



TECHNICAL DATA SHEET

1983-TDS-ENG-2025

PRAZICUANTEL (EUR. PH.)		
DESCRIPTION DCI: PRAZIQUANTEL		DESCRIPTION DOE: PRAZICUANTEL
CAS Nº: 55268-74-1	EC Nº: 259-559-6	AEMPS CODE: 5001A
MOL. WEIGHT: 312,41	MOL. FORMULA: C ₁₉ H ₂₄ N ₂ O ₂	ARTICLE CODE: 1983

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Very slightly soluble in water, freely soluble in ethanol (96 %) and in methylene chloride
Identification	Complies
Related substances	
Impurity A	=< 0.2 %
Impurity B	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a well ventilated place. Protect from light.

REMARKS

Praziquantel is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

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

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.