



METAPHARMACEUTICAL

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08/07/2023

SUPRIYA LIFESCIENCE LTD.

Creating true values that bind global health

Certificate of Analysis

R0-CEP 2018-294-Rev 00

Product Name and grade	: Pentoxifylline Ph. Eur.	License No.	: KD-129
Batch No.	: SLL/PT/0523009	Month of Manufacturing	: May -2023
Batch Qty.	: 580.00kg	Month of re-test / expiry	: Apr. -2028
Dispatch Qty	: 5.00 kg		
A. R. No.	: SLL/QC/FP/23/1266	Date of Release	: 16/07/2023

Sr.No.	Test	Specifications	Results
I.	Characters:		
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder.
2.	Solubility	Soluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96%).	Conforms
II.	Identification (First identification is A and B and Second identification is A,C and D)		
	i. Melting Point (°C)	103 to 107	105.3
	ii. IR	The infrared absorption spectrum of sample should be concordant with infrared absorption spectrum of Pentoxifylline working standard or reference standard.	Complies
III.	Tests		
1.	Appearance of solution (5.0 %,w/v solution in water)	Solution S is clear and not more intensely coloured than reference solution Y ₇ .	Resultant solution is clear and less intensely coloured than reference solution Y ₇ .
2.	Acidity (mL)	Not more than 0.2 mL of 0.01M sodium hydroxide required to change the colour of the indicator to blue.	0.1
3.	Related substance by HPLC (%)		
	i. Impurity A	Not more than 0.1	BDL
	ii. Impurity C	Not more than 0.1	BDL
	iii. Impurity F	Not more than 0.1	BDL
	iv. Impurity J	Not more than 0.1	BDL
	v. Any other impurity	Not more than 0.1	0.08
	vi. Total impurities	Not more than 0.5	0.11

QA/011/F03-03 /Effective date 15/12/2022

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Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063, Maharashtra, India.

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GOVT. RECOGNISED EXPORT HOUSE

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Sr.No.	Test	Specifications	Results
4.	Chlorides (ppm)	Maximum 100	Less than 100
5.	Sulfates (ppm)	Maximum 200	Less than 200
6.	Loss on drying in vacuo at 60°C (Over about 100 of molecular sieve at pressure not exceeding 2.5 kPa) (% w/w)	Maximum 0.5	0.19
7.	Sulfated ash (%)	Maximum 0.1	0.03
8.	Assay on dry basis (%)	99.0 to 101.0	100.10
IV.	Additional test:		
1.	Residual solvents by GC-HS (ppm)		
	i. Chloroform	Not more than 60	BDL
	ii. Methanol	Not more than 3000	BDL
	iii. Toluene	Not more than 890	1
	iv. Dimethylformamide	Not more than 880	BDL
2.	Benzene content by GC-HS (ppm)	Not more than 2	BDL
3.	Genotoxic impurities by GC (ppm)		
	i. 6-Chloro-2-hexanone	Not more than 1	BDL
	ii. 6-chloro-2-hexanol	Not more than 1	BDL
	iii. 1-bromo-3-chloropropane	Not more than 1	BDL
	iv. 3-chloro-1-propanol	Not more than 1	BDL
4.	Genotoxic impurities-1 by HPLC (ppm)		
	i. Amino methyl nitroso uracil (AMNU)	Not more than 1	BDL
	ii. Cyano acetyl methyl urea (CAMU)	Not more than 1	BDL
5.	Dimethyl sulfate by GC (ppm) Genotoxic impurity.	Not more than 1	Less than 1

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6.	Genotoxic impurities-2 by HPLC (ppm)		
	i. 1-(3-chloropropyl)Theobromine	Not more than 1	BDL
	ii. 1-(3-bromopropyl)Theobromine	Not more than 1	BDL
7.	Palladium content by ICP (ppm)	Not more than 1	Less than 1

Where,

BDL: Below Disregard Limit For Related substance by HPLC.

BDL: Below Detection Limit For Residual Solvents by GC-HS.

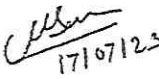
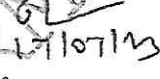
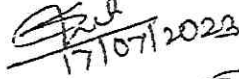
BDL: Below Detection Limit For Benzene content by GC-HS

BDL: Below Detection Limit For Genotoxic impurities by GC.

BDL: Below Detection Limit For Genotoxic impurities by HPLC

Remarks: The product is complies with respect to above mentioned test as per grade Ph.Eur.11.0.

Storage Condition: Protected from light.

 17/07/23 Prepared by QA Chemist (M.M.Ambre)	 17/07/23 Checked by QA Executive (S.A.Wakshe)	 17/07/2023 Approved by Head-QA/Designee Sr.Executive (J.D.Thorat)
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