



Spécialités Septodont
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Opening authorization M13/25
GMP Certificate HPF/FR/56/2013

Certificate of Analysis
SCANDONEST 30 MG/ML, SOLUTION FOR INJECTION

Batch:	B20420AAH	Importing country:	Lithuania
Manufacturing date:	06/29/2017	Marketing authorization:	LT/1/01/2595/001
Expiry date:	2020-06	Package size and type:	Boite de 50 - Box of 50

Tests	Acceptance criteria	Results
Appearance	Glass cartridge containing a colourless and clear liquid	Conform
Identification Mepivacaine HCL - HPLC	Complies with reference	Conform
pH	6,0-6,8	6.5
Particulate contamination - Sub-visible particles > or = 10 µm (per cartridge)	<6000	30
Particulate contamination - Sub-visible particles > or = 25 µm (per cartridge)	<600	1
Extractable volume - Average	1.70-1.95 mL	1.82
Mepivacaine HCl content	2.85-3.15 g/100mL	3.00
Bacterial endotoxines - in IU/mg og Mepivacaine HCl	≤0.8 IU/mg	<0.2
Sterility	Conform	Conform

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing and packaging records were reviewed and found to be in compliance with GMP.

Elodie Barroukel
QA Product Manager/Qualified person
09/29/2017