

METILO SALICILATO (EUR. PH.)

PRODUCT CODE: 1285	CAS Nº: 119-36-8	ANALYSIS Nº: 238/21
MANUFACTURER BATCH: RMS2022611	CERTIFICATE ID: 32.740	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 13/08/2020	
METAPH BATCH: 0220921	RETEST DATE: 13/08/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly yellow liquid	Slightly yellow liquid
Solubility	Very slightly soluble in water, miscible with ethanol (96 %) and with fatty and essential oils	Complies
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	< 0.01 mL of 0.1 M NaOH
Relative density	1.182 - 1.188	1.185
Refractive index	1.535 - 1.538	1.538
Related substances		
Impurity B	=< 50 ppm	< 50 ppm
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Assay	99.0 - 101.0 %	100.4 %

COMPLIES WITH

European Pharmacopoeia 10.0

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.

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: 04/11/2021
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies

Manufacturer: 40000359

