Caffeine (CAS number- 58-08-2)

SPECIFICATIONS. CAFFEINE ANHYDROUS BP, USP

Taj Active Pharmaceuticals Ingredients (CNS STIMULANT)

TAJNW-CCTWAMT770

www.tajapi.com

Active Pharmaceutical Ingredients TAJ PHARMACEUTICALS LIMITED INTIA

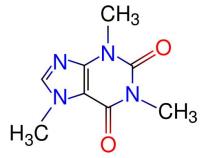












STANDARD TESTING SPECIFICATIONS

CAFFEINE ANHYDROUS BP, USP

Product information Grade Ph Eur, BP, USP Synonyms: 7-Methyltheobromine, 1,3,7-Trimethylxanthine, 3,7-Dihydro-1,3,7-trimethyl-1Hpurine-2,6-dione Hill Formula C₈H₁₀N₄O₂ HS Code 2939 30 00 EC number : TAJNW-CCTWAMT770 Molar mass 194.19 g/mol EC index number TAJNW-CFV CAS number : 58-08-2

1. Description : A white, crystalline powder or silky, white crystals, sublimes readily.

2. Solubility : Sparingly soluble in water, freely soluble in boiling water, slightly soluble in ethanol. It dissolves in concentrated solutions of alkali benzoates or salicylates. 3. Identification : A. Melting Point: 234° C to 239° C B. Infrared absorption spectrophotometry C,D. Chemical Test E. Loss on drying F. Reaction of xanthines 4. Appearance of solution : To meet the test. 5. Acidity : Not more than 0.2ml of 0.01M NaOH is required 6. Related Substances : Thin-Layer Chromatography 7. Sulphates : Not more than 500 ppm 8. Heavy Metals : Not more than 10 ppm Pb 9. Loss on drying : Not more than 0.5% 10. Sulphated Ash : Not more than 0.1% 11. Assay

(on dried basis)

: Not less than 98.5%

Not more than 101.5%

Transport information

Declaration (railroad and road) ADR, RID Declaration (transport by sea) IMDG-Code Declaration (transport by air) IATA-DGR LD 50 oral LD50 rat 261 - 381 mg/kg

LD 50 dermalLD50 rat > 2000 mg/kg

Specifications

	Specification
Assay	
- perchloric acid titration,	
calculated on dried	98.5 - 101.0 %
substance - HPLC	98.5 - 101.0 %
Identity	passes test
Appearance of	
solution (1 %; water)	passes test
Acidic substances	passes test
Sulphate (SO₄)	≤ 0.0500 %
Heavy metals (as Pb)	≤ 0.001 %
Chloroform (HS-GC)	≤ 60 ppm
related substances (HPLC,	
EP) - Highest single impurity	≤ 0.10 %
- Sum of all impurities	< 0.1 %
chromatographic purity	_ 011 /0
(USP)	< 0.10 %
- Highest single impurity	≤ 0.10 %
 Sum of all impurities 	≤ 0.1 %
Theophylline (HPLC)	≤ 0.10 %
Other residual	excluded by production process
Sulfated ash	≤ 0.1 %
Loss on drying (105 °C)	≤ 0.5 %
,	

Residues of metal catalysts or metal reagents acc. to EMEA/C HMP/SWP/4446/2000 are not likely to be present.

Corresponds to Ph Eur, BP, USP

Chemical and physical data

Ignition temperatur Solubility Melting point Molar mass Density Bulk density pH value Vapor pressure	e >600 °C 20 g/l (20 °C) 235 - 239 °C 194.19 g/mol 1.23 g/cm3 (18 °C) 300 - 600 kg/m3 5.5 - 6.5 (10 g/l, H ₂ O, 20 °C) 20 hPa (80 °C) Safety information according to GHS
Hazard Statement(s Signal Word) H301: Toxic if swallowed. Danger
Hazard Pictogram(s	
Storage class WGK	10 - 13 Other liquids and solids WGK 1 slightly water endangering 3
Disposal	Relatively unreactive organic reagents should be collected in container A. If halogenated, they should be collected in container B. For solid residues use container C. Safety information
R Phrase	R 22 Harmful if swallowed.
Categories of danger	harmful

Hazard Symbol



Packaging

Plastic bottle	1KG
Fibre carton	50 kg

Origin: INDIA

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**** (CNS STIMULANT)