



PTEROSTILBENE-PICOLINIC ACID CO-CRYSTAL

PRODUCT CODE: 151418	CAS Nº: ---	ANALYSIS Nº: 240/24
MANUFACTURER BATCH: C017180824	CERTIFICATE ID: 43.532	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 15/08/2024	
METAPH BATCH: 0230924	RETEST DATE: 14/02/2027	

ATTRIBUTES	SHOULD BE	IS
Description [USP]	Yellow color solid	Yellow color solid (*)
Identification		
FT-IR [In-house]	Complies	Complies (*)
HPLC [In-house]	Complies	Complies
Loss on drying [USP]	=< 1.0 %	0.05 %
Residue on ignition [USP]	=< 0.2 %	0.06 %
Related substances		
Cis-Pterostilbene	=< 0.15 %	0.04 %
Methyl impurity	=< 0.15 %	< LoQ
THP protected pterostilbene	=< 0.15 %	< LoQ
Dimer impurity	=< 0.5 %	0.04 %
Any unspecified impurity	=< 0.3 %	0.03 %
Total impurities	=< 1.0 %	0.11 %
Assay [In-house]		
Pterostilbene	66.0 - 69.0 %	66.8 %
Picolinic acid	31.0 - 34.0 %	32.4 %
Total Assay	97.0 - 103.0 %	99.3 %
Residual solvents [In-house]		
Methanol	=< 3000 ppm	Not Detected
Ethanol	=< 5000 ppm	92 ppm
Acetone	=< 5000 ppm	Not Detected
Dichloromethane	=< 600 ppm	Not Detected
Hexanes	=< 290 ppm	Not Detected
Tetrahydrofuran	=< 720 ppm	Not Detected
Ethyl acetate	=< 5000 ppm	Not Detected
n-Heptane	=< 5000 ppm	32 ppm
Toluene	=< 890 ppm	Not Detected
2-Metoxytetrahydropyran	=< 360 ppm	Not Detected
Elemental impurities [In-house]		
Arsenic	=< 1 ppm	< LoQ
Mercury	=< 1 ppm	Not Detected
Cadmium	=< 1 ppm	Not Detected
Lead	=< 1 ppm	< LoQ
Microbial limit tests [USP<2021>]		(*)
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Tests for specified microorganisms [USP<2022>]		
Pseudomonas aeruginosa	Should be absent	Absent
Salmonella	Should be absent	Absent
Staphylococcus aureus	Should be absent	Absent

Analysis date: 21/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies

Manufacturer: 40001225



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Escherichia coli	Should be absent	Absent (*)
C. Albicans	Should be absent	Absent (*)
Identification by XRD [In-house]	Report result	Sample diffractogram exhibit crystalline nature
Particle size analysis [In-house]		
DV90	= < 80 µm	20 µm

COMPLIES WITH

Manufacturer Specifications

REMARKS

Metapharmaceutical Industrial hereby declares 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.

(*) Data controlled by Metapharmaceutical Industrial SL.

STORAGE

Store in a well closed container at room temperature.

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