

CERTIFICATE OF ANALYSIS

Material No: **292201**
 Name: **Nicotine Polacrilex 20%**
 Quality: Ph.Eur./USP
 Lot No: Manufacturing date: 18-Oct-2021
 CAS No. 96055-45-7 Retest date: 18-Apr-2024
 Formula: - Specification date: 02-Sep-2021
 Molecular Weight: -

Test	Method	Specification	Result
Description	BE-292201	white or slightly yellowish powder	Complies
Identity (IR)	IRA-292201	in accordance with reference spectrum of nicotine	Complies
	IRB-292201	in accordance with reference spectrum of polacrilex	Complies
Identity (UV)	UV-292201	complies with nicotine release test	Complies
Release	UV-292201	NLT 70 % of the content determined under assay in 10 min (calculated on dried substance)	81 %
Identity (HPLC)	LCGV-292201	retention time corresponds to reference	Complies
Assay (HPLC)	LCGV-292201	95.0 - 115.0 % of labelled content (calculated on dried substance)	102.5 %
Related substances (HPLC)	LCGV-292201	NMT 0.15 % cotinine	<0.05 %
	LCGV-292201	NMT 0.15 % nicotine N-oxide	<0.05 %
	LCGV-292201	NMT 0.15 % myosmine	<0.05 %
	LCGV-292201	NMT 0.15 % normicotine	<0.05 %
	LCGV-292201	NMT 0.10 % β -nicotyrine	<0.05 %
	LCGV-292201	NMT 0.15 % anatabine	<0.05 %
	LCGV-292201	NMT 0.10 % anabasine	<0.05 %
	LCGV-292201	NMT 0.10 % greatest unknown impurity	0.05 %
Loss on drying	TV-292201	NMT 7.0 %	2.1 %

Release comment: **meets specification**

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured including packaging and quality control in compliance with GMP requirements.

Released On: 11-Nov-2021 12:54 (UTC+01:00)
 on behalf of Siegfried Ltd
 Released By: J. Bobst
 Quality Assurance

This certificate of analysis is signed electronically.
 It has been created automatically by the validated Siegfried Laboratory Information Management System (LIMS)