



alchem International, Inc
Compounding Chemicals You Can Trust

PRODUCT:	PYRILAMINE MALEATE, USP	EXPIRATION DATE:	05/2023
FINISHED LOT NO:	SLL/QC/FP/20/0703	MFG DATE:	06/2020
CAS#	59-33-6	SPECIFICATIONS:	USP
MANUFACTURER:	SUPRIYA LIFE SCIENCE LTD.	COUNTRY OF ORIGIN:	INDIA

Certificate of Analysis

TEST CRITERIA	SPECIFICATIONS		RESULTS
	MIN.	MAX.	
DESCRIPTION	White crystalline powder usually having a faint odor.		White powder
SOLUBILITY	Very soluble in water; freely soluble in alcohol and in chloroform.		Conforms
ASSAY (DRIED BASIS)	98.0 %	100.5%	99.49%
*ASSAY (DRIED BASIS)	98.0%	100.5%	99.3%
MELTING RANGE (°C)	99° C	103°C	101.3°- 102.0°C
LOSS ON DRYING Under vacuum (1.5kPa to 2.5kPa=11-19mmHg or 15 to 25mbar) over phosphorus pentoxide for 5 hrs. (% w/w)		0.5	0.16
RESIDUE ON IGNITION (%w/w)		0.1%	0.06 %
RELATED COMPOUNDS			
Test 1: by TLC	No secondary spot from the chromatogram of test solution is larger or more intense than the principal spot from standard solution A (0.5%) and the sum of the intensities of all secondary spots from the test solution corresponds to not more than 1.0%		Complies

Test 2: by HPLC		
Any individual impurity	Not more than 0.3%	0.06%
Total impurities	Not more than 1.0%	0.06%
IDENTIFICATION (A): IR Absorption	The IR absorption spectrum of sample is concordant with infrared absorption spectrum of Pylamine Maleate working standard or reference standard.	Complies
(B): UV Absorption	At the wavelength of maximum absorbance at about 236 and 312 nm, do not differ by more than 3.0%	At 236-1.69 At 312-2.74
*IDENTIFICATION <197K>		Conforms
ADDITIONAL TEST:		
RESIDUAL SOLVENTS BY GC-HS (ppm)		
METHANOL	Not more than 3000	84
O-XYLENE	Not more than 2170	8
ISOPROPYL ALCOHOL	Not more than 5000	176

Remarks: the product complies with respect to above mentioned test as per USP specifications.

Storage: Preserve in tight, light-resistant containers.

*Kalchem International additional testing.

DATE OF RELEASE: 09/22/20 ANALYSIS # ETX-200902-0077

APPROVED BY/ DATE: _____

Kalyn R Tabor, Quality Control