

QUALITY CONTROL LABORATORY

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

METAPHARMACEUTICAL

N DE LOTE:

0240222



23/02/2022

CERTIFICATE OF ANALYSIS

1	Name of the Product	Pseudoephedrine HCl Pharm. Eur			
2	CAS No.	[345-78-8]			
3	Customer Name	FSA NV			
4	Batch No.	209221	9	QC Release Date	20 December 2021
5	Quantity Manufactured	1006.730 Kg	10	Manufacturing Date	December - 2021
6	QC Analysis No.	FP/PSE/2112/14	11	Expiry Date	November - 2026
7	Quantity Dispatched	100.0 Kg	12	Pack Size	(04 x 25.0 Kg)
8	COA Issue Date: 19 January 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)	183.6	About 184.0
2	Identification		
	A) Specific Optical Rotation (Dried substance) (α_D) (°) (At 20.0 $\pm$ 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.
	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°C)	+ 62.0	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

Page 1 of 2

FM/805-0

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)	0.14		NMT 0.5	
8	Sulphated Ash (% w/w)	0.06		NMT 0.1	
9	Assay (Potentiometric on dried basis) (% w/w)	99.6		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		0.02	NMT 0.10	
	c. Total Unspecified Impurities		0.02	NMT 0.20	
11	d. Total Impurities				
			0.02	NMT 0.40	
	Residual Solvents by GC (ppm)				
	A) Acetone		181	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 : 0.05%					
CONCLUSION : The material referred above complies with the prescribed standard Quality of above Specifications.					
Prepared By: Suvarna Yadav (Officer QC)		Checked By: Sarvesh kumar (Sr. Manager QC)			
Reviewed By: Megha Shirke (Officer QA)		Approved By: Pulak Sarkar (Head Quality)			
Page 2 of 2					

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