

Tadalafil

CODE ARTICLE: 10616	BATCH: 0128467	Active pharmaceutical ingredient
TEST DATE: 12/06/2024	TEST: QC-00265251	
EXPIRY DATE: 30/01/2029	FABRICATION DATE: 01/02/2024	MR: 389,40
CAS: [171596-29-5]	FORMULA: C22H19N3O4	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS			POWDER	PH.EUR.*
COLOUR	PASS			WHITE	PH.EUR.*
SOLUBILITY					
SOLUBLE	PASS -			SLIGHTLY SOLUBLE IN DICHLOROME THANE	PH.EUR.*
SOLUBLE	PASS -			EASILY SOLUBLE IN DMSO	PH.EUR.*
INSOLUBLE	PASS			PRACTICALLY INSOLUBLE IN WATER	PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	PASS				PH.EUR.*
IDENTIFICATION (HPLC)	PASS				PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
SULPHATED ASHES	0,03 %		-	0,1	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	<LQ=0,05% (PASS) -			<= 0.3% (<= 3xarea RS a)	PH.EUR.*
UNSPECIFIED IMPURITIES	<LQ=0,05% (PASS) -			<= 0.10% (<= area RS A)	PH.EUR.*
IMPUREZAS A, B Y C (HPLC)					
UNSPECIFIED IMPURITIES	<LQ=0,05% (PASS) -			<= 0.10% (<= area RS B)	PH.EUR.*
IMPUREZA A	<LQ=0,05% (PASS) -			<= 0.15% (<= 1.5xarea rs b)	PH.EUR.*
ASSAY (DRY SUBSTANCE)	101,8 %		97,5	102	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	< LIMIT OF QUANTIFICATION	ppm		3000	Manufacture's Standard
2- PROPANOL	< LIMIT OF QUANTIFICATION	ppm		5000	Manufacture's Standard
DIMETHYL FORMAMIDE	N.D.	ppm		880	Manufacture's Standard
CLORURO DE METILO	51	ppm		600	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				

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.



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Elemental Impurities ICHQ3D	PASS				



Silvia Sancho-Tello Ripoll
Technical Director.

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