



TECHNICAL DATA SHEET

002803-TDS-ENG-2019

DIOSMINA		
DESCRIPTION DCI: DIOSMIN		DESCRIPTION DOE: DIOSMINA
CAS Nº: 520-27-4	EC Nº: 208-289-7	AEMPS CODE: ---
MOL. WEIGHT: 608.5	MOL. FORMULA: C ₂₈ H ₃₂ O ₁₅	ARTICLE CODE: 002803

ATTRIBUTES	SHOULD BE
Appearance	Greyish-yellow or light yellow hygroscopic powder
Solubility	Practically insoluble in water, soluble in dimethyl sulfoxide, practically insoluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides
Identification A	Complies
Identification B	Complies
Iodine	=< 0.1 %
Related substances	
Impurity B	=< 4.0 %
Impurity C	=< 3.0 %
Impurity E	=< 3.0 %
Impurity F	=< 2.0 %
Impurity D	=< 0.6 %
Impurity A	=< 0.5 %
Unspecified impurities	=< 0.4 %
Total impurities	=< 8.5 %
Water	=< 6.0 %
Sulfated ash	=< 0.2 %
Assay	90.0 - 102.0 %
Residual solvents	
Pyridine	=< 200 ppm
Microbiological control	
TAMC	< 1000 CFU/g
TYMC	< 100 CFU/g
Coliforms	Absence/1g

COMPLIES WITH

European Pharmacopoeia 9.0

STORAGE

In full and well closed container. Keep at room temperature in a dark and dry place.

REMARKS

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

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

Mechanism of action

Venotonic and vasoprotective agent (produces a venoconstricción, increase in the resistance of the vessels and decrease in their permeability).



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Therapeutic indications

Short-term relief of edema and symptoms related to insuff. chronic venous

Administration

Orally. Take with meals.

Contraindications

Hypersensitivity to flavonoids.

Adverse reactions

Nausea, vomiting, diarrhea, dyspepsia.