



Certificate of analysis

CAS # 59-33-6

Product	: Pyriline Maleate USP	License No.	: KD-129
Batch No.	: SLL/M/0122003	Date of Manufacturing	: Jan-2022
Batch Qty.	: 300.000 kg	Date of re-test/Expiry	: Dec-2026
A. R. No.	: SLL/QC/FP/22/0086	Date of Release	: 04/02/2022

S.No.	Test	Specifications	Results
1.	Description	White, crystalline powder, usually having a faint odor.	White crystalline powder Usually having a faint odor.
2.	Litmus test	Its solution are acid to litmus	Conforms
3.	Solubility	Very soluble in water; freely soluble in alcohol and in chloroform. Slightly soluble in ether and in benzene.	Conforms
4.	Identification:		
	i. Test A: IR Absorption	The IR absorption spectrum of sample is concordant with infrared absorption spectrum of Pyriline Maleate working standard or reference standard.	Complies
	ii. Test B: UV Absorption	Absorptivities at 236 nm and 312 nm, calculated on dried basis, do not differ by more than 3.0%	At 236 = 0.11 At 312 = 0.90
5.	Melting range (°C)	Between 99 to 103	101.2 - 102.3
6.	Loss on drying under vacuum (1.5kPa to 2.5kPa=11-19mmHg or 15 to 25mbar) over phosphorus pentoxide for 5 hrs. (% w/w)	Not more than 0.5	0.17
7.	Residue on ignition (% w/w)	Not more than 0.1	0.03
8.	Related compounds		
	Test 1: by TLC	No secondary spot from the chromatogram of the 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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**Corporate Office :** 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063. Maharashtra, India.

Tel: +91 22 40332727 / 66942507 Fax : +91 22 26860011

**CIN : U51900MH2008PLC180452** Email: [supriya@supriyalifescience.com](mailto:supriya@supriyalifescience.com) Website: [www.supriyalifescience.com](http://www.supriyalifescience.com)

**Factory :** A 5/2, Lote Parshuram Industrial Area, M.I.D.C, Tal. - Khed, Dist.-Ratnagiri, 415 722, Maharashtra, India.

Tel. : +91 2356 272299 Fax : +91 2356 272178 E-mail: [factory@supriyalifescience.com](mailto:factory@supriyalifescience.com)

**GOVT. RECOGNISED EXPORT HOUSE**



**SUPRIYA LIFESCIENCE LTD.**

Creating true values that binds global health

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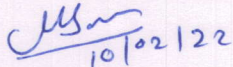
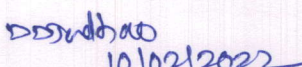
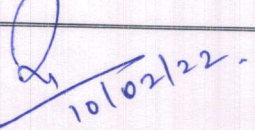
S.No.	Test	Specifications	Results
	Test 2: by HPLC (%)		
	i. Any individual impurity	Not more than 0.3	0.11
	ii. Total impurities	Not more than 1.0	0.11
9.	Assay on dry basis (% w/w)	Not less than 98.0 and Not more than 100.5	99.93
10.	Additional test:		
10.1	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Isopropyl alcohol	Not more than 5000	68
	iii. o-Xylene	Not more than 2170	BDL

Where,

BDL: Below Detection Limit For Residual Solvent by GC

**Remarks:** The product complies with respect to above mentioned test as per **USP 43** specifications.

**Storage:** Preserve in tight, light-resistant containers.

 10/02/22 Compiled by QC QC Chemist (M.M.Sawant)	 10/02/2022 Checked by QC QC Executive (D.D.Jadhav)	 10/02/22 Approved by QC QC Dy.Sr.Manager (S.U.Takale)
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