

SILDENAFIL CITRATO (EUR. PH.)

PRODUCT CODE: 003734	CAS Nº: 171599-83-0	ANALYSIS Nº: 212/24
MANUFACTURER BATCH: SLC0400724	CERTIFICATE ID: 43.255	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/04/2024	
METAPH BATCH: 0060824	RETEST DATE: 30/03/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, slightly hygroscopic, crystalline powder	White, slightly hygroscopic, crystalline powder
Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane	Complies (*)
Identification A	Complies	Complies
Impurity E	= < 0.1 %	< 0.1 %
Related substances		
Impurity A	= < 0.15 %	Not Detected
Impurity D	= < 0.15 %	Not Detected
Unspecified impurities	= < 0.10 %	< 0.05 %
Total of impurities	= < 0.5 %	< 0.05 %
Water	= < 2.5 %	1.7 %
Sulfated ash	= < 0.1 %	< 0.1 %
Assay	98.0 - 102.0 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.4

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 16/09/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000276

