

CERTIFICATE OF ANALYSIS

				(Nicotine	
No.	: 106/2016	Date of I	ssuing :	20/05/2016	
Product Name:NICOTINEDate of Manufacturing:11/05/2016Date of Expiry:10/05/2021		Batch Number		469102705051	
		Batch Siz	ze :	300.052 Liter	
		Dispatch	Quantity :	300.000 Liter	
Analytical Protoc	col Reference: 4691/E-Rev.08			Page 1 of 1	
<u>Test</u> <u>Speci</u>	fication		<u>Result</u>		
Character					
Appea	arance (Visual test)				
	Colourless or brownish viscous	liquid, volatile,		olourless viscous liquid, volatile,	
Colub	hygroscopic ility (Visual test)		hygroscopic		
Solub	Soluble in water		Soluble in w	ator	
	Miscible with anhydrous ethanol			anhydrous ethanol	
Identification					
Speci	fic optical rotation (∞) ²⁰ ₀ (Polarimet	er)			
	Should conforms		Conforms		
IR Spe	ectrum (IR spectrophotometer)				
	Corresponding to reference spec	trum	Corresponds	s to reference spectrum	
	solution (Limit test)		Corresponds	s to reference spectrum	
The so	solution (Limit test) plution is clear and not more intensel		The solution	is clear and not more	
The so	solution (Limit test)		The solution		
The so referen	solution (Limit test) plution is clear and not more intensel		The solution intensely col	is clear and not more	
The so referen Related substan Anatal	solution (Limit test) blution is clear and not more intensely nce solution Y ₅ , BY ₅ or R ₅ nces (Liquid Chromatography) bine (EP Impurity A)	y coloured than : NMT 0.3%	The solution intensely col solution Y ₅ Less than 0.	is clear and not more oured than reference 05%*	
The so referen Related substan Anatal β-nico	solution (Limit test) blution is clear and not more intensely nce solution Y ₅ , BY ₅ or R ₅ nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B)	y coloured than NMT 0.3% NMT 0.3%	The solution intensely col solution Y₅ Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%*	
The so referen Related substan Anatal β-nico Cotinir	solution (Limit test) blution is clear and not more intensely nce solution Y ₅ , BY ₅ or R ₅ nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C)	y coloured than NMT 0.3% NMT 0.3% NMT 0.3%	The solution intensely col solution Y₅ Less than 0. Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%*	
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The so referen Related substan Anatal β-nico Cotinir Myosn Nicotir Nornic	solution (Limit test) blution is clear and not more intensely nce solution Y_5 , BY_5 or R_5 nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C) nine (EP Impurity D) ne-N-Oxide (EP Impurity E) cotine (EP Impurity F)	y coloured than NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3%	The solution intensely col solution Y₅ Less than 0. Less than 0. Less than 0. Less than 0. Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%* 05%* 05%*	
The so referen Related substan Anatal β-nico Cotinir Myosn Nicotir Nornic Anaba	solution (Limit test) blution is clear and not more intensely nce solution Y_5 , BY_5 or R_5 nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C) nine (EP Impurity D) ne-N-Oxide (EP Impurity E) cotine (EP Impurity F) asine (EP Impurity G)	y coloured than NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3%	The solution intensely col solution Y₅ Less than 0. Less than 0. Less than 0. Less than 0. Less than 0. Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%* 05%* 05%* 05%* 05%*	
The so referen Related substan Anatal β-nico Cotinir Myosn Nicotir Nornic Anaba Unspe	solution (Limit test) blution is clear and not more intensely nce solution Y_5 , BY_5 or R_5 nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C) nine (EP Impurity D) ne-N-Oxide (EP Impurity E) cotine (EP Impurity F)	y coloured than NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3%	The solution intensely col solution Y₅ Less than 0. Less than 0. Less than 0. Less than 0. Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%* 05%* 05%* 05%* 05%* 05%*	
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The so referen Related substan Anatal β-nico Cotinir Myosn Nicotir Nornic Anaba Unspe Total ii	solution (Limit test) blution is clear and not more intensely nce solution Y_5 , BY_5 or R_5 nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C) nine (EP Impurity D) ne-N-Oxide (EP Impurity E) cotine (EP Impurity F) asine (EP Impurity G) ecified impurities (for each impurity) mpurities rotation (∞) ²⁰ _D (Polarimeter) (-)140° to (-)152° (calculated on anhydrous	y coloured than NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.10% NMT 0.8%	The solution intensely col solution Y ₅ Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%* 05%* 05%* 05%* 05%* 05%*	
The so referen Related substan Anatal β-nico Cotinir Myosn Nicotir Nornic Anaba Unspe Total ii Specific optical Water (Karl Fisc	solution (Limit test) blution is clear and not more intensely nce solution Y_5 , BY_5 or R_5 nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C) nine (EP Impurity D) ne-N-Oxide (EP Impurity E) cotine (EP Impurity F) asine (EP Impurity G) ecified impurities (for each impurity) mpurities rotation (∞) ²⁰ _D (Polarimeter) (-)140° to (-)152° (calculated on anhydrous her titration) NMT 0.5%	y coloured than NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.10% NMT 0.8%	The solution intensely col solution Y ₅ Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%* 05%* 05%* 05%* 05%* 05%*	
The so referen Related substan Anatal β-nico Cotinir Myosn Nicotir Nornic Anaba Unspe Total ii	solution (Limit test) blution is clear and not more intensely nce solution Y_5 , BY_5 or R_5 nces (Liquid Chromatography) bine (EP Impurity A) tyrine (EP Impurity B) ne (EP Impurity C) nine (EP Impurity D) ne-N-Oxide (EP Impurity E) cotine (EP Impurity F) asine (EP Impurity G) ecified impurities (for each impurity) mpurities rotation (∞) ²⁰ _D (Polarimeter) (-)140° to (-)152° (calculated on anhydrous her titration) NMT 0.5%	y coloured than NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.3% NMT 0.10% NMT 0.8%	The solution intensely col solution Y ₅ Less than 0. Less than 0.	is clear and not more oured than reference 05%* 05%* 05%* 05%* 05%* 05%* 05%* 05%*	

