



PRODUCT: Nicotine	BATCH N°: NA99/03/16	INTERNAL N° : 01336
SOURCE: Nico Orgo Marketing India		
ANALYSIS: Monography raw material	DATE OF ANALYSIS: April 12 th , 2016	REFERENCE: LAA LD/33/120 ; HD/33/150
PROCEDURE: European Pharmacopoeia 01/2009 :1452 (corrected 6.6)		
TYPE :	Routine <input checked="" type="checkbox"/>	R&D <input type="checkbox"/> Stability <input type="checkbox"/>

TEST	SPECIFICATIONS	RESULTS
CHARACTERS	Colourless or brownish viscous liquid volatile, hygroscopic	Complies
IDENTIFICATIONS		
A	See tests	Complies
B	IR spectrum complies with EP reference spectrum	Complies
TESTS		
- Appearance of the solution	Clear, coloration $\leq Y_5$, BY_5 or R_5	Clear, coloration =Y5
- Specific optical rotation (on dry substance) (2.2.7)	-140 to -152	-147
- Related substances (2.2.29)		
Impurity A	$\leq 0.3\%$	0.1%
Impurity B	$\leq 0.3\%$	Not detected
Impurity C	$\leq 0.3\%$	Not detected
Impurity D	$\leq 0.3\%$	0.1%
Impurity E	$\leq 0.3\%$	Not detected
Impurity F	$\leq 0.3\%$	0.1%
Impurity G	$\leq 0.3\%$	0.1%
Each unspecified impurity	$\leq 0.10\%$	< DL*
Total impurities	$\leq 0.8\%$	0.4%

*) DL : Disregard Limit (0.05%)

Date	May 3 rd , 2016	May 3 rd 2016	May 3 rd , 2016
	D.Lando Chemist	L.Innocenti Laboratory Manager	Christian Sarbach Pharmacist Qualified Person



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TYPE :

Routine

R&D

Stability

TEST	SPECIFICATIONS	RESULTS
TESTS		
- Water (2.5.12)	≤ 0.5%	0.1 %
- ASSAY		
- Nicotine (2.2.20)	99.0 to 101.0 p.cent (anhydrous substance)	100.8 p.cent

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	D.Lando Chemist	E.Innocenti Laboratory Manager	Christian Sarbach Pharmacist Qualified Person