



K alchem International, Inc  
Compounding Chemicals You Can Trust



**SUPRIYA LIFESCIENCE LTD.**  
Creating true values that bind global health

**Certificate of analysis**

**CAS# 59-33-6**

Product	: Ppyrilamine Maleate USP	License No.	: KD-129
Batch No.	: SLL/M/0220002	Date of Manufacturing	: Feb-2020
Batch Qty.	: 300.00kg	Date of re-test/Expiry	: Jan-2023
A. R. No.	: SLL/QC/FP/20/0211	Date of Release	: 25/02/2020

S.No.	Test	Specifications	Results
1.	Description	White, crystalline powder usually having a faint odor.	White, crystalline powder usually having a faint odor
2.	Solubility	Very soluble in water; freely soluble in alcohol and in chloroform; slightly soluble in ether and in benzene.	Conforms
3.	Identification:		
	i. IR Absorption	The IR absorption spectrum should be concordant with that of Ppyrilamine Maleate working standard.	Complies
	ii. UV Absorption	At the wavelength of maximum absorbance at about 236 and 312 nm, do not differ by more than 3.0%	At 236-1.08 At 312-0.48
4.	Melting range (°C)	Between 99 to 103	101.3 to 101.9
5.	Loss on drying under vacuum over phosphorus pentoxide @80°C for 5 hrs. (% w/w)	Not more than 0.5	0.14
6.	Residue on ignition (% w/w)	Not more than 0.1	0.05
7.	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

QA/011/F03-02/Effective date 05/08/2015

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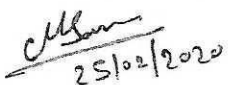
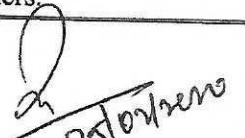

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S.No.	Test	Specifications	Results
	Test 2 by HPLC (%)		
	i. Any individual impurity	Not more than 0.3	0.08
	ii. Total impurities	Not more than 1.0	0.08
8.	Assay on dry basis (% w/w)	98.0 to 100.5	99.80
9.	<b>Additional test:</b>		
	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	89
	ii. O-Xylene	Not more than 2170	BDL
	iii. Isopropyl Alcohol	Not more than 5000	90
Where, BDL : Below Detection Limit For Residual Solvent by GC			
<b>Remarks:</b> The product complies with respect to above mentioned test as per USP 42 specifications.			
<b>Storage:</b> Preserve in tight, light-resistant containers.			
 25/02/2020 Compiled by QC QC Chemist (M.M.Sawant)	 25/02/2020 Checked by QC QC Dy.Sr.Manager(S.U.Takale)	 25/02/2020 Approved by QC QC Head (S.H.Kambale)	

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