* Disregard limit of impurity is 0.05%

Evaluation: Product corresponds with the requirements of current European Pharmacopoeia. **Storage Conditions:** Store under nitrogen in well closed containers below 20 °C protected from light and moisture.

Transportation Temperature: Below 30°C.

20/05/16 05/16 30 Checked by Manager Q.C. Prepared by

Alchem International Private Limited (Formerly – Alchem International Limited)

Factory: 25/2, Main Mathura Road, Village Kaili, Ballabgarh, Faridabad – 121 004, Haryana, India Registered Office: 201, Empire Plaza, Mehrauli-Gurgaon Road, Sultanpur, New Delhi – 110 030, India Contact: Telephone – 91-129-4266 000 Fax – 91-129-230 9990, 230 9991, 230 7971 E-mail: contact@alcheminternational.com



CERTIFICATE OF ANALYSIS

No.	. 106/2016	Date of I	(Nicotine EP)
Product Name : NICOTINE EP		Batch Number 469102705051	
Date of Manufacturing	: 11/05/2016	Batch Si	
Date of Expiry	10/05/2021	Dispatch	Quantity : 300.000 Liter
Analytical Protocol Refe	rence: 4691/E-Rev.08		Page 1 of 1
Test Specification			Result
Character			
Appearance (
Colourless or brownish viscous liquid, volatil		iquid, volatile,	Colourless viscous liquid, volatile,
	roscopic		hygroscopic
Solubility (Vis	uble in water		Soluble in water
	cible with anhydrous ethanol		Miscible with anhydrous ethanol
dentification	allo mar annyarous cardhor		mediale war annyarous calandi
	cal rotation (∝) ²⁰ D (Polarimet	er)	
Sho	uld conforms		Conforms
IR Spectrum (IR spectrophotometer)			
Cori	responding to reference spec	trum	Corresponds to reference spectrum
reference solu Related substances (Li			The solution is clear and not more intensely coloured than reference solution Y_5
Anatabine (EF β-nicotyrine (E		: NMT 0.3% : NMT 0.3%	Less than 0.05%* Less than 0.05%*
Cotinine (EP l		: NMT 0.3%	Less than 0.05%*
Myosmine (EF		NMT 0.3%	Less than 0.05%*
	ide (EP Impurity E)	NMT 0.3%	Less than 0.05%*
Nornicotine (E		: NMT 0.3%	Less than 0.05%*
Anabasine (El	P Impurity G)	: NMT 0.3%	Less than 0.05%*
	npurities (for each impurity)	: NMT 0.10%	Less than 0.05%*
Total impuritie	S	: NMT 0.8%	Less than 0.05%*
Specific optical rotatio	n (∝) ²⁰ ₀ (Polarimeter) (-)140º to (-)152º (calculated on anhydrous	hasis)	(-)147.9°
Water (Karl Fischer titra		66666	
	NMT 0.5%		0.07%
Assay (Potentiometer)	99.0% to 101.0%		99.6%

Transportation Temperature: Below 30°C.

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Prepared by	Checked by	Manager Q.C.

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