

Laurus Labs Limited

Plot No: 18, Jawaharlal Nehru Pharma City
Parawada, Anakapalli - 531021,
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Certificate of Analysis

Product Name	Pterostilbene-Picolinic acid Co-crystal	A.R. No.	FD/454/0323
Batch No.	C004320323	Date of Release	01/03/2023
Manufacturing Date	18/02/2023	Dispatch Qty.	80.000 Kg
Retest/Expiry Date	17/08/2023	Specification No.	FS(R)/25266/01
		Test Procedure No.	FT(R)/25266/01

S. No.	Test Parameter	Specification	Result	Method Reference
1.	Description	Pale yellow to Yellow color solid	Yellow color solid	USP
2.	Identification by			
	a. FT-IR	IR spectrum of the sample should be concordant with that of standard.	IR spectrum of test sample concordant with that of standard.	USP/ Ph.Eur.
	b. HPLC	Retention time of major peak in the chromatogram of sample solution should correspond to that of standard solution as obtained in Assay by HPLC	Retention time of major peak in the chromatogram of sample solution correspond to that of standard solution as obtained in Assay by HPLC	In-house
3.	Loss on drying (% w/w, 50°C Under vacuum for 3 hours)	Not more than 1.0	0.21	USP
4.	Residue on ignition(% w/w)	Not more than 0.2	0.08	USP
5.	Related substances by HPLC			In-house
	a. Cis-Pterostilbene(% area)	Not more than 0.15	BQL	
	b. Methyl Impurity(% w/w)	Not more than 0.15	BQL	
	c. THP protected Pterostilbene(%w/w)	Not more than 0.15	BQL	
	d. Dimer Impurity(%w/w)	Not more than 0.5	0.02	
	e. Any unspecified impurity(% area)	Not more than 0.3	BQL	
	f. Total impurities(%)	Not more than 1.0	0.02	
6.	Assay by HPLC			In-house
	Pterostilbene (%w/w)	Between 66.0 and 69.0	66.3	
	Picolinic acid(%w/w)	Between 31.0 and 34.0	33.8	
	Total Assay (%w/w, on dried basis)	Not less than 97.0 and Not more than 103.0	100.3	

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S. No.	Test Parameter	Specification	Result	Method Reference
7	Residual solvents by GC-HS (ppm)			In-house
	a.Methanol	Not more than 3000	Not Detected	
	b.Ethanol	Not more than 5000	95	
	c.Acetone	Not more than 5000	Not Detected	
	d.Dichlorometane	Not more than 600	Not Detected	
	e.Hexanes	Not more than 290	Not Detected	
	f.Tetrahydrofuran	Not more than 720	Not Detected	
	g.Ethyl acetate	Not more than 5000	Not Detected	
	h.n-Heptane	Not more than 5000	31	
	i.Toluene	Not more than 890	Not Detected	
	j.2-Methoxy tetrahydropyran	Not more than 360	Not Detected	
8.	Elemental impurities by ICP-MS (ppm)			In-house
	a. Arsenic	Not more than 1	Not Detected	
	b.Mercury	Not more than 1	Not Detected	
	c. Cadmium	Not more than 1	Not Detected	
	d. Lead	Not more than 1	BQL	
9.	Microbial limit tests (cfu/g)			USP <2021>
	a.Total Aerobic Microbial count	Not more than 1000	< 10 CFU/g	
	b.Total combined Yeasts	Not more than 100	< 10 CFU/g	
10.	Test for Specified microorganisms			USP <2022>
	a. P.aeruginosa	Should be absent	Absent	
	b. Salmonella		Absent	
	c. Staphylococcus		Absent	
	d. Escherichia coli		Absent	

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S. No.	Test Parameter	Specification	Result	Method Reference
11.	Identification by PXRD	Report result	Sample diffractogram exhibit crystalline nature	In-house
12.	Particle size analysis Dv ₉₀ (µm)	Not more than 80	14	In-house

BQL: Below Quantitation Limit.

Remarks: The Material Complies/Does not comply as per the above specification.

	Prepared By	Reviewed By	Approved By
Name	S.MURALIMOHAN RAO	B.VEERABADHRA RAO	V N V S KUMAR
Designation	Asst. Manager	Manager	Dy. Manager
Signature			
Date	01/03/2023	01/03/2023	01/03/2023
Department	Quality Control	Quality Control	Quality Assurance

Form No.: FM/QA/062/13

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