

QUALITY CONTROL LABORATORY
METAPHARMACEUTICAL

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

N DE LOTE:

0020622



08/06/2022

CERTIFICATE OF ANALYSIS

1	Name of the Product	Pseudoephedrine HCl Pharm. Eur			
2	CAS No.	[345-78-8]			
3	Customer Name	FSA Chemicals NV			
4	Batch No.	205522B	9	QC Release Date	20 April 2022
5	Quantity Manufactured	600.650 Kg	10	Manufacturing Date	April - 2022
6	QC Analysis No.	FP/PSE/2204/16	11	Expiry Date	March - 2027
7	Quantity Dispatched	150.0 Kg	12	Pack Size	(06 x 25.0 Kg)
8	COA Issue Date: 04 May 2022				

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)	183.1	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 $20.0 \pm 0.5^\circ\text{C}$)	+ 61.9	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)	0.11	NMT 0.5
8	Sulphated Ash (% w/w)	0.04	NMT 0.1
9	Assay (Potentiometric on dried basis) (% w/w)	100.1	Between 99.0 and 101.0
In-house Tests			
10	Impurities by HPLC (%w/w)		
	a. Individual Specified Impurities		
	i) l-Ephedrine HCl	Below LOQ (0.01)	NMT 0.10
	ii) Acetyephedrine	Below LOD (0.017)	NMT 0.10
	iii) Benzaldehyde	Below LOD (0.003)	NMT 0.10
	b. Individual Unspecified Impurities	Below LOQ (0.01)	NMT 0.10
	c. Total Unspecified Impurities	Below LOQ (0.01)	NMT 0.20
11	d. Total Impurities	Below LOQ (0.01)	NMT 0.40
	Residual Solvents by GC (ppm)		
	A) Acetone	86	NMT 1000
	B) Toluene	Below LOD (11)	NMT 100

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

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

Prepared By: Aishwarya Utekar (Chemist QC)	<i>[Signature]</i> 04/05/22	Checked By: Sarvesh kumar (Sr. Manager QC)	<i>[Signature]</i> 04/05/22
Reviewed By: Megha P. Shirke (Officer QA)	<i>[Signature]</i> 04/05/22	Approved By: Pulak Sarkar (Head Quality)	<i>[Signature]</i> 04/05/22

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