GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Sildenafil citrate

CODE ARTICLE: 8554	**BATCH:** 0117483 **Active pharmaceutical ingredient**
TEST DATE: 24/10/2022	**TEST:** QC-00246951
EXPIRY DATE: 30/07/2027 **FABRICATION DATE:** 30/08/2022	**MR:** 667,00
CAS: [171599-83-0]	**FORMULA:** C22H30N6O4S.C6H8O7
SYNONYMS / BOTANICAL NAME: 5-[2-Ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]phenyl]-1-methyl-3-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one dihydrogen 2-hydroxypropane-1,2,3-tricarboxylate.	
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	SPARINGLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SPARINGLY SOLUBLE IN ETHANOL				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	< DISREGARD LIMIT	%		<=0,5	PH.EUR.*
UNSPECIFIED IMPURITIES	< DISREGARD LIMIT	%		<=0,10	PH.EUR.*
IMPURITY A	N.D.	%		<=0,15	PH.EUR.*
IMPURITY D	N.D.	%		<=0,15	PH.EUR.*
WATER	0,81	%	0,0	2,5	PH.EUR.*
SULPHATED ASHES	0,1	%	0,0	0,1	PH.EUR.*
ASSAY (ANHIDROUS BASIS)	98,1	%	98	102	PH.EUR.*
SOLVENT RESIDUE					
METHANOL	114	ppm		1500	Manufacture's Standard
METHYLENE CHLORIDE	N.D.	ppm		400	Manufacture's Standard
TOLUENE	N.D.	ppm		500	Manufacture's Standard
ETHYL ACETATE	N.D.	ppm		3000	Manufacture's Standard
N,N-DIMETHYL FORMAMIDE	N.D.	ppm		500	Manufacture's Standard
ACETONE	<LOQ	ppm		3000	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 10				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				

This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.

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.

Manufacturer: 52459 R. P. LIMITED (India) Manufacturer Batch: 200190010822 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
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GOOD MANUFACTURING PRACTICE GMP

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TEST	RESULTS	Units	MIN	MAX	METHOD

Silvia Sancho-Tello Ripoll
Technical Director.

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