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CERTIFICATE OF ANALYSIS

CA.3034/014/11

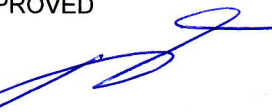

Product name:	RONIDAZOLE	CAS Number:	[7681-76-7]
Chemical name:	(1-methyl-5-nitroimidazol-2-yl)methyl carbamate		
Molec.Formula:	C ₆ H ₈ N ₄ O ₄	Molec.Weight:	200.2
Batch N°:	3034/60852-3	Delivered qty.:	0.5 kg
Date of Manufacture:	FEB-2016	Retest Date:	JAN-2019

TESTS	SPECIFICATIONS	RESULTS
Appearance	White to yellowish-brown powder. Odourless or almost odourless.	Complies
Solubility	Slightly soluble in water, in chloroform and in ethanol (96%). Very slightly soluble in ether.	Complies
Identification		
IR Spectrum	Concordant with the reference spectrum.	Complies
UV Spectrum	Absorbance at maximum 270 nm about 0.64.	Complies
Melting point	About 167°C.	169°C
Colour of solution	A 0.5% w/v solution in methanol is not more intensely coloured than reference solution Y ₆ .	Complies
TLC		
(1-methyl-5-nitroimidazol-2-yl)methanol	Not more than 0.5%.	Complies
Water	Not more than 0.5% w/w.	0.06%
Sulphated ash	Not more than 0.1%.	0.02%
Assay (Titration)	98.5 - 101.0% on anhydrous substance.	99.1%

nd: not detected

NOTE: The product meets the requirements of the current BPV monograph for Ronidazole.

Date of issue: 03/02/17

QC Responsible APPROVED  A. PERA 22/02/16	Quality Manager APPROVED  C. HERNÁNDEZ 22/02/16
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