

TETRACAINA HCL (EUR. PH.)

PRODUCT CODE: 1703	CAS Nº: 136-47-0	ANALYSIS Nº: 042/24
MANUFACTURER BATCH: TH0180823	CERTIFICATE ID: 41.262	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/08/2023	
METAPH BATCH: 0290224	RETEST DATE: 30/07/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, slightly hygroscopic, crystalline powder	White, slightly hygroscopic, crystalline powder
Solubility	Freely soluble in water, soluble in ethanol (96 %)	Complies (*)
Melting range	134 - 150 °C	147 - 148 °C (*)
Identification A	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	4.5 - 6.5	5.3
Related substances		
Impurity A	=< 0.05 %	0.004 %
Impurity B	=< 0.15 %	< 0.05 %
Impurity C	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 1.0 %	0.1 %
Sulfated ash	=< 0.1 %	0.07 %
Assay	99.0 % - 101.0 %	99.7 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Tetracaine 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

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

Analysis date: 12/03/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001021
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