

Ciclosporin

CODE ARTICLE: 92090	BATCH: 0119769	Active pharmaceutical ingredient
TEST DATE: 18/04/2023	TEST: QC-00252370	
EXPIRY DATE: 30/01/2027	FABRICATION DATE: 28/02/2023	MR: 1203,00
CAS: [59865-13-3]	FORMULA: C62H111N11O12	
SYNONYMS / BOTANICAL NAME: OL-27-40; Ciclosporina a		
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	FREELY SOLUBLE IN ABSOLUTE				PH.EUR.*
	ETHANOL				
SOLUBLE	FREELY SOLUBLE IN				PH.EUR.*
	DICHLOROMETHANE				
INSOLUBLE	PRACTICALLY INSOLUBLE IN				PH.EUR.*
	WATER				
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION (HPLC)	CONFORM				PH.EUR.*
SPECIFIC ROTATION	-190 DEGREES		-193	-185	PH.EUR.*
DISSOLUTION ASPECT	CONFORM -			Limpid and color <Y5, BY5 or R7	PH.EUR.*
LOSS ON DRYING	0,3 %		0,0	2	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
IMPUERZA B+E	0,4 %		-	0,5	PH.EUR.*
IMPURITY G	0,2 %		-	0,4	PH.EUR.*
UNSPECIFIED IMPURITIES	0,3 %		-	0,3	PH.EUR.*
TOTAL IMPURITIES	1,1 %		-	1,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	98,8 %		97	102	PH.EUR.*
RESIDUAL SOLVENTS					
ACETONE	65 ppm		-	4.500	Manufacture's Standard
ETHYL ACETATE	35 ppm		-	2.000	Manufacture's Standard
PARTICLE SIZE					
PARTICLE SIZE 90%	60 MICRONS			In informative	Manufacture's Standard
MICROBIOLOGICAL CONTROL					
TOTAL AEROBICS	<10 UFC/G			1000	Manufacture's Standard
MOLDS AND YEASTS	<10 UFC/G			100	Manufacture's Standard
E. COLI	ABSENT/g				Manufacture's Standard
SALMONELLA	ABSENT/10g				Manufacture's Standard
STAPHYLOCOCCUS AUREUS	ABSENT/g				Manufacture's Standard
PSEUDOMONAS AERUGINOSA	ABSENT/g				Manufacture's Standard
C. ALBICANS	ABSENT/g				Manufacture's Standard

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: 44224 C. B. LTD. (India) Manufacturer Batch: 1213A423045 Manufacturer original CoA available under request

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CAS: [59865-13-3]	FORMULA: C62H111N11O12	
SYNONYMS / BOTANICAL NAME: OL-27-400; Ciclosporina a		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
CLOSTRIDIUM SPOROGENES	ABSENT/g				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				
Risk Assessment Evaluation for Nitrosamines	CONFORM				

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



This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.

Silvia Sancho-Tello Ripoll
Technical Director.

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