



FAGRON IBERICA S.A.U · JOSEP TAPIOLAS,150 · ES-08226 TERRASSA · BARCELONA
Tel 937310722
Fax 937311644
www.fagron.es

Pg. 1
18/05/2018

Certificado de Análisis

CLOTRIMAZOL

PM	344,8	Fecha de caducidad	28/10/22
Nº CAS	23593-75-1	Nº Análisis / Analysis Nº	KEUR-157605
Nº Producto	30441-00	Nº Lote / Batch No	18A18-B05
Fecha Conclusión	02/02/18	Cod Muestra / Sample No	KEUR-157605
Cod.Fab	F00458	Calidad Final	PH.EUR. 9.3
Nº Lote Fab	CLT/1711/0077A		

INCI

Características Polvo cristalino blanco o amarillo pálido, prácticamente insoluble en agua, soluble en alcohol y cloruro de metileno, poco soluble en éter.

Description White or pale yellowish crystalline, practically insoluble in water, soluble in alcohol and in methylenechloride, slightly soluble in ether.

ENSAYOS/TESTS	ESPECIFICACIONES / SPECIFICATIONS	RESULTADOS / RESULTS	METODO / METHOD	TIPO TEST/TEST TYPE
Identificación	B	Conforme	A0130441-00	External
Sustancias relacionadas	Test Ph.Eur.	Conforme	A0730441-00	External
Pérdida por desecación	<0.5 %	0,2 %	A0830441-00	External
Riqueza	98.5 - 100.5 %	99,5 %	A1030441-00	External
Cenizas sulfúricas	<0.1 %	0.0 %	A1330441-00	External
Disolventes residuales	Test Ph.Eur.	Conforme	AEB30441-00	External
Residuos metálicos	CHMP/SWP/4446/2000	Conforme	BWM30441-00	External

Fabricante AMOLI ORGANICS Pvt. Ltd.
Conservación En envase bien cerrado, protegido de la luz
Storage In a well-closed container
Puede obtener el CoA original en www.fagron.es

Anna Viñas
Directora Técnica Farmacéutica



Amoli Organics Pvt. Ltd.

Regd. Office & Factory : Plot No.322/4, 40 Shed Area, G.I.D.C., Vapi-396 195, Gujarat
Phone : (0260) 2400383, 2400882 Fax : (0260) 2401982
E-mail : vapi@amoliindia.com

CERTIFICATE OF ANALYSIS

Product Name: CLOTRIMAZOLE Ph.Eur.		Sampling Date : 19/11/2017	
Batch No. : <u>CLT/1711/0077A</u>		Mfg. Date : Nov. 2017	
Batch Size : 219.62 Kgs.		Exp. Date : Oct. 2022	
		Released Date : 29/11/2017	
		A.R. No. : ACLT/17/0114	
TEST	OBSERVATION	SPECIFICATION	
Appearance	White crystalline powder	White or pale yellow, crystalline powder.	
Solubility	Complies	Soluble in ethanol (96%) and in methylene chloride, & Practically insoluble in water.	
Identification (A) By Melting Point (B) By IR Spectroscopy (C) By TLC	142.2°C to 144.5°C Conformed Conformed	Melting point 141°C to 145°C The Infrared absorption spectrum of the sample must be concordant with that of Clotrimazole reference/working standard spectrum. The principal spot in the chromatogram obtained with the test solution is similar in position & size of the principal spot in the chromatogram obtained with reference solution.	
Related Substances (By HPLC)	0.03 % 0.02 % Below Detection Limit Below Detection Limit 0.05 % 0.01 % 0.12 %	Impurity-A Not more than 0.2 % Impurity-B Not more than 0.2 % Impurity-D Not more than 0.2 % Impurity-E Not more than 0.2 % Impurity-F Not more than 0.1 % Unspecified Impurities Not more than 0.10 % Total Impurities Not more than 0.5 %	
Loss on drying (At 105°C)	0.12 % (w/w)	Not more than 0.5 % (w/w)	
Sulphated Ash	0.06 % (w/w)	Not more than 0.1 % (w/w)	
Assay (Calculated on dry basis)	99.6 % (w/w)	Not less than 98.5 % and Not more than 100.5 % w/w	
Additional In-House Test			
Residual solvents Acetone Toluene Triethylamine Benzene	193.68 ppm 17.54 ppm Below Detection Limit Below Detection Limit	Not more than 5000 ppm Not more than 890 ppm Not more than 50 ppm Not more than 2 ppm	
Conclusion : The Sample complies as per Ph.Eur. 9.2 & Additional in-house test.			
Sign & Date Name & Designation SOP No. : VQC/O/006	Prepared By	Checked By	Released for Dispatch
	 M.R. Bhandari, Exe. -QC	 R.D. Mehta, Mgr. -QC	 A.N. Nehate, Asst. Mgr. -QA
Format No. : VQC/F/089-00 CLT- Gefco Forwarding Nederland BV, Netherlands-EXP 0855-100			