



TECHNICAL DATA SHEET

002737-TDS-ENG-2024

EPINEFRINA TARTRATO (ADRENALINA TARTRATO) (EUR. PH.)		
DESCRIPTION DCI: ADRENALINE TARTRATE		DESCRIPTION DOE: ADRENALINA TARTRATO
CAS Nº: 51-42-3	EC Nº: 200-097-1	AEMPS CODE: 813TB
MOL. WEIGHT: 333,30	MOL. FORMULA: C13H19NO9	ARTICLE CODE: 002737

ATTRIBUTES	SHOULD BE
Appearance	White or greyish-white, crystalline powder
Solubility	Freely soluble in water, slightly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Specific optical rotation	-53.5 / -50.0
Appearance of solution	Not more opalescent than ref. sus. II Not more intensely coloured than ref. sol. BY5
Related substances	
Impurity A	=< 0.3 %
Impurity B	=< 0.2 %
Impurity C	=< 0.2 %
Impurity D	=< 0.1 %
Impurity E	=< 0.1 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.6 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

In an airtight container, or preferably in a sealed tube under vacuum or under an inert gas, protected from light.

REMARKS

Epinephrine Tartrate 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.