



Signatory to EA, ILAC and IAF
Multilateral Agreements

Organisme belge d'Accréditation
Belgische Accreditatie-instelling
Belgian Accreditation Body

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

363-TEST

EN ISO/IEC 17025:2005

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Nicole Meurée-Vanlaethem

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 N.V.
Romeinsestraat, 12
3001 LEUVEN**

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P.M.E., Classes moyennes et Energie
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Abbreviations:

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

Internal method	Matrix	Parameter/analyte	Reference / Analytical method
I. Biology (Microbiology and Toxicology)			
SOP 3.1.2.24	MD FPP GP	Bacterial endotoxins -	USP<85> USP<161> E.P. 2.6.14 Bacterial endotoxins by LAL Chromogenic
SOP 3.1.2.3	MD GP	Cytotoxicity (qualitative and quantitative determination)	ISO 10993-5 ISO 10993-12 USP<87> Cytotoxicity Test by MEM Elution
SOP 3.1.2.8	MD GP	Total viable count	ISO 11737-1 Total Bioburden Test Membrane filtration
SOP 3.1.2.25	FPP	Total Aerobic count	USP <61> E.P. 2.6.12 Microbial enumeration/Microbial Limit test
SOP 3.1.2.26	FPP	Detection of Specified Micro-organisms	USP <62> E.P. 2.6.13 Membrane filtration, selective plating and identification
SOP 3.1.2.5	MD	Sterility (qualitative)	ISO 11737-2 Sterility Testing by: Direct contact Membrane filtration
SOP 3.1.2.5	FPP	Sterility (qualitative)	USP <71> E.P. 2.6.1 Sterility Testing by: Direct contact Membrane filtration

Internal method	Matrix	Parameter/analyte	Reference / Analytical method
II. Chemistry			
SOP 3.2.7	Acidified WFI extracts of GP Microwave-assisted digestion of GP FPP	Quantification of Metals: Ag, Al, B, Ba, Bi, Ca, Cd, Co, Cr, Cu, Fe, In, K, Li, Mg, Mn, Na, Ni, Pb, Sr, S, Si, Sn, Ti, Tl, V, W and Zn	USP <730> EP 2.2.57 Inductive Coupled Plasma (ICP)- Optical emission spectrometer with axial viewed plasma
SOP 3.2.11	WFI extracts of GP FPP	Quantification of Anions: chloride (Cl-), fluoride (F-), nitrite (NO2-), nitrate (NO3-), phosphate (PO43-), sulphate (SO42-), bromide (Br-) Acetate (CH3COO-) and Formate (HCOO-)	USP <1065> Ion Chromatography (IC) employing conductivity detection
SOP 3.2.47	Neat material GP	Identification of Volatile Organic Compounds	USP<621> EP 2.2.28
SOP 2.2.3.66 (instrument)	Solvent extracts of GP FPP	Specific Quantitative Methods in function of the product for Volatile Organic (target) Compounds.	Headspace Gas Chromatography / Mass spectrometry (HS-GC/MS)
SOP 3.2.8 SOP 3.2.39	Neat material GP	Identification of Semi-Volatile Organic Compounds.	USP<621> EP 2.2.28
Instrument procedures: - SOP 2.2.3.70 (GC/MS) - SOP 2.2.3.56 (GC/MS QQQ)	Solvent extracts of GP FPP	Specific Quantitative Methods in function of the product for Semi-Volatile Organic (target) Compounds.	Gas Chromatography / Mass spectrometry (GC/MS)

Internal method	Matrix	Parameter/analyte	Reference / Analytical method
SOP 3.2.39 SOP 3.2.53 (APCI) SOP 3.2.76 (APCI)		Identification of Non-Volatile Organic Compounds	
Instrument procedures: - SOP 2.2.3.24, SOP 2.2.3.35, SOP 2.2.3.49 (LC/UV) - SOP 2.2.3.30 (LC/MS) - SOP 2.2.3.39 (LC/MS QQQ)	Solvent extracts of GP FFP	Specific Quantitative Methods in function of the product for (target) Non Volatile Organic Compounds.	USP<621> EP 2.2.29 Liquid Chromatography/ Mass Spectrometry UV
SOP 3.2.44	WFI extracts of GP FFP Aqueous samples	Quantification of total organic carbon (TOC)	USP <643> EP 2.2.44 Total Organic Carbon by conductometric detection



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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, that the test laboratory

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has the competence to perform the tests as described in the annex which is an integral part of the present certificate, in accordance with the requirements of the standard EN ISO/IEC 17025:2005. The present accreditation is the subject of regular surveillance in order to confirm the compliance with the accreditation conditions.

The Chair of the Accreditation Board BELAC,

A handwritten signature in black ink, appearing to read 'Nicole Meurée-Vanlaethem', is written over a faint dotted line.

Nicole MEURÉE-VANLAETHEM

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