



Ide: 0151217

MENADIONA
Pol. Ind. Mas Puigvert s/n
08389 PALAFOLLS
BARCELONA – SPAIN
Phone: (+34) 937.640.711
Fax: (+34) 937.640.725

CERTIFICATE OF ANALYSIS

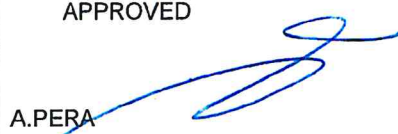

CA.3034/014/11

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|-----------------------------|---|----------------------|--------------------|
| Product name: | RONIDAZOLE | CAS Number: | [7681-76-7] |
| Chemical name: | (1-methyl-5-nitroimidazol-2-yl)methyl carbamate | | |
| Molec.Formula: | C₆H₈N₄O₄ | Molec.Weight: | 200.2 |
| Batch N°: | 3034/70860 | | |
| Date of Manufacture: | SEP-2017 | Retest Date: | AUG-2020 |

| 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. | 167°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. | 0.03% |
| Sulphated ash | Not more than 0.1%. | 0.01% |
| Assay (Titration) | 98.5 - 101.0% on anhydrous substance. | 99.5% |

nd: not detected

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

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| Q.Laboratory Manager APPROVED  A. PERA 21/09/17 | Quality Director APPROVED  C. HERNÁNDEZ 21/09/17 |
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