



TECHNICAL DATA SHEET

003734-TDS-ENG-2024

SILDENAFIL CITRATO (EUR. PH.)		
DESCRIPTION DCI: SILDENAFIL CITRATE		DESCRIPTION DOE: SILDENAFILO CITRATO
CAS N°: 171599-83-0	EC N°: 638-824-3	AEMPS CODE: 2816CI
MOL. WEIGHT: 666,70	MOL. FORMULA: C22H30N6O4S·C6H8O7	ARTICLE CODE: 003734

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, slightly hygroscopic, crystalline powder
Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane
Identification A	Complies
Impurity E	=< 0.1 %
Related substances	
Impurity A	=< 0.15 %
Impurity D	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total of impurities	=< 0.5 %
Water	=< 2.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.4

STORAGE

Keep in tightly closed containers. Store it in a cool and dry place.

REMARKS

Sildenafil Citrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.