

## **CERTIFICATE OF ANALYSIS**

## **MEPYRAMINE MALEATE BP**

TEST	REQUIREMENT	RESULT
DESCRIPTION	A WHITE OR STRICTLY YELLOWISH CRYSTALLINE POWDER	A WHITE CRYSTALLINE POWDER
SOLUBILITY	VERY SOLUBLE IN WATER, FREELY SOLUBLE IN ALCOHOL	VERY SOLUBLE IN WATER, FREELY SOLUBLE IN ALCOHOL
IDENTIFICATION A. MELTING POINT B. BY IR	99ºC-103ºC SOULD COMPLY	99.9⁰C COMPLIES
C. BY UV	SPECIFIC ABSORVANCE AT - 239 NM BETWEEN 431-477 - 316 NM BETWEEN 196-220	463 209
D. BY TLC	SHOULD COMPLY	COMPLIES
E. COLOUR REACTION	A VIOLET PINK COLOUR DEVELOPS	COMPLIES
APPEARANCE OF SOLUTION	SHOULD BE CLEAR AND NOT MORE INTENSELY COLOURED THAN REFERENCE Y6	COMPLIES
PH	BETWEEN 4.9-5.2	5.00
CHLORIDES	NOT MORE THAN 100 PPM	LESS THAN 100 PPM
HEAVY METALS	NOT MORE THAN 20 PPM	LESS THAN 20 PPM
LOSS ON DRYING	NOT MORE THAN 0.25%	0.13%
SULPHATED AS	NOT MORE THAN 0.1	0.02%
	INDIVIDUAL- NOT MORE THAN 0.2%	LESS THAN 0.2%
COMPOUNDS (BY TLC) ASSAY (ON DRY BASIS)	99.0% TO 101.0% W/W	99.6%

REMARK: THE PRODUCT COMPLIES AS PER BP / Ph Eur.