

QUALITY CONTROL LABORATORY

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

Date: 0181020

embio

CERTIFICATE OF ANALYSIS

1	Name of the Product	Pseudoephedrine HCl BP / Pharm.Eur			
2	CAS No.	[345-78-8]			
3	Customer Name	AZELIS UK LTD.			
4	Batch No.	206720D	9	QC Release Date	20 April 2020
5	Quantity Manufactured	250.300 Kg	10	Manufacturing Date	April- 2020
6	QC Analysis No.	FP/PSE/2004/05	11	Expiry Date	March- 2025
7	Quantity Dispatched	250.0 Kg	12	Pack Size	(10 x 25.0 Kg)
8	COA Issue Date: 16 May 2020				

RESULTS OF ANALYSIS

Sr.No.	TESTS	RESULTS	LIMITS
*9	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
In-house Tests			
10	Impurities by HPLC (%w/w)		
	a. Individual Specified Impurities		
	i) l-Ephedrine HCl	0.02	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	0.004	NMT 0.10
	c. Total Unspecified Impurities	0.004	NMT 0.20
	d. Total Impurities	0.02	NMT 0.40
11	Residual Solvents by GC (ppm)		
	A) Acetone	123	NMT 1000
	B) Toluene	Below LOD (11)	NMT 100

REMARK : 1)The material complies with BP 2018/ PHARM.EUR 9.0 -2017 and In-house Specifications.
2)*Disregard Limit : Below 0.05%

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

Prepared By:
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(Jr.Officer QC)

Suvarna P. Yadav
16/05/20

Checked By:
Sarvesh kumar
(Sr. Manager QC)

Sarvesh Kumar
16/05/20

Reviewed By:
Megha P. Shirke
(Officer QA)

Megha P. Shirke
16/05/20

Approved By:
Pulak Sarkar
(Head Quality)

Pulak Sarkar
16/05/20

Page 2 of 2

FM/805-0

Eff.Date:15/01/19

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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)	183.0	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 0.1 mL of 0.01M NaOH Solution, the Solution is yellow. On addition of 0.2 mL of 0.01M HCl the Solution is red
5	Loss on Drying (% w/w) (At 105°C to constant weight)	0.13	NMT 0.5
6	Specific Optical Rotation (Dried substance) (α_D) (°) (At 20.0 $\pm$ 0.5°C)	+ 61.8	Between + 61.0 and + 62.5
7	Sulphated Ash (% w/w)	0.04	NMT 0.1
8	Assay (Potentiometric on dried basis) (% w/w)	100.4	Between 99.0 and 101.0

Page 1 of 2

FM/805-0

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