

MEPIVACAINA HCL (EUR. PH.)

PRODUCT CODE: 151390	CAS Nº: 1722-62-9	ANALYSIS Nº: 273/22
MANUFACTURER BATCH: 401	CERTIFICATE ID: 36.819	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 08/04/2022	
METAPH BATCH: 0121222	RETEST DATE: 08/04/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	Whitr crystalline powder
Solubility	Freely soluble in water and in ethanol (96 %), very slightly soluble in methylene chloride	Complies (*)
Melting point	About 260 °C, with decomposition	About 260 °C (*)
Identification A	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B7	Complies
pH	4.0 - 5.0	4.5
Optical rotation	-0.10° / +0.10°	0.00°
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Impurity A	=< 20 ppm	< 20 ppm
Loss on drying	=< 1.0 %	< 0.01 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.5 - 101.0 %	100.2 %
Microbiological control		(*)
TAMC	=< 1000 CFU/g	< 1000 CFU/g
TYMC	=< 100 CFU/g	< 100 CFU/g
Residual solvents [In-house]		(*) (**)
Acetone	=< 1000 ppm	231 ppm

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Mepivacaine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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 certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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 well-ventilated place. Store at room temperature. Keep container closed when not in use.

Analysis date: 03/01/2023
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

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