

METILO SALICILATO (EUR. PH.)

PRODUCT CODE: 1285	CAS Nº: 119-36-8	ANALYSIS Nº: 103/24
MANUFACTURER BATCH: RMS2309611	CERTIFICATE ID: 41.859	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 06/04/2023	
METAPH BATCH: 0150424	EXPIRY DATE: 05/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly yellow liquid	Colourless liquid (*)
Identification A	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7	Complies
Acidity	=< 0.4 mL of 0.1 M NaOH	0.10 mL of 0.1 M NaOH
Relative density	1.182 - 1.188	1.1845 (*)
Refractive index	1.535 - 1.538	1.537
Related substances		
Impurity B	=< 50 ppm	38 ppm
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.1 %
Assay	99.0 - 101.0 %	99.0 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) Data controlled by Metapharmaceutical Industrial SL.

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

Keep tightly closed. In a well-ventilated, cool, dry place and away from sources of ignition.

Analysis date: 23/04/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40000359

