

Certificate of Analysis

Product Name		Pterostilbene-Picolinic acid Co-crystal	A.R. No.	FD/1619/0824
Batch No.		C017180824	Date of Release	31/08/2024
Manufacturing Date		15/08/2024	Sample Qty.	5 X 40 g
Retest/Expiry Date		14/02/2027	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	In-house
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<197> Ph.Eur. <2.2.24>
	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	0.05	USP<731> Ph.Eur. <2.2.32>
4.	Residue on ignition (% w/w)	Not more than 0.2	0.06	USP<281> Ph.Eur. <2.4.14>
5.	Related substances by HPLC			In-house
	a. Cis-Pterostilbene (% area)	Not more than 0.15	0.04	
	b. Methyl Impurity (% w/w)	Not more than 0.15	BQL(LOQ=0.02)	
	c. THP protected Pterostilbene (% w/w)	Not more than 0.15	BQL(LOQ=0.03)	
	d. Dimer Impurity (% w/w)	Not more than 0.5	0.04	
	e. Any unspecified impurity(% area)	Not more than 0.3	0.03	
	f. Total impurities (%)	Not more than 1.0	0.11	

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6	Assay by HPLC			In-house
	Pterostilbene (% w/w)	Between 66.0 and 69.0	66.8	
	Picolinic acid(% w/w)	Between 31.0 and 34.0	32.4	
	Total Assay (% w/w, on dried basis)	Not less than 97.0 and Not more than 103.0	99.3	
7	Residual solvents by GC-MS (ppm)			In-house
	a. Methanol	Not more than 3000	Not Detected	
	b. Ethanol	Not more than 5000	92	
	c. Acetone	Not more than 5000	Not Detected	
	d. Dichloromethane	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	32	
	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	BQL(LOQ=0.100)	
	b. Mercury	Not more than 0.1	Not Detected (LOQ=0.010)	
	c. Cadmium	Not more than 1	Not Detected (LOQ=0.100)	
	d. Lead	Not more than 1	BQL(LOQ=0.100)	
	e. Antimony	Not more than 1	BQL(LOQ=0.100)	
9	Microbial limit tests (cfu/g)			USP <2021>
	a. Total Aerobic Microbial count	Not more than 1000	< 100 CFU/g	
	b. Total combined Yeasts and Mold counts	Not more than 100	< 100 CFU/g	

Form No.: FM/QA/031/09

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

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S. No.	Test Parameter	Specification	Result	Method Reference
10	Test for Specified microorganisms			USP <2022> and USP <62>
	a. P.aeruginosa	Should be absent in 10g	Absent in 10g	
	b. Salmonella	Should be absent in 10g	Absent in 10g	
	c. Staphylococcus	Should be absent in 10g	Absent in 10g	
	d. Escherichia coli	Should be absent in 10g	Absent in 10g	
	e. Candida albicans	Should be absent in 1g	Absent in 1g	
11.	Identification by PXRD	X-Ray diffractogram of the sample should be consistent with characteristic 2θ Values at 5.6,11.3,12.3,13.4,13.9,21.0 and $26.2 \pm 0.2^\circ$ and absence of diffraction peaks of Relative intensity Not more than 4% at 3.3,4.9,6.5,8.3,8.6,8.7,9.8,11.8, 17.5 and $17.9 \pm 0.2^\circ$ theta.	X-Ray diffractogram of the sample is consistent with characteristic 2θ Values at 5.6,11.3,12.3,13.4, 14.0,21.0 and 26.2° and diffraction peaks at 3.3,4.9,6.5,8.3,8.6, 8.7 9.8,11.8,17.5 and 17.9° are absent	In-house
12.	Particle size analysis Dv_{90} (μm)	Not more than 80	20	In-house

BQL: Below Quantitation Limit, LOQ: Limit of Quantitation

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

	Prepared By	Reviewed By	Approved By
Name	D.RAMA RAO	S.MURALIMOHAN RAO	V N V S KUMAR
Designation	Asst. Manager	Dy. Manager	Dy. Manager
Signature			
Date	05/09/2024	05/09/2024	05/09/2024
Department	Quality Control	Quality Control	Quality Assurance

