



## TECHNICAL DATA SHEET

002793-TDS-ENG-2025

PROSTAGLANDINA E1 (ALPROSTADIL) (EUR. PH.)		
DESCRIPTION DCI: alprostadil		DESCRIPTION DOE: ALPROSTADIL
CAS Nº: 745-65-3	EC Nº: 212-017-2	AEMPS CODE: 33A
MOL. WEIGHT: 354,48	MOL. FORMULA: C <sub>20</sub> H <sub>34</sub> O <sub>5</sub>	ARTICLE CODE: 002793

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish, crystalline powder
Solubility	Practically insoluble in water, freely soluble in ethanol (96%), soluble in acetone, slightly soluble in ethyl acetate
Identification A	Complies
Identification B	Complies
Identification C	Complies
Related substances	
Impurity A	=< 1,5 %
Impurity B	=< 0,5 %
Any other impurity	=< 0,5 %
Total impurities	=< 1,5 %
Water	=< 0,5 %
Assay	95,0 - 102,5 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store in a dark, dry place at a temperature of 2 to 8 °C.

### REMARKS

Alprostadil 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.