

Caffeine

CODE ARTICLE: 98055	BATCH: 0121166	Active pharmaceutical ingredient
TEST DATE: 26/07/2023	TEST: QC-00255671	
EXPIRY DATE: 30/05/2026	FABRICATION DATE: 31/05/2022	MR: 194,20
CAS: [58-08-2]	FORMULA: C8H10O2N4	
SYNONYMS / BOTANICAL NAME: Guaranina; Metilteobromina; Teina; 7-Metilteofilina; 1,3,7-Trimetilxantina		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO	PH.EUR.*
COLOUR	CONFORM	-		BLANCO	PH.EUR.*
SOLUBILITY					
SOLUBLE	SPARINGLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN HOT WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN				PH.EUR.*
IDENTIFICATION					
MELTING POINT	238 °C		234	239	PH.EUR.*
IR IDENTIFICATION	CONFORM				PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
DISSOLUTION ASPECT	CONFORM	-		clean and colorless	PH.EUR.*
ACIDITY	CONFORM	ml NaOH 0.01M		<=0,2	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	<LQ=0,05% (PASS)	-		<=0,5xArea SR A (0,10%)	PH.EUR.*
INDIVIDUAL IMPURITIES	<LQ=0,05% (PASS)	-		<=0,5xArea SR A (0,10%)	PH.EUR.*
SULPHATES	<500 ppm			<=500	PH.EUR.*
SULPHATED ASHES	0,1 %			<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,2 %		98,5	101,5	PH.EUR.*
RESIDUAL SOLVENTS					
CHLOROFORM	CONFORM	ppm		<=60	Manufacture's Standard
HEAVY METALS	<0,001 %			<=0,001	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR	11			Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

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: 43307 S. X. PHARMACEUTICAL, CO., LTD. (China) Manufacturer Batch: 2205982 Manufacturer original CoA available under request

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