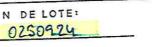
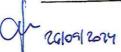
## METAPHARMACEUTICAL

0250924





QUALITY CONTROL LABORATORY SOP Reference No.: Q/SOP/MSC-015



		CERTIFICATE	OF ANAL	YSIS	
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 Augus	st 2024			

	RESU	LT OF ANALYSIS				
SR.NO.	TESTS	RESULTS	LIMITS			
	Characters					
	1.1 Appearance	White crystalline powder	White or almost white crystalline powder, or colourless crystals			
1	1.2 Solubility	Passes	<ul><li>a) Freely soluble in water.</li><li>b) Freely soluble in ethanol (96%)</li><li>c) Sparingly soluble in methylene chloride</li></ul>			
	1.3 Melting Point (°C)	185	About 184			
	Identification					
	A) Specific Optical Rotation ( Dried substance) (αD) (°) ( At 20.0 ± 0.5°C)	Passes	Between + 61.0 and + 62.5			
2	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			
	Related Substances by HPLC (%w/w)					
6	<ul><li>a) Impurity 'A' Ephedrine</li><li>b) Any other impurity</li><li>c) Total Impurities other than 'A'</li></ul>	BDL (0.05) BDL (0.05) BDL (0.05)	NMT 0.5 NMT 0.10 NMT 1.0			

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Effective Date:01/08/23

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Plant

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## **QUALITY CONTROL LABORATORY**

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



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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)							
	Impurities by HPLC (%w/w)		4				
	a. Individual Specified Impurities						
ध।	i) I-Ephedrine HCl	Below LOQ (0,01)	NMT 0.10				
10	ii) Acetylephedrine	Below LOD (0.017)	NMT 0.10				
k:	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				
	Residual Solvents by GC (ppm)						
11	A) Acetone	98	NMT 1000				
	B) Toluene	Below LOD (11)	NMT 100				
	K: The material complies with PHARM.EUR		*				
CONCL	USION: The material referred above complies	with the prescribed standard Qualit	ty of above Specifications.				
Prepared	By:	Checked By:					
	atkar(294 QC) 10 08 24	Sarvesh Kumar					
(Chemist		(Sr. Manager QC) Approved By:	10108124				
Reviewed	.0						
Megha P (Officer		Pournima Venkatesh (Manager OA)					
(Officer QA) (Manager QA)							

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