

## Metronidazole

<b>CODE ARTICLE:</b> 97480	<b>BATCH:</b> 0121449	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 01/08/2023	<b>TEST:</b> QC-00255820	
<b>EXPIRY DATE:</b> 28/02/2027	<b>FABRICATION DATE:</b> 14/03/2023	<b>MR:</b> 171,20
<b>CAS:</b> [443-48-1]	<b>FORMULA:</b> C6H9N3O3	
<b>SYNONYMS / BOTANICAL NAME:</b> METRONIDAZOLE; MÉTRONIDAZOLE; [2-(2-metil-5-nitroimidazol-1-il)et.];		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO CRISTAL	PH.EUR.*
COLOUR	CONFORM	-		BLANCO O AMARILLENTO	PH.EUR.*
<b>SOLUBILITY</b>					
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.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM	-		<Suspension II &lt;Sol. GY6	PH.EUR.*
<b>RELATED SUBSTANCES</b>					
TOTAL IMPURITIES	0,04% (PASS)	-		<=0,2% (<2xÁrea SR A)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,02% (CONFORME)	-		<=0,1% (<Área SR A)	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	0,5	PH.EUR.*
SULPHATED ASHES	0,03 %		0,0	0,1	PH.EUR.
ASSAY (DRY SUBSTANCE)	100,8 %		99	101	PH.EUR.*
<b>RESIDUAL SOLVENTS</b>					
METHANOL	PASS	ppm		23000	Manufacture's Standard*
CORRECT BATCH	YES				Manufacture's Standard
ORIGIN PACKAGING MATERIAL	NATURAL	PELD			Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				
Risk Assessment Evaluation for Nitrosamines	PASS				

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



**Silvia Sancho-Tello Ripoll**  
Technical Director.

**Este producto ha sido manipulado en sala NO estéril, para lotes aptos uso estéril consultar disponibilidad.**

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: 0182303185 Manufacturer original CoA available under request

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