



TECHNICAL DATA SHEET

151418-TDS-ENG-2024

PTEROSTILBENE-PICOLINIC ACID CO-CRYSTAL		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: ---	EC Nº: ---	AEMPS CODE: ---
MOL. WEIGHT: 379,41	MOL. FORMULA: C22H21NO5	ARTICLE CODE: 151418

ATTRIBUTES	SHOULD BE
Description [USP]	Yellow color solid
Identification	
FT-IR [In-house]	Complies
HPLC [In-house]	Complies
Loss on drying [USP]	=< 1.0 %
Residue on ignition [USP]	=< 0.2 %
Related substances	
Cis-Pterostilbene	=< 0.15 %
Methyl impurity	=< 0.15 %
THP protected pterostilbene	=< 0.15 %
Dimer impurity	=< 0.5 %
Any unspecified impurity	=< 0.3 %
Total impurities	=< 1.0 %
Assay [In-house]	
Pterostilbene	66.0 - 69.0 %
Picolinic acid	31.0 - 34.0 %
Total Assay	97.0 - 103.0 %
Residual solvents [In-house]	
Methanol	=< 3000 ppm
Ethanol	=< 5000 ppm
Acetone	=< 5000 ppm
Dichloromethane	=< 600 ppm
Hexanes	=< 290 ppm
Tetrahydrofuran	=< 720 ppm
Ethyl acetate	=< 5000 ppm
n-Heptane	=< 5000 ppm
Toluene	=< 890 ppm
2-Metoxytetrahydropyran	=< 360 ppm
Elemental impurities [In-house]	
Arsenic	=< 1 ppm
Mercury	=< 1 ppm
Cadmium	=< 1 ppm
Lead	=< 1 ppm
Antimonio	=< 1 ppm
Microbial limit tests [USP<2021>]	
TAMC	=< 1000 CFU/g



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ATTRIBUTES	SHOULD BE
TYMC	=< 100 CFU/g
Tests for specified microorganisms [USP<2022>]	
Pseudomonas aeruginosa	Should be absent
Salmonella	Should be absent
Staphylococcus aureus	Should be absent
Escherichia coli	Should be absent
C. Albicans	Should be absent
Identification by XRD [In-house]	Report result
Particle size analysis [In-house]	
DV10	Report result
DV50	Report result
DV90	=< 80 µm

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a well closed container at room temperature.

REMARKS

We Metapharmaceutical Industrial hereby declare the methods being used in and facilities and controls being used for sampling, analyzing, fractionating, labelling and storage of Pterostilbene-Picolinic acid Co-crystal [internal code 151418] is in conformity with EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines.

Food declarations and statements available upon request.