

# Certifications:

## *Table of Contents*

Document #	Title	Page(s)
1	<b>ISO 17025:</b> Certificate of Accreditation	2
2	<b>ISO 17025:</b> Scope of Accreditation	3-8
3	<b>FDA:</b> Drug Establishments Registration	9
4	<b>FAMHP (AFMPS/FAGG):</b> European Certificate of GMP Compliance	10-15
5	<b>GLP:</b> Statement of Compliance	16



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](http://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.*



Organisme belge d'Accréditation  
Belgische Accreditatieinstelling  
Belgische Akkreditierungsstelle  
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	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**

**Abbreviations:**

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 enumeration/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  FFP  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

Flex sope			
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 (*) FFP (*) 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.



# Drug Establishments Current Registration Site

[f Share](#)[t Tweet](#)[in LinkedIn](#)[✉ Email](#)[🖨 Print](#)

[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

Data Current through: Sunday, Dec 10, 2023

Previous

1

Next

## *Federal Agency for Medicines and Health Products*

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

# **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

<sup>1, 2</sup>

### **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 <sup>3</sup>

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.

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> 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

-----  
**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**<sup>1,2</sup>

### **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<sup>3</sup>

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.

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> 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

-----  
**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**

<sup>1, 2</sup>

### **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 <sup>3</sup>

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.

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> 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

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

# **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'