

Caffeine

CODE ARTICLE: 98055	BATCH: 0127976	Active pharmaceutical ingredient
TEST DATE: 13/05/2024	TEST: QC-00264273	
EXPIRY DATE: 30/01/2027	FABRICATION DATE: 03/01/2023	MR: 194,20
CAS: [58-08-2]	FORMULA: C ₈ H ₁₀ O ₂ N ₄	
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	PASS -			CRYSTALLINE POWDER	PH.EUR.*
COLOUR	PASS -			WHITE	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	SPARINGLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN BOILING WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN ETHANOL 96°				PH.EUR.*
<u>IDENTIFICATION</u>					
MELTING POINT	237 °C		234	239	PH.EUR.*
IR IDENTIFICATION	PASS				PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
DISSOLUTION ASPECT	PASS -			CLEAR AND COLOURLESS	PH.EUR.*
ACIDITY	PASS ml NaOH 0.01M			<=0,2	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	< DL (0,05%) -			<=0,1	PH.EUR.*
INDIVIDUAL IMPURITIES	< DL (0,05%) -			<=0,1	PH.EUR.*
SULPHATES	<500 ppm			<=500	PH.EUR.*
SULPHATED ASHES	0,1 %			<=0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,2 %		98,5	101,5	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
CHLOROFORM	PASS ppm			<=60	Manufacture's Standard
HEAVY METALS	<0,001 %			<=0,001	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	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: 43307 S. X. PHARMACEUTICAL, CO., LTD. (China) Manufacturer Batch: 2301038 Manufacturer original CoA available under request

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