ph.Eur. 2.6.14	N/A
NEL-SOP-0228	MD GP	Cytotoxicity (qualitative and quantitative determination)	ISO 10993-5 ISO 10993-12 USP<87>	N/A
NEL-SOP-0514	MD	Irritants	ISO 10993-12 ISO 10993-23 In Vitro Irritation	N/A
NEL-SOP-0231	MD GP	Total viable count	ISO 11737-1	N/A

Test code **(reference of the internal test procedure (if relevant) or other unique identifier for the activity)**	**Product/ Matrix**	**Measured property/ parameter (type of test)**	**Reference to test method** **(reference of the standardised method, reference of the kit, reference of the derived or in houde method)**	***Column to be retained only if relevant :*** **Reference to product standard(s)**
NEL-SOP-0235	FPP	Total Aerobic count	USP <61> Ph.Eur. 2.6.12	N/A
NEL-SOP-0236	FPP	Screening for possible/presumptive presence of Specified Micro-organisms (Bile-tolerant Gram-negative bacteria, *Escherichia coli*, *Salmonella spec.*, *Pseudomonas paraeruginosa*, *Staphylococcus aureus*, *Clostridium spec.*, *Candida albicans*)	USP <62> Ph.Eur. 2.6.13 (without confirmation)	N/A
NEL-SOP-0229	MD	Sterility (qualitative)	ISO 11737-2	N/A
NEL-SOP-0229	FPP	Sterility (qualitative)	USP <71> Ph.Eur. 2.6.1	N/A
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	N/A

Test code **(reference of the internal test procedure (if relevant) or other unique identifier for the activity)**	**Product/ Matrix**	**Measured property/ parameter (type of test)**	**Reference to test method** **(reference of the standardised method, reference of the kit, reference of the derived or in houde method)**	***Column to be retained only if relevant :*** **Reference to product standard(s)**
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	N/A
NEL-SOP-0476 (Steam sterilization validation)	MD	Sterility	ISO 11737-1 ISO 11737-2 ISO 11138-7 AAMI ST79 AAMI ST77	N/A
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	N/A

Test code **(reference of the internal test procedure (if relevant) or other unique identifier for the activity)**	**Product/ Matrix**	**Measured property/ parameter (type of test)**	**Reference to test method** **(reference of the standardised method, reference of the kit, reference of the derived or in houde method)**	***Column to be retained only if relevant :*** **Reference to product standard(s)**
II. Chemistry				
NEL-SOP-0244 NEL-SOP-0269	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	N/A
NEL-SOP-0247	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>	N/A
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	N/A

Test code **(reference of the internal test procedure (if relevant) or other unique identifier for the activity)**	**Product/ Matrix**	**Measured property/ parameter (type of test)**	**Reference to test method** **(reference of the standardised method, reference of the kit, reference of the derived or in houde method)**	***Column to be retained only if relevant :*** **Reference to product standard(s)**
NEL-SOP-0245 NEL-SOP-0487 NEL-SOP-0251	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	N/A
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	N/A
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	N/A

Test code **(reference of the internal test procedure (if relevant) or other unique identifier for the activity)**	**Product/ Matrix**	**Measured property/ parameter (type of test)**	**Reference to test method** **(reference of the standardised method, reference of the kit, reference of the derived or in houde method)**	***Column to be retained only if relevant :*** **Reference to product standard(s)**
NEL-SOP-0262	MD	Subvisible particles	USP <787>, USP<788>, USP<789> Ph.Eur. 2.9.19	N/A
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)	N/A

Abreviations:

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

General code (unique identifier for the group of activities)	Product/ Matrix	Measured property/ parameter (type of test)	*Column to be retained only if relevant :* Reference to product standard(s)
FLEXIBLE SCOPE			
II. Chemistry			
FLEX-1	Neat material GP (*) Solvent extracts of GP (*) FFP (*) MD (*)	Specific Quantitative Methods in function of the product for Volatile Organic (target) Compounds.(*)	N/A
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. (*)	N/A

FLEX-3	Solvent extracts of GP (*) FFP (*) MD (*)	Specific Quantitative Methods in function of the product for (target) Non Volatile Organic Compounds (*).	N/A
FLEX-4	Solvent extracts of FFP (*)	Specific Quantitative Methods for the detection of Silicon oil through elemental analysis of atomized Silicon (Si) (*).	N/A

(*) The laboratory is authorised to determine under accreditation the properties/parameters mentioned 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 measured properties/parameters, specific products/matrices belonging to the mentioned group of products/matrices and specific test methods) that are executed under accreditation

(*) The laboratoryis authorised to determine under accreditation the properties/parameters, belonging to the mentioned group of measured properties/parameters, for the products/matrices mentioned and this according to methods that use the mentioned test or measurement principle or the mentioned measuring 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 management system of the laboratory 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 products/matrices, specific measured properties/parameters belonging to the mentioned group of measured properties/parameters, and specific test methods) that are executed under accreditation.

(*) 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

Drug Establishments Current Registration Site

New Search

Search Results for *nelson labs*

Keyword Search | Reset | Showing 1 to 1 of 1 entries | Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Nelson Labs NV	3005742674	766951479	ANALYSIS	Romeinsestraat 12, Leuven, B-3001, Belgium (BEL)	12/31/2025

Federal Agency For Medicines And Health Products

CERTIFICATE NUMBER: ***BE/GMP/2024/058***

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, GPS: 50.844598, 4.737226***
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 ***2024-04-30***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

Part 2

Veterinary 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

2024-07-18

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/2024/057***

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, GPS: 50.844598, 4.737226***
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 ***2024-04-30***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[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

2024-07-18

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'