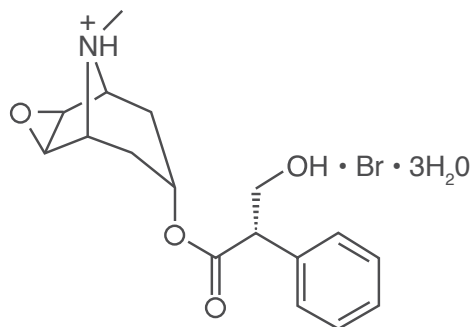


## TECHNICAL DATA SHEET

# HYOSCINE HYDROBROMIDE – EP

(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												
APPEARANCE:	White, or almost white crystalline powder or colorless crystals, efflorescent	Current EP monograph												
SOLUBILITY:	Freely soluble in water, soluble in ethanol (96%)	Current EP monograph												
IDENTIFICATION B:	I.R. spectrum corresponds to reference spectrum	Current EP monograph												
IDENTIFICATION E:	Complies with reaction for Bromides	Current EP monograph												
pH 5% (or a 5% w/v soln):	4.0 – 5.5	Current EP monograph												
SPECIFIC OPTICAL ROTATION:	-24° to -27°	Current EP monograph												
RELATED SUBSTANCES (HPLC):	<table border="0"> <tr> <td>Norhyoscyne</td> <td>NMT 0.5%</td> </tr> <tr> <td>Aphyoscyne</td> <td>NMT 0.1%</td> </tr> <tr> <td>Tropic Acid</td> <td>NMT 0.1%</td> </tr> <tr> <td>Hyoscyamine</td> <td>NMT 0.1%</td> </tr> <tr> <td>Other Impurity</td> <td>NMT 0.1%</td> </tr> <tr> <td><b>Total</b></td> <td><b>NMT 0.7%</b></td> </tr> </table>	Norhyoscyne	NMT 0.5%	Aphyoscyne	NMT 0.1%	Tropic Acid	NMT 0.1%	Hyoscyamine	NMT 0.1%	Other Impurity	NMT 0.1%	<b>Total</b>	<b>NMT 0.7%</b>	Current EP monograph
Norhyoscyne	NMT 0.5%													
Aphyoscyne	NMT 0.1%													
Tropic Acid	NMT 0.1%													
Hyoscyamine	NMT 0.1%													
Other Impurity	NMT 0.1%													
<b>Total</b>	<b>NMT 0.7%</b>													
WATER (KFT):	10.0% - 13.0%	Current EP monograph												
SULFATED ASH:	NMT 0.1%	Current EP monograph												
ASSAY (Potentiometric titration):	99.0% - 101.0%	Current EP monograph												
RESIDUAL SOLVENTS:	COMPLIES	Current EP 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))