

CERTIFICATE OF ANALYSIS

DROTAVERINE HYDROCHLORIDE

TEST	SPECIFICATIONS
DESCRIPTION	LIGHT YELLOW OR GREENISH YELLOW CRYSTALLINE POWDER, ALMOST WITHOUT ODOUR
SOLUBILITY	MODERATELY SOLUBLE IN WATER, SOLUBLE IN ALCOHOL (96%) EASILY SOLUBLE IN CHLOROFORM
IDENTIFICATION	
A) BY IR	IR SPECTRUM S CONCORDANT WITH WORKING REFERENCE STANDARD
B) BY UV SPECTRUM	UV SPECTRUM IS CONCORDANT WITH WORKING REFERENCE STANDARD
C) BY CHLORIDE REACTION AND WITH FeCl ₃	PASSES
MELTING POINT	ABOUT 210°C (WITH DECOMPOSITION 205°C-215°C)
CLARITY OF THE SOLUTION	CLEAR OR NOT MORE THAN REFERENCE SOLUTION
COLOUR OF THE SOLUTION	NOT MORE INTENSIVE THAN REFERENCE STANDARD G ⁵ OR Y ⁵
PH (1.0% AQ. SOLUTION)	BETWEEN 3.50-5.50
FOREIGN IMPURITIES (BY TLC)	NMT 1.00%
WATER CONTENT BY KF	NOT MORE THAN 2.00%W/W
LOSS ON DRYING	NOT MORE THAN 5.00%W/W
SULPHATED ASH	NOT MORE THAN 0.20%W/W
HEAVY METALS AND FERRUM	NOT MORE THAN 0.002%W/W OF LEAD OR FERRUM
SULPHATES	NOT MORE THAN 0.05%W/W
ASSAY (NON AQUEOUS TITRATION)	BETWEEN 98.0% - 101.05 W/W