

RONIDAZOLE (BP - Veterinary Use)

PRODUCT CODE: 009415	CAS N°: 7681-76-7	ANALYSIS N°: 173/21
MANUFACTURER BATCH: 3034/00882	CERTIFICATE ID: 32.235	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 30/09/2020	
METAPH BATCH: 0010721	RETEST DATE: 31/08/2023	

ATTRIBUTES	SHOULD BE	IS
Appearance	A white to yellowish brown powder; odourless or almost odourless	Yellowish brown powder; odourless
Melting point	about 167 °C	169.5 °C
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Colour of solution (1-Methyl-5-nitroimidazol-2-yl) methanol	Not more intensely coloured than ref. sol. Y6 = < 0.5 %	Complies (*) = < 0.50 % (*)
Water	= < 0.5 %	0.18 %
Sulfated ash	= < 0.1 %	0.06 %
Assay	98.5 - 101.0 %	100.1 %

COMPLIES WITH

British Pharmacopoeia 2021

REMARKS

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

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.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

STORAGE

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

Analysis date: 07/07/2021
 Signature: Ferran Gonzalez de Rivera Riera (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000241

