

QUALITY CONTROL LABORATORY
METAPHARMACEUTICAL

SOP Reference No.: Q/SOP/MS-015

N DE LOTE:

0040423

embio

04/04/2023

CERTIFICATE OF ANALYSIS

1	Name of the Product	Pseudoephedrine HCl Pharm.Eur			
2	CAS No.	[345-78-8]			
3	Customer Name				
4	Batch No.	216620	9	QC Release Date	28 September 2020
5	Quantity Manufactured	1004.220 Kg	10	Manufacturing Date	September - 2020
6	QC Analysis No.	FP/PSE/2009/17	11	Expiry Date	August - 2025
7	Quantity Dispatched	NA	12	Pack Size	NA
8	COA Issue Date: 17 November 2020				

RESULT OF ANALYSIS

Sr.No.	TESTS	RESULTS	LIMITS
1	Characters		
	1.1 Appearance	White crystalline powder	White or almost white crystalline powder, or colourless crystals
	1.2 Solubility	Passes	Freely soluble in water and in ethanol (96%), sparingly soluble in methylene chloride
	1.3 Melting Point (°C)	183.2	About 184.0
2	Identification		
	A) Specific Optical Rotation (Dried substance) (α_D) (°) (At $20.0 \pm 0.5^\circ\text{C}$)	Passes	Between + 61.0 and + 62.5
	B) IR	Complies	IR absorption spectrum of sample must be concordant with the reference spectrum of Pseudoephedrine Hydrochloride.
	D) Chlorides	Positive	Solution gives reaction of chlorides.
3	Appearance of Solution	Clear & Colourless	Must be clear & colourless
4	Acidity or Alkalinity	Passes	On addition of 0.1mL of 0.01M NaOH Solution, the Solution is yellow. On addition of 0.2 mL of 0.01M HCl the Solution is red
5	Specific Optical Rotation (Dried substance) (α_D) (°) (At $20.0 \pm 0.5^\circ\text{C}$)	+ 61.8	Between + 61.0 and + 62.5
*6	Related Substances by HPLC (%w/w)		
	a) Impurity 'A' Ephedrine	BDL	NMT 0.5
	b) Any other impurity	BDL	NMT 0.1
	c) Total Impurities other than 'A'	BDL	NMT 1.0

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Eff.Date:15/01/19

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RESULTS OF ANALYSIS

Sr.No.	TESTS	RESULTS	LIMITS
7	Loss on Drying (% w/w) (At 105°C to constant weight)	0.12	NMT 0.5
8	Sulfated Ash (% w/w)	0.06	NMT 0.1
9	Assay (Potentiometric on dried basis) (% w/w)	100.3	Between 99.0 and 101.0
In-house Tests			
10	Impurities by HPLC (%w/w)		
	a. Individual Specified Impurities		
	i) l-Ephedrine HCl	0.01	NMT 0.10
	ii) Acetyephedrine	Below LOD (0.009)	NMT 0.10
	iii) Benzaldehyde	Below LOD (0.007)	NMT 0.10
	b. Individual Unspecified Impurities	0.003	NMT 0.10
	c. Total Unspecified Impurities	0.003	NMT 0.20
11	d. Total Impurities	0.01	NMT 0.40
	Residual Solvents by GC (ppm)		
	a) Acetone	84	NMT 1000
	b) Toluene	Below LOD (11)	NMT 100

REMARK : 1) The material complies with European Pharmacopoeia 10.0 and In-house Specifications.
2) *Disregard Limit : Below 0.05% 3) Preshipment COA

CONCLUSION : The material referred above complies with the prescribed standard Quality of above Specifications.

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Reviewed By: Chinmay C. Pawar (Jr.Officer QA)	Approved By: Pulak Sarkar (Head Quality)

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