

METAPHARMACEUTICAL

N DE LOTE:

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CERTIFICATE OF ANALYSIS

Material No: 702184
Name: Phenelzine Sulfate
Quality: USP, BP
Batch No: 25154035 Manufacturing date: 14-Apr-2025
CAS No. 156-51-4 Retest date: 14-Apr-2030
Formula: - Specification date: 24-Feb-2025
Molecular Weight: -

Test	Method	Specification	Result
IMPURITIES (HPLC) II	16090__DEF03400	2-Phenylethanol: max. 0.15 %	<0.05 %
	16090__DEF03400	Any unknown impurity: max. 0.10 %	<0.05 %
	16090__DEF03400	Sum of impurities: max. 0.5 %	<0.05 %
DESCRIPTION	16090__DEF00100	white to yellowish white powder	Complies
IDENTIFICATION UV	16090__DEF00300	complies with reference	Complies
IDENTIFICATION IR	16090__DEF00400	complies with reference	Complies
IDENTIFICATION	16090__DEF08100	sulfate test	Complies
	16090__DEF08100	test B: red to yellow-red precipitate	Complies
MELTING POINT	16090__DEF02800	164 - 168 °C	167 °C
pH	16090__DEF01000	1.4 - 1.9 (1 % aqueous solution)	1.7
LOSS ON DRYING	16090__DEF01200	max. 1.0 %	0.1 %
HEAVY METALS	16090__DEF02200	max. 20 ppm	Complies
SULPHATED ASHES	16090__DEF01300	max. 0.1 %	0.0 %
GRANULOMETRY	16090__DEF02400	> 500 µm: max. 10 %	0 %
	16090__DEF02400	< 425 µm: indicative	100 %
	16090__DEF02400	< 150 µm: indicative	100 %
	16090__DEF02400	< 75 µm: indicative	100 %
ASSAY (HPLC)	16090__DEF03400	98.0 - 102.0 %	99.9 %
IMPURITIES (HPLC)	16090__DEF07300	Hydrazine: max. 0.1 %	0.0 %
TLC	16090__DEF03600	sum of impurities: max. 2.0 %	Complies
RESIDUAL SOLVENTS	16090__DEF18600	Isopropanol: max. 1000 ppm	39 ppm
	16090__DEF18600	any other solvent: max. 1000 ppm	0 ppm
	16090__DEF26200	Isopropanol: max. 1000 ppm	47 ppm
	16090__DEF26200	any other solvent: max. 1000 ppm	<20 ppm

Release comment: meets specification

Batch impacted by the amendment: new validated batch size and addition of desiccant agent

Released On: 27-May-2025 10:54 (UTC+02:00)
on behalf of Siegfried Evionnaz SA

Released By: LAGE ANNE
QA-Manager

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