



CERTIFICATE OF ANALYSIS  
 NAME OF THE PRODUCT; HYOSCINE N BUTYL BROMIDE  
 MFG DT: SEPT 2010 EXP DT; SEPT 2015  
 BATCH NUMBER; 255101604002

TESTS	LIMIT	RESULTS
DESCRIPTION	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
SOLUBILITY	FREELY SOLUBLE (1 GM IN 1 TO 10ML)IN WATER AND IN METHYLENE CHLORIDE,SPARINGLY SOLUBLE (1GM IN 30 TO 100 MI) IN ETHANOL	FREELY SOLUBLE IN WATER AND IN METHYLENE CHLORIDE
IDENTIFICATION	FIRST: A.C.F SECOND:A,B,D,E,F A.IT COMPLIE WITH THE TEST FOR SPECIFIC OPTICAL ROTATION B.MELTING POINT (2.2.14) ;139°C TO 141°C C.EXAMINE BY INFRARED ABSORPTION SPECTROPOTOMETRY (2.2.24)COMPARING WITH THE SPECTRUM OBTAINED WITH HYOSCINE BUTYL BROMIDE CRS. D.TO ABOUT 1MG ADD 0.2 ML OF NITRIC ACID R AND EVAPORATE TO DRYNESS ON WATER BATH DISSOLVE THE RESIDUE IN 2ML OF ACETONE R AND ADD 0.1 ML OF A 30G/1 SOLN OF POTASSIUM HYDROXIDE R IN METHANOL R A VIOLET COLOUR DEVELOPS E.TO 5ML OF SOLN(SEC TESTS) ADD 2ML OF DILUTE SODIUM HYDROXIDES SOLN R NO PRECIPITATES IS FORMED) F.IT GIVES REACTION (a) OF BROMIDE (2,3:1)	COMPLIES  139°C TO 141°C  A VIOLET COLOUR DEVELOPED  NO PRECIPTATE IS FORMED  GIVES REACTION (a)OF BROMIDES
APPEARANCE OF SOLN	SOLN S (DISSOLVE 1.25 GM IN CO2 FREE WATER R AND DILUTE TO 25ML WITH THE SAME SOLVENT)IS CLEAR (2.2.1) AND COLOURLESS(METHOD II 2.2.2)	SOLN S IS CLEAR AND COLOURLESS
P (OF SOLN S)	5.5 TO 6.5	6.08
SPECIFIC OPTICAL ROTATION (ODS) [OF SOLN S]	( - ) 18° TO ( - ) 20°	( - ) 18.75°
LOSS ON DRYIN	NMT 2.5%	0.36%
SULPATED ASH	NMT 0.1%	0.07%
RESIDUAL SOLVENTS		
METHANOL	NMT 3000 PPM	557 PPM
ETHANOL	NMT 5000 PPM	NOT DETECTED
ACETONITRILE	NMT 410 PPM	NOT DETECTED
METHYLENE CHLORIDE	NMT 600 PPM	NEGLEGIBLE
N-BUTYL BROMIDE	NMT 100 PPM	41 PPM
ASSAY ( ODS)	98.0% TO 101%	99.59%
HYOSCINE	NMT 0.1%	LESS THAN 0.1%
OTHER RELATED SUBSTANCES	NMT 0.2%	LESS THAN 0.2%