

Metronidazole

CODE ARTICLE: 92630	BATCH: 0126250	Active pharmaceutical ingredient
TEST DATE: 26/02/2024	TEST: QC-00261721	
EXPIRY DATE: 30/05/2027	FABRICATION DATE: 13/06/2023	MR: 171,20
CAS: [443-48-1]	FORMULA: C ₆ H ₉ N ₃ O ₃	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS	-		CRYSTAL POWDER	PH.EUR.*
COLOUR	PASS	-		WHITE OR YELLOW	PH.EUR.*
SOLUBILITY					
SOLUBLE	SLIGHTLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN ACETONE				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS	-		<Suspension II y <Sol. GY6	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	0,02	-		<=0,2% (<2xÁrea SR A)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,01	-		<=0,1% (<Área SR A)	PH.EUR.*
LOSS ON DRYING	0,1	%	0,0	0,5	PH.EUR.*
SULPHATED ASHES	0,1	%	0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100	%	99	101	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	<3000	ppm		23000	Manufacture's Standard*
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
ORIGIN PACKAGING MATERIAL	NATURAL PELD				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				

NON-sterile



Silvia Sancho-Tello Ripoll
Technical Director.

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

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: 43205 H. H. P. T. CO., LTD. (China) Manufacturer Batch: 0182306145 Manufacturer original CoA available under request

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