

**Eurofins Polska Sp. z o.o.**
**CHEMNOVATIC Ławecki Gęca Sp. j.**

 THE BUILDING OF LUBLIN SCIENCE  
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**UL. DOBRZAŃSKIEGO 3, LOK. BS002**
**20-262 LUBLIN, POLAND**
[www.chemnovatic.com](http://www.chemnovatic.com)

Al. Wojska Polskiego 90A

82-200 Malbork

tel. +48 55 272 04 73; fax. +48 55 272 04 75

[www.eurofins.pl](http://www.eurofins.pl)

Date: 30-03-2016

**Analytical Report AR-16-ST-022181-01\_EN**

<b>Sample code</b>	<b>720-2016-00015999</b>
<b>Sample description</b>	<b>Pharmaceutical Nicotine: PureNic 99+</b> Batch No. NIC/X/20160121, Production Date: 21.01.2016, Expiry Date: 20.01.2018
<b>Sample Sender</b>	CHEMNOVATIC Ławecki Gęca Sp. j.
<b>Prescriber</b>	CHEMNOVATIC Ławecki Gęca Sp. j.
<b>Sample taken by</b>	the client
<b>Transport by</b>	delivery company
<b>Sample reception date</b>	17-02-2016
<b>Sample condition</b>	proper
<b>Purpose of the testing</b>	legal requirements / quality control
<b>Start of analysis</b>	17-02-2016
<b>End of analysis</b>	23-03-2016

**TEST RESULTS**

Code	Analysis	Method	Results
<b>USP 36 (monograph: Nicotine) (*)</b>			
<b>FGU40</b>	<b>Chromatographic purity</b>  <b>Chromatographic purity</b> <b>Individual impurity</b> <b>Total impurity</b>	USP 36, monograph	<b>corresponds</b> <b>&lt; 0.5 %</b> <b>&lt; 1.0 %</b>
<b>FGU04</b>	<b>Identification UV (Ultraviolet Absorption)</b>	USP 36, monograph	<b>passes test</b>
<b>FGU52</b>	<b>Heavy metals</b>  Heavy metals as Lead	USP 36, USP <231>, Method II, Visual examin.	<b>&lt; 0.002 %</b>
<b>FGU60</b>	<b>Water determination</b>	USP 36, USP <921>, Method I, Karl-Fisher titration	<b>&lt; 0.1 %</b>
<b>FGU3G</b>	<b>Specific optical rotation calculated on dried basis</b>	USP 36, monograph	<b>-143 °</b>

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Code	Analysis	Method	Results
<b>EP 8.6 (monograph: 1452) (*)</b>			
FIH43	Appearance	EP 8.6, Ph.Eur., Visual Examination	<b>colorless liquid</b>
FIA04	Appearance of solution  Clarity Color	EP 8.6, EP 2.2.1. – EP 2.2.2, Visual Examination	<b>clear against water &lt;BY5</b>
FIC51	Assay calculated on the anhydrous substance	EP 8.6, Titration	<b>100.4 %</b>
FIF03	Water	EP 8.6, EP 2.5.12, Titration	<b>&lt; 0.1 %</b>
FIA07	Specific optical rotation i.o.	EP 8.6, EP 2.2.7, Polarimetry	<b>-145 °</b>
FGB20	Related Substances A: Anatabin B: Beta-Nicotrin C: Cotinin D: Myosmin E: Nicotin N'-oxid F: Normicotin G: Anabasin  Individual impurity (A, B, C, D, E, F, G) Unspecified impurities Total Impurity	EP 8.6, EP 2.2.29, LC-UV/DAS	<b>passes test</b>       <b>&lt; 0.3 %</b> <b>&lt; 0.10 %</b> <b>&lt; 0,8 %</b>
FIA13	Identification (IR)	EP 8.6, EP 2.2.24, Spectrophotometry (IR), method film	<b>passes test</b>

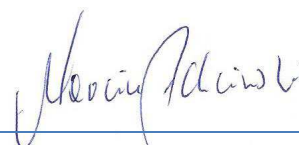
(\*) Subcontracted to Eurofins laboratory: Eurofins Fintelmann und Meyer GMP GmbH (Hamburg, Germany)

## JUDGEMENT:

Deviating from the monograph nitrogen has been used as carrier gas. In consequence the gas flow had to be adjusted. The SST test laid down in the monograph has been passed

With regard to the analysed parameters the test sample material meets the respective requirements of EP 8.6 (monograph: 1452) and USP 36 (monograph: Nicotine)

Signature



Marcin Achciński, Eurofins Polska Sp. z o.o.

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