

Sildenafil citrate

CODE ARTICLE: 11639	BATCH: 0123398	Active pharmaceutical ingredient
TEST DATE: 20/11/2023	TEST: QC-00258806	
EXPIRY DATE: 28/02/2028	FABRICATION DATE: 30/03/2023	MR: 667,00
CAS: [171599-83-0]	FORMULA: C22H30N6O4S.C6H8O7	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
SOLUBILITY					
SOLUBLE	SLIGHTLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN METHANOL				PH.EUR.*
INSOLUBLE	IN HEXAN				PH.EUR.
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IMPURITY E	<0,1 %			<=0,1	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	<RT=0,05 %			<=0,5	PH.EUR.*
UNSPECIFIED IMPURITIES	<RT=0,05 %			<=0,10	PH.EUR.*
IMPURITY A	N.D. %			<=0,15	PH.EUR.*
IMPURITY D	N.D. %			<=0,15	PH.EUR.*
WATER	0,7 %		0,0	2,5	PH.EUR.*
SULPHATED ASHES	0,04 %		0,0	0,1	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	101 %		98	102	PH.EUR.*
SOLVENT RESIDUE					
METHANOL	10 ppm			1500	Manufacture's Standard
METHYLENE CHLORIDE	N.D. ppm			400	Manufacture's Standard
TOLUENE	N.D. ppm			500	Manufacture's Standard
ETHYL ACETATE	7 ppm			3000	Manufacture's Standard
N,N-DIMETHYL FORMAMIDE	N.D. ppm			500	Manufacture's Standard
ACETONE	11 ppm			3000	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				
NON-sterile					



Silvia Sancho-Tello Ripoll
Technical Director.

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

