



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224305

Product:	TADALAFIL
Lot:	224305
Expiry date:	30/05/2027
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C ₂₂ H ₁₉ N ₃ O ₄
Molecular weight:	389,4 g/mol

Assay	Result	Specification	
Identification	Conform (A,C)	Test PhEur (A,C)	
Organoleptic properties	Conform	PhEur	
Impurities A, B and C	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,05 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,7 %	97,5 - 102,0 %	
Impurity A	NDT	<= 0,15 %	
	NDT	<= 0,10 %	
	<= 0,05 %	<= 0,10 %	
Total impurities	<= 0,05 %	<= 0,3 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Elemental impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride.

Conservation:

Date of analysis: 19/09/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00434 SMS PHARMACEUTICALS Ltd.

Manufacturer batch: TAD-0622014

Product	Name	Capacity	Batch
1100050	TADALAFILO	1 g	224305-D-1

1100050	TADALAFILO	1 g	224305-D-2
1100050	TADALAFILO	1 g	224305-D-3
1100050	TADALAFILO	1 g	224305-D-4
1100051	TADALAFILO	25 g	224305-G-1
1100051	TADALAFILO	25 g	224305-G-2
1100051	TADALAFILO	25 g	224305-G-3
1100051	TADALAFILO	25 g	224305-G-4
1100051	TADALAFILO	25 g	224305-G-5
1100055	TADALAFILO	1 kg	224305-P-1
1100055	TADALAFILO	1 kg	224305-P-2
1100055	TADALAFILO	1 kg	224305-P-3

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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