



Certificate of Analysis

Product Name	Pterostilbene-Picolinic acid Co-crystal	A.R.No.	FD/096/1022
		Date of Release	17 th October 2022
Batch No.	25266HYD10021022(M)	Dispatch Qty	5.000 Kg
Manufacturing Date	03/10/2022	Specification No.	FS(R)/25266/01
Retest date	02/04/2023	Test Procedure No.	FT(R)/25266/01

S. No.	Test parameter	Specification	Result	Method Reference
1.	Description	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 the sample is concordant with that of standard	In-house
2.	b) By 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 corresponds 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)	NMT 1.0	0.19	USP
4.	Residue on ignition (% w/w)	NMT 0.2	0.08	USP
5.	Related substances by HPLC			In-house
	a) Cis-Pterostilbene (% area)	NMT 0.15	BQL (LOQ=0.03)	
	b) Methyl impurity (% w/w)	NMT 0.15	BQL (LOQ=0.02)	
	c) THP protected pterostilbene (% w/w)	NMT 0.15	BQL (LOQ=0.03)	
	d) Dimer impurity (% w/w)	NMT 0.5	0.03	
	e) Any unspecified impurity (% area)	NMT 0.3	0.04	
	f) Total impurities (%)	NMT 1.0	0.07	

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6.	Assay by HPLC			In-house
	Pterostilbene (% w/w)	Between 66.0 and 69.0	66.9	
	Picolinic acid (% w/w)	Between 31.0 and 34.0	32.2	
	Total Assay (% w/w, on dried basis)	NLT 97.0 and NMT 103.0	99.2	
7.	Residual solvents by GC-HS (ppm)			In-house
	a) Methanol	NMT 3000	BQL (LOQ=26)	
	b) Ethanol	NMT 5000	101	
	c) Acetone	NMT 5000	ND	
	d) Dichloromethane	NMT 600	ND	
	e) Hexanes	NMT 290	BQL (LOQ=2)	
	f) Tetrahydrofuran	NMT 720	ND	
	g) Ethyl acetate	NMT 5000	ND	
	h) n-Heptane	NMT 5000	64	
	i) Toluene	NMT 890	ND	
	j) 2-Methoxy tetrahydropyran	NMT 360	ND	
8.	Elemental Impurities by ICP-MS (ppm)			In-house
	a. Arsenic	Report result	Less than 0.1	
	b. Mercury		0.1	
	c. Cadmium		Less than 0.1	
	d. Lead		Less than 0.1	

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LAURUS Generics
API & Formulations

LAURUS Synthesis
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LAURUS Bio
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9.	Microbial limit tests (Cfu/g)			USP<2021>
	a) Total Aerobic Microbial count		Less than 10	
	b) Total Combined Yeasts		Less than 10	
10.	Tests for specified microorganisms			USP<2022>
	a) P.aeruginosa	Should be Absent	Absent	
	b) Salmonella		Absent	
	c) Staphylococcus		Absent	
	d) Escherichia coli		Absent	
11.	Identification by XRD	Report result	Sample Diffractogram exhibited crystalline nature	In-house
12.	Particle size analysis	Report result	Dv ₁₀ = 2.59 Dv ₅₀ = 11.51 Dv ₉₀ = 60.93	In-house

NMT: Not more than; NLT: Not less than

ND: Not detected

BQL: Below Quantitation Limit; LOQ: Limit of Quantitation

Remarks: The Material complies as per the above specifications.

	Prepared By	Reviewed By	Approved By
Name	Ch. R.K.K.K.Raju	T. Gopala krishna	V. Srihari babu
Designation	Executive-4	Sr. Manager	Dy. Manager
Signature			
Date	29/10/2022	29/10/2022	29/10/2022
Department	Quality Control	Quality Control	Quality Assurance

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