Institute for Reference Materials and Measurements

ERM European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- BB124

PORK MUSCLE		
Nitroimidazoles in the reconstituted material [1]	Mass fraction	
	Certified value [3] [µg/kg]	Uncertainty [4] [µg/kg]
Ronidazole (RNZ) [2]	2.09	0.25
Metronidazole (MNZ) [2]	1.93	0.15
2-hydroxymethyl-1-methyl-5-nitroimidazole (HMMNI) [2]	0.69	0.09
Hydroxymetronidazole (MNZOH) [2]	6.2	0.9
Hydroxyipronidazole (IPZOH) [2]	1.67	0.12

1) Values are applicable to the material when reconstituted according to the specified procedure (page 3).
2) The measurand is defined by quantification with liquid chromatography-isotope dilution mass spectrometry. Different sample preparation procedures (extraction and clean-up) were applied.
3) The certified values are the unweighted mean of 11 - 12 accepted set of results, independently obtained in 10 - 11 laboratories, using the calibration solution provided. The values are traceable to the International System of Units (SI).
4) Expanded uncertainty with a coverage factor k = 2 corresponding to a level of confidence of about 95 % estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM), ISO, 1995.

Nitroimidazole in the reconstituted material [1]	Mass fraction
	Certified value [3] [µg/kg]
Dimetridazole (DMZ) [2]	< 0.25

1) Values are applicable to the material when reconstituted according to the specified procedure (page 3).
2) The measurand is defined by quantification with liquid chromatography-isotope dilution mass spectrometry.
3) This value corresponds to the limit of quantification (LOQ) of the most sensitive method in the characterisation study. With a probability of 95% the certified value is below 0.25 µg/kg. The value is traceable to the International System of Units (SI).

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 5 g reconstituted material (prepared using 1.25 g of powder).

Accepted as an ERM®, Geel, October 2008

Signed:

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JRC EUROPEAN COMMISSION

NOTE

European Reference Material ERM®-BB124 was produced and certified under the responsibility of the Institute for Reference Materials and Measurements of the European Commission's Joint Research Centre according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (http://www.erm-crm.org).

DESCRIPTION OF THE SAMPLE

One unit contains 10 g of lyophilised pork muscle tissue filled under inert gas in a 100 mL amber glass bottle. The content corresponds to 40 g of fresh muscle tissue derived from animals to which nitroimidazoles have been administered (incurred material). The water mass fraction of the lyophilised powder is 32.6 ± 0.2 g/kg.

ANALYTICAL METHOD USED FOR CERTIFICATION

All results were obtained employing liquid chromatography-isotope dilution mass spectrometry methods. Different sample preparation procedures (extraction and clean-up) were applied.

Note: The occurrence of a biased result cannot be excluded in case GC-MS is used for sample analysis (for details please refer to the certification report).

PARTICIPANTS

Agence Française de Sécurité des Aliments, Laboratoire d'Etudes et de Recherches sur les Médicaments Vétérinaires et les Désinfectants (FR)
(Measurements performed under ISO/IEC 17025 accreditation; COFRAC 1-0247)

Agri-Food and Biosciences Institute, Veterinary Sciences Division (GB)
(Measurements performed under ISO/IEC 17025 accreditation; UKAS 2632)

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (DE)
(Measurements performed under ISO/IEC 17025 accreditation; AKS-PL-12005)

C.E.R. Groupe, Laboratoire d'Hormonologie (BE)
(Measurements performed under ISO/IEC 17025 accreditation; Beltest 103-T)

Chemisches und Veterinäruntersuchungsamt Freiburg (DE)
(Measurements performed under ISO/IEC 17025 accreditation; SAL-BW-L14-03-03)

Chemisches und Veterinäruntersuchungsamt Ostwestfalen-Lippe (DE)
(Measurements performed under ISO/IEC 17025 accreditation; SAL-NRW-L04-01-03)

European Commission, Joint Research Centre, Institute for Reference Materials and Measurements (IRMM) (BE)

Institut Scientifique de Santé Publique (BE)
(Measurements performed under ISO/IEC 17025 accreditation; BELAC 081-TEST)

Kantonales Labor Zürich (CH)
(Measurements performed under ISO/IEC 17025 accreditation; STS 172)

LGC Limited (GB)
(Measurements performed under ISO/IEC 17025 accreditation; UKAS 0003)

RIKILT – Institute of Food Safety (NL)
(Measurements performed under ISO/IEC 17025 accreditation; RvA L014)

SAFETY INFORMATION

The usual laboratory safety precautions apply.

INSTRUCTIONS FOR USE AND INTENDED USE

This material is intended to be used for method performance control and validation purposes.

For assessing the method performance, the measured values of the CRMs are compared with the certified values following a procedure described by Linsinger [Comparison of a measurement result with the certified value, ERM Application Note 1, July 2005, http://www.erm-crm.org]. The procedure is described here in brief:

- Calculate the absolute difference between mean measured value and the certified value (Δ_m).

- Combine measurement uncertainty (u_{meas}) with the uncertainty of the certified value (u_{CRM}):

$$u_{\Delta} = \sqrt{u_{meas}^2 + u_{CRM}^2}$$

- Calculate the expanded uncertainty (U_{Δ}) from the combined uncertainty (u_{Δ}) using a coverage factor of two (k = 2), corresponding to a confidence interval of approximately 95 %.
- If $\Delta_m \leq U_{\Delta}$ then there is no significant difference between the measurement result and the certified value, at a confidence level of about 95 %.

Reconstitution of the sample

- Allow the bottle to warm up to ambient temperature before opening.
- Weigh accurately an aliquot of 1.25 ± 0.01 g. The weighing should be performed immediately after opening of the vial to minimise water uptake by the lyophilised powder.
- Add an accurately weighed amount of 3.75 ± 0.01 g of distilled water to the powder.
- In case the working instruction of the laboratory's method foresees a higher sample intake than 5 g of reconstituted material, the 1:3 m/m ratio of powder to distilled water has to be maintained.
- Mix to a homogeneous sample, for instance by vortexing the mixture for at least 1 min at maximum speed. Proceed with the sample preparation as foreseen in the laboratory's working instruction.

STORAGE

The material should be stored at a temperature of - 20 ± 2 °C.

However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.

LEGAL NOTICE

NOTE

A detailed technical report is available on www.erm-crm.org. A paper copy can be obtained from the Joint Research Centre, Institute for Reference Materials and Measurements on request.

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