METAPHARMACEUTICAL IND SL
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PSEUDOEFEDRINA HCL (EUR. PH.)

PRODUCT CODE: 002922	CAS Nº: 345-78-8	ANALYSIS Nº: 242/24	
MANUFACTURER BATCH:	210924	CERTIFICATE ID:	43.534
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/07/2024
METAPH BATCH:	0250924	EXPIRY DATE:	30/06/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals	White crystalline powder
Solubility	Freely soluble in water and in ethanol (96 %), sparingly soluble in methylene chloride	Coomplies (*)
Melting point	about 184 ºC	184.5 ºC
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Acidity or alkalinity	Complies	Complies
Specific optical rotation	+61.0 / +62.5	+61.8
Related substances		
Impurity A	=< 1.0 %	Not Detected
Any other impurity	=< 0.5 %	Not Detected
Sum of impurities other than A	=< 1.0 %	Not Detected
Loss on drying	=< 0.50 %	0.1 %
Sulfated ash	=< 0.10 %	0.07 %
Assay	99.0 - 101.0 %	100.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Pseudoephedrine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Protected from light.

Analysis date: 18/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000914