



## TECHNICAL DATA SHEET

009781-TDS-ENG-2019

TADALAFIL EP COS		
DESCRIPTION DCI: TADALAFIL		DESCRIPTION DOE: TADALAFILO
CAS N°: 171596-29-5	EC N°: 687-782-2	AEMPS CODE: 2892A
MOL. WEIGHT: 389.40	MOL. FORMULA: C22H19N3O4	ARTICLE CODE: 009781

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Impurities A, B, and C	
Impurity A	=< 0.15 %
Unspecified impurities	=< 0.10 %
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.3 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %
Residual solvents	
Ethanol	=< 0.5 %
Methylamine	=< 500 ppm

### COMPLIES WITH

European Pharmacopoeia 9.0

### STORAGE

Keep the container tightly closed in a dry and well-ventilated area.

### REMARKS

Tadalafil is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE are available upon request.