

TECHNICAL DATA SHEET

002544-TDS-ENG-2019

SINEFRINA TARTRATO			
DESCRIPTION DCI: SYNEPHRINE		DESCRIPTION DOE: SINEFRINA	
CAS Nº: 16589-24-5	EC Nº: 240-647-8		AEMPS CODE: 8158A
MOL. WEIGHT: 167.205	MOL. FORMULA: 2(C9H13NO2).C4H6O6		ARTICLE CODE: 002544

ATTRIBUTES SHOULD BE

Appearance White or almost white, crystalline powder

Identification ACompliesIdentification BCompliesIdentification CCompliesIdentification DComplies

Appearance of solution Clear and colorless

5.0 - 6.5 рΗ Specific optical rotation +11 / +15 =< 0.1 % Ketones Melting point 176 - 187 °C Iron =< 5 ppm Heavy metals =< 10 ppm Arsenic =< 1 ppm Cadmium =< 1 ppm Mercury =< 0.1 ppm Lead =< 3 ppm =< 0.5 % Loss on drying Sulfated ash =< 0.1 %

Residual solvents

Assay

Ethanol =< 5000 ppm

Microbiological control

 $\begin{array}{lll} {\sf TAMC} & = < 1000 \ {\sf UFC/g} \\ & = < 100 \ {\sf UFC/g} \\ & = < 1000 \ {\sf UF$

COMPLIES WITH

Manufacturar Specifications

STORAGE

Store in a cool, dry and well-ventilated place.

REMARKS

Synephrine Tartrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

=> 99.0 %

Certificates of residual solvents, non-GMO and BSE-TSE are available upon request.