

PSEUDOEFEDRINA HCL (EUR. PH.)

PRODUCT CODE: 002922	CAS Nº: 345-78-8	ANALYSIS Nº: 083/23
MANUFACTURER BATCH: 216620	CERTIFICATE ID: 37.992	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2020	
METAPH BATCH: 0040423	EXPIRY DATE: 30/08/2025	

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	Complies (*)
Melting point	about 184 °C	183.2 °C (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	Complies	Complies
Specific optical rotation	+61.0 / +62.5	+61.7
Related substances		
Impurity A	=< 1.0 %	Not Detected
Any other impurity	=< 0.5 %	Not Detected
Sum of impurities other than A	=< 1.0 %	< 0.05 %
Loss on drying	=< 0.50 %	0.02 %
Sulfated ash	=< 0.10 %	0.08 %
Assay	99.0 - 101.0 %	100.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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.

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

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: 15/05/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000914
 EMBIO LIMITED
 501, Sentinel, Hiranandani Gardens,
 Powai,
 400 076 Mumbai

