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Analytical report AR-18-RE-011391-02

Translation of report No.: AR-18-RE-011391-01



Sample code 122-2018-00010106

Type of sample	Pharmaceutical Nicotine; PureNic 99+
Sample sender	CHEMNOVATIC Sp. z o. o. Sp. k.
Prescriber	CHEMNOVATIC Sp. z o. o. Sp. k.
Purchase order date	26.02.2018
Reception date	26.02.2018
Transport by	Courier
Sample condition	unreservedly
Sample taken by	Customer
Type of sampling	lack of data
Purpose of the testing	indefinite
Best before date	25.09.2019
Partie-no.	NIC/X/20170926
Packaging	box UN
Production date	26.09.2017
Number of tested samples	1
Start analysis	05.03.2018
End Analysis	14.03.2018

Results

SK025	water KF (A)			
Method	ŠPP 031-F, Titrimetry			
Subcontracted to the accredited Eurofins laboratory Eurofins Bel/Novamann (Bratislava), accreditation nr. S-106				
	water by Karl-Fisher titration	0.036	%	± 2,5%
		Limit string value max 0,5%		
SK04Z	Specific optical rotation (#)			
Method	ŠPP 044-F (USP.), Polarimetry			
Subcontracted to the Eurofins laboratory Eurofins Bel/Novamann (Bratislava)				
	Specific optical rotation	-137.2	°	± 3,5%
		Limit string value -143° - -130°		
SK0D0	Heavy metals (A)			
Method	ŠPP 021-F (USP), Visual examination			
Subcontracted to the accredited Eurofins laboratory Eurofins Bel/Novamann (Bratislava), accreditation nr. S-106				
	Heavy metals	<20	ppm	
		Limit string value max 20 ppm		
SK0D2	Chromatographic purity of nicotine (A)			
Method	ŠPP 016-F (USP), GC-FID			

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Subcontracted to the accredited Eurofins laboratory Eurofins Bel/Novamann (Bratislava), accreditation nr. S-106			
Sum of impurities	<0.5	%	
	Limit string value max 1%		
Single unknown impurities	<0.25	%	
	Limit string value max 0,50 %		
SK0D1	Identification: Nicotine (A)		
Method	ŠPP 017-F (USP), Spectrophotometry (UV/VIS)		
Subcontracted to the accredited Eurofins laboratory Eurofins Bel/Novamann (Bratislava), accreditation nr. S-106			
Identification: Nicotine	conforms		
	Limit string value ¹		

= Not accredited

A = Method accredited

+/- Uncertainty of result presented as expanded uncertainty of measurement (95%; k=2). The uncertainty does not include the sampling. The result and its uncertainty refer to the analyzed sample.

Supplement:

¹ Sample spectrum is identical to spectrum of reference material.



Approved by: Anna Broda-Cnota
Analytical Service Manager

1. The results refer only to the tested samples.

2. The test results shall not be reproduced except in full without the written permission of Eurofins Polska Sp. z o.o.

3. Laboratory measurement uncertainty is given when it is relevant to the validity of the test result, or for compliance with specified limits and the customer's wish.

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