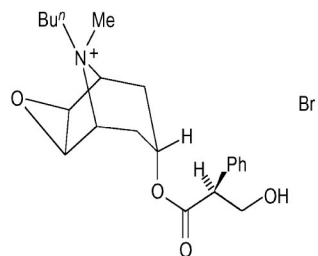




SCOPOLAMINE (EP) HYOSCINE-BUTYLBROMIDE

NAME OF THE PLANT:	Duboisia leichardtii
PART OF THE PLANT USED:	Leaves
FORMULA:	C ₂₁ H ₃₀ BrNO ₄
IUPAC NAME:	[7(S)-(1 α,-2β, 4β, 5 α , 7β)]-9-butyl-7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9-methyl-3-oxa-9-azoniatricyclo [3.3.1.0 ^{2,4}] nonane bromide
SYNONYMS:	(1S,3S,5R,6R,7S,8r)-6,7-epoxy-8-butyl-3-[(S)-tropoyloxy] tropanium bromide. Scopolamine N-Butyl bromide. N-Butyl Scopolammonium Bromide

STRUCTURAL FORMULA:



MOLECULAR WEIGHT: 440,40

CAS N. 149-64-4

TECHNICAL DESCRIPTION:

Characters: white or almost white, crystalline powder

Solubility: freely soluble in water and methylene chloride, sparingly soluble in ethanol

Identification:

- A) Optical rotation test : complies with the test for optical rotation
- B) Melting point : between 139 °c and 141 °c
- C) IR spectrum : complies with reference standard
- D, E) Colorimetric : complies with tests
- F) Bromides test : it gives the reaction of bromides

Appearance of solution : the 5 % water solution is clear and colourless

pH : between 5.5 and 6.5

specific optical rotation : between -20.0 and -18.0

Loss on drying: not more than 2.5 %

Sulphated ash: not more than 0.1 %

HPLC related substances: complies with EP:

- (-)-scopolamine hydrobromide: nmt 0.1%
- pseudo-hyoscine butylbromide: nmt 0.2%
- apo-n-hyoscine butylbromide: nmt 0.2%
- tropic acid: nmt 0.2%
- (-)-scopolamine methylbromide: nmt 0.2%
- (-)-scopolamine propylbromide: nmt 0.2%
- n-butyl norscopolamine bromide: nmt 0.2%
- each unidentified impurity: nmt 0.1%
- total of all impurities: nmt 0.4%

Assay: between 98.0 % and 101.0 % dry basis AgNO₃

Microbiology: complies with EP

Storage: Sealed container

PRODUCT APPLICATIONS: Hyoscine-N-Butylbromide is an antispasmodic that acts by relaxing the muscles of the gastro intestinal (GI) tract.

THERAPEUTIC CATEGORY: Antispasmodic.