



Spécialités Septodont
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Opening authorization MM 15/17
GMP Certificate HPF/FR/265/2017

Certificate of Analysis

NEOCONES KÜGELIAI, SKIRTI NAUDOTI STOMATOLOGIJOJE - 50

Batch:	B21618AL	Importing country:	Lithuania
Manufacturing date:	10/11/2017	Marketing authorization:	LT/1/03/3481
Expiry date:	2019-04	Package size and type:	FLACON - BOTTLE

Tests	Acceptance criteria	Results
Appearance	Small cones	Conform
Colour	White	Conform
Odor	Odourless	Conform
Identification - Neomycin sulfate	Conforms to reference	Conform
Identification - Benzocain	Conforms to reference	Conform
Disintegration	≤15 min	9
Average mass	45-55 mg	50
Mass uniformity	Conform	Conform
Content of Benzocaine	4,75-5,25 mg/cône	5.07
Content of Neomycin sulfate	13860-16940 IU/1 cône	15530

Commentaire : -

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, packaging and analysis records were reviewed and found to be in compliance with GMP.

Sébastien Clavel
Deputy Qualified Person
03/02/2018

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