



TECHNICAL DATA SHEET

009415-TDS-ENG-2024

RONIDAZOLE USO VETERINARIO (BRIT. PH.)		
DESCRIPTION DCI: ronidazole		DESCRIPTION DOE: RONIDAZOL
CAS Nº: 7681-76-7	EC Nº: 231-675-1	AEMPS CODE: 90731A
MOL. WEIGHT: 200,15	MOL. FORMULA: C ₆ H ₈ N ₄ O ₄	ARTICLE CODE: 009415

ATTRIBUTES	SHOULD BE
Appearance	A white to yellowish brown powder; odourless or almost odourless
Melting point	about 167 °C
Identification A	Complies
Identification B	Complies
Identification C	Complies
Solution color	Not more intensely coloured than ref. sol. Y6
(1-Methyl-5-nitroimidazol-2-yl) methanol	=< 0.5 %
Water	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

British Pharmacopoeia 2023

STORAGE

Store in a dry and well-ventilated place, and protected from the light.

REMARKS

Ronidazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.