Phytex
Leading Global Manufacturing Phytochemists

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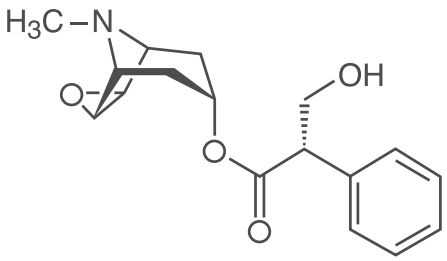
TECHNICAL DATA SHEET

SCOPOLAMINE BASE (HYOSCINE E.P.)



Formula : $C_{17}H_{21}NO_4$

CAS No	Mol. Weight	DMF Status
51-34-3	303.4	ACTIVE – Type II USDMF 7408 : Scopolamine Base

BATCH RELEASE SPECIFICATIONS

TEST	SPECIFICATION	METHOD	VALIDATION
APPEARANCE:	White or almost white, crystalline powder or colourless crystals.	Visual	Visual Observation
SOLUBILITY:	Soluble in water, Freely soluble in ethanol (96%)	EP <2167> EP <Gen Notes>	Current EP Monograph
MELTING POINT:	66° to 70°C	EP Mono <2167> EP Method 2.2.14	Current EP Monograph
ID A: SPECIFIC OPTICAL ROTATION	-33° to -39° on anhydrous basis @ 20°C	EP Mono <2167> EP Method 2.2.7 EP Reagents 4.1.1	Current EP Monograph
ID B: IR	I.R. spectrum corresponds to reference spectrum	EP Mono <2167> EP Method 2.2.24 EP Reagents 4.1.1	Current EP Monograph
SPECIFIC OPTICAL ROTATION:	-33°to -39° on anhydrous basis @ 20°C	EP Mono <2167> EP Method 2.2.7 EP Reagents 4.1.1	Current EP Monograph
WATER CONTENT - KF:	NMT 0.5 %	EP Mono <2167> EP Method 2.5.12	Current EP Monograph
RESIDUAL SOLVENTS:	Complies with Class 3 Solvents: < 5000 ppm	EP Mono <2167> EP Method 2.4.24	Current EP Monograph
SULFATED ASH:	NMT 0.1 %	EP Mono <2167> EP Method 2.4.14	Current EP Monograph

CHART KEY

IR = infrared; N/A = not applicable; NMT = no more than; HPLC = high performance liquid chromatography; EP = European Pharmacopeia;

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BATCH RELEASE SPECIFICATIONS CONTINUED

TEST	SPECIFICATION	METHOD	VALIDATION
ASSAY	98.5 to 101.0 %	EP Mono <2167> EP Method 2.2.20	Current EP Monograph
RELATED SUBSTANCES - HPLC:	Norhyoscine NMT 0.5 % Tropic Acid NMT 0.1 % Hyoscyamine NMT 0.1 % Apohyoscine NMT 0.1 % Any Other Individ. NMT 0.1 % **Total Impurities NMT 0.5 %**	EP Mono <2167> EP Method 2.2.29 EP Method 2.2.46	Current EP Monograph
Water Content – KF (Quantitative)	NMT 0.5 %	In-house EP method qualification	Validated. Method available for purchase
Residual Solvents (Quantitative)	Complies with Class 3 Solvents: <5000 ppm	Validated in-house method	Validated. Method available for purchase
Related Substances - HPLC: (Quantitative)	Norhyoscine NMT 0.5 % Tropic Acid NMT 0.1 % Hyoscyamine NMT 0.1 % Apohyoscine NMT 0.1 % Apoatropine NMT 0.1 % Any Other Individ. NMT 0.1 % **Total Impurities NMT 0.5 %**	Validated in-house method	Validated. Method available for purchase

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* All in-house validated methods are available for reference in the closed part of the DMF.
Validated methods are proprietory information and are available for purchase.

Products are manufactured according to the ICH GMP Guide for APIs
Products are manufactured under Phytex Australia GMP License (Australian Therapeutic Goods Administration (TGA)