Phytex
Leading Global Manufacturing Phytochemists

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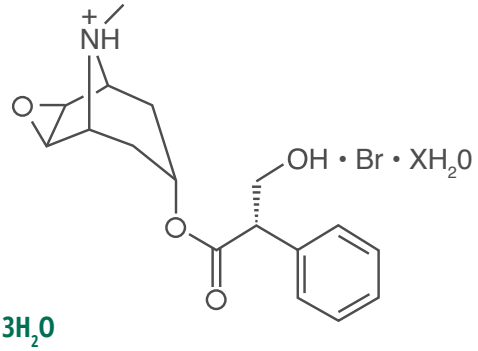
TECHNICAL DATA SHEET

SCOPOLAMINE HYDROBROMIDE USP (HYOSCINE HYDROBROMIDE B.A.N.)



Formula : $C_{17}H_{21}NO_4 \cdot HBr \cdot 3H_2O$

CAS No	Mol. Weight	DMF Status
6533-68-2	438.31	ACTIVE - Type II USDMF 7415 : Scopolamine Hydrobromide ACTIVE - Type I (Health Canada) : Scopolamine Hydrobromide

ANALYSIS	SPECIFICATION	METHOD
DESCRIPTION:	White, crystalline powder, colourless.	Visual
IDENTIFICATION A:	Infrared Absorption	Current USP monograph
IDENTIFICATION B:	Yellow/Brown colour	Current USP monograph
IDENTIFICATION C:	Retention time of the Scopolamine peak corresponds to the Standard Solution (Assay)	Current USP monograph
ASSAY:	98.0% - 102.0%	Current USP monograph
ORGANIC IMPURITIES:	Tropic Acid NMT 0.20 % Norscopolamine NMT 0.5 % Hyoscyamine NMT 0.20 % Apohyoscine NMT 0.20 % Apoatropine NMT 0.20 % Other NMT 0.10 % **Total Impurities NMT 0.7 %**	Current USP monograph
RESIDUE ON IGNITION:	NMT 0.1%	Current USP monograph
OPTICAL ROTATION:	-24° to -26°	Current USP monograph
pH (of a 5 % w/v soln):	4.0 – 5.5	Current USP monograph
WATER DETERMINATION:	NMT 13.0%	Current USP monograph
RESIDUAL SOLVENTS:	Complies with Class 2 Solvents: < 60 ppm	Current USP monograph

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