METAPHARMACEUTICAL

N DE LOTE: 0250924

26/09/2024

embio

CERTIFICATE OF ANALYSIS					
1	Name of the Product	**Pseudoephedrine HCl Pharm.Eur**			
2	CAS No.	[345-78-8]			
3	Factory Address	E-21, MIDC Industrial Estate, Mahad, Dist. Raigad, Maharashtra – 402309, India			
4	Customer Name	MAGIS- PHARMA NV			
5	Batch No.	210924	10	QC Release Date	05 August 2024
6	Quantity Manufactured	1003.100 Kg	11	Manufacturing Date	July - 2024
7	QC Analysis No.	FP/PSE/2407/48	12	Expiry Date	June - 2029
8	Quantity Dispatched	100.000 Kg	13	Pack Size	(4 x 25.000 Kg)
9	COA Issue Date: 10 August 2024				

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	a) Freely soluble in water. b) Freely soluble in ethanol (96%) c) Sparingly soluble in methylene chloride
	1.3 Melting Point (°C)	185	About 184
2	Identification		
	A) Specific Optical Rotation (Dried substance) (αD) (°) (At 20.0 ± 0.5°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.
	C) 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) (αD) (°) (At 20.0 ± 0.5°C)	+ 62.1	Between + 61.0 and + 62.5
6	Related Substances by HPLC (%w/w) a) Impurity 'A' Ephedrine b) Any other impurity c) Total Impurities other than 'A'	 BDL (0.05) BDL (0.05) BDL (0.05)	 NMT 0.5 NMT 0.10 NMT 1.0

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RESULTS OF ANALYSIS			
SR.NO.	**TESTS**	**RESULTS**	**LIMITS**
7	Loss on Drying (% w/w) (At 105°C to constant weight)	0.10	NMT 0.5
8	Sulfated Ash (% w/w)	0.06	NMT 0.1
9	Assay by Potentiometric (on dried basis)(%w/w)	99.4	Between 99.0 and 101.0
In-house and additional tests (if any)			
10	Impurities by HPLC (%w/w)		
	a. Individual Specified Impurities i) l-Ephedrine HCl	Below LOQ (0.01)	NMT 0.10
	ii) Acetylephedrine	Below LOD (0.017)	NMT 0.10
	iii) Benzaldehyde	Below LOD (0.003)	NMT 0.10
	b. Individual Unspecified Impurities	Below LOD (0.003)	NMT 0.10
	c. Total Unspecified Impurities	Below LOD (0.003)	NMT 0.20
	d. Total Impurities	Below LOQ (0.01)	NMT 0.40
11	Residual Solvents by GC (ppm)		
	A) Acetone	98	NMT 1000
	B) Toluene	Below LOD (11)	NMT 100
REMARK: The material complies with PHARM.EUR 11.0 and In-house Specifications.			
CONCLUSION : The material referred above complies with the prescribed standard Quality of above Specifications.			

Prepared By: **Rutika Tatkare** **(Chemist QC)** 10/08/24	**Checked By:** **Sarvesh Kumar** **(Sr. Manager QC)** 10/08/24
Reviewed By: **Megha P. Shirke** **(Officer QA)** 10/08/24	**Approved By:** **Pournima Venkatesh** **(Manager QA)** 10/08/24

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