Rzeszów, dnia 22.02.2024 r.

Odpowiedzi na pytania Wykonawcy II

Dotyczy: Zapytania ofertowego „Sukcesywna dostawa odczynników chemicznych i wzorców dla Wojewódzkiej Stacji Sanitarno- Epidemiologicznej w Rzeszowie"

Znak sprawy: OZ.272.1.5.2024.AO

Wojewódzka Stacja Sanitarno- Epidemiologiczna w Rzeszowie, przekazuje odpowiedzi na pytania Wykonawcy, które wpłynęły do Zamawiającego w dniu 21.02.2024 r. i dotyczyły zapisów Zapytania ofertowego i jego załączników:

Pytanie 1

Dotyczy Pakiet nr 3:

Pozycja 5 - 10003661 AFLATOXIN M1 - 0.5 µg/mL, 1 ML - nie jest produkowana przez Romer Labs metodą zgodnie z normą ISO 17034. Czy Zamawiający wyrazi zgodę na zaproponowanie tego wzorca bez akredytacji ISO 17034. W załączeniu certyfikat produktu.

Odpowiedź:

Zamawiający wyraża zgodę na dostarczenie zaproponowanego wzorca.

Pytanie 2

Dotyczy Pakiet nr :

Wzorce Romer Labs dostępne są aktualnie z następującymi terminami ważności:

Pozycja 7. 10006718 Biopure Zearalenone (CRM, ISO 17034) - 100 µg/mL in acetonitrile, 1 ml - termin ważnosci 20.02.2025

Pozycja 10. 10006719 Biopure Ochratoxin (CRM, ISO 17034) - 10 µg/mL in acetonitrile, 5 ml - termin ważnosci 15.01.2025

Czy Zamawiający wyrazi zgodnnę na zaoferowanie wzorców z podanymi wyżej terminami ważności?

Odpowiedź:

Zamawiający wyraża zgodę na dostarczenie wzorców z podanymi terminami ważności, z zastrzeżeniem możliwości zakupu materiałów z nowymi datami ważności w sytuacji recertyfikacji.

Z upoważnienia
DYREKTORA
Wojewódzkiej Stacji Sanitarno Epidemiologicznej
w Rzeszowie
Z-CA PODKARPACKIEGO PAŃSTWOWEGO
WOJEWÓDZKIEGO INSPEKTORA SANITARNEGO

mgr Dorota Gibała

AFLATOXIN M1 IN ACETONITRILE

1. General information

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO Guide 31 [1] and Eurachem / CITAC Guides [2,3].

2. Description of the Reference Material (RM)

Name:	Aflatoxin M1 in acetonitrile
CAS number:	6795-23-9
Catalog number:	10000349 (5 mL), 10003661 (1 mL)
Lot #:	1000069476
Certificate version:	1
Expiry date:	12.08.2026
Starting material:	Aflatoxin M1, Lot #S16142M, Romer Labs Diagnostic GmbH
Matrix:	Acetonitrile, LiChrosolv Lot # I1240730241, Merck 1000302500
Physical description of RM:	Solution of Aflatoxin M1 in acetonitrile
Packaging and amount of RM:	10000349: Amber glass ampoules fitted with teflon faced butyl septa and PP screw caps, solution of 5 mL 10003661: Amber glass ampoules fitted with teflon faced butyl septa and aluminium crimp cap, solution of 1 mL
Name and address of the supplier:	Romer Labs Division Holding GmbH Technopark 5 3430 Tulln, Austria www.romerlabs.com, office.romerlabseu@dsm.com

2.1 Intended use of the RM

- for laboratory use only
- calibration of analytical instruments

2.2 Instruction for the correct use of the RM

The ampoules should be stored at -18 to -22°C or below in a dark place. Before usage of the RM, the ampoules should be allowed to warm to room temperature. The recommended minimum sub-sample amount for all kinds of application is 100 µL. The expiry date of this RM is based on the current knowledge and holds only for proper storage conditions in the originally closed flasks/packages.

2.3 Hazardous situation

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available as material safety data sheet (MSDS).

3. Certified values and their uncertainties

Aflatoxin M1 in acetonitrile		
Compound	Mass concentration [a]	
	Certified value [b]	Uncertainty [c]
Aflatoxin M1	0.502 µg/mL	± 0.01 µg/mL

[a] Values are based on preparation data and confirmed experimentally by HPLC-UV
[b] Mass concentration based on weighed amount, purity and dilution steps
[c] Expanded uncertainty U (k = 2) of the value u_c according to GUM [4]

3.1 Calculation of uncertainty

The uncertainty of the calibrant solution was calculated on the basis of preparation [5].

Uncertainty components	Description	Standard uncertainty (u)	
Purity (P) of solid Aflatoxin M1 (the uncertainty of the purity corresponds to the standard deviation of repeated measurements)	P = 99 ± 1 %	u (P) = 0.6 %	a
Weighing procedure weighted sample: m_{ws}= 2.536 mg	U(m) = 0.0019 mg + 7.83 * 10^{-6} * m_{Toxin} u(m) = U(m)/2	u (m) = 0.001 mg	b
Dilution procedure volumetric flask 1: V_{f1} = 250 mL volumetric flask 2: V_{f2} = 500 mL one-mark glass pipette: V_p = 25 mL	calibration flask 1: 250 mL ± 0.15 mL repeatability flask 1: 0.03 mL volume expansion solvent flask 1	u (cal1) = 0.06 mL u (rep1) = 0.03 mL u (Vol. exp.1) = 0.59 mL u (V1) = 0.59 mL	c d e f
	calibration flask 2: 500 mL ± 0.25 mL repeatability flask 2: 0.1 mL volume expansion solvent flask 2	u (cal2) = 0.1 mL u (rep2) = 0.1 mL u (Vol. exp.2) = 1.2 mL u (V2) = 1.2 mL	g h i j
	calibration pipette: 25 mL ± 0.03 mL volume expansion solvent pipette	u (cal3) = 0.01 mL u (Vol. exp.3) = 0.06 mL u (V3) = 0.06 mL	k l m

[a] Maximum tolerance of purity was divided by $\sqrt{3}$

[b] Calculation of this u-value is based upon the uncertainty formula for the weighed amount as given in the calibration report from annual balance calibration

[c,g,k] A triangular distribution (division by $\sqrt{6}$) was chosen for the calculation of u (cal)

[d,h] Based on a series of ten fill and weigh experiments on a typical 250 and 500 mL flask; the values were used directly as a standard deviation

[e,i,l] Based on the density of 0.7857 g/cm³ at temperature T = 20°C and a maximum temperature variation of ± 3°C, of volume expansion relative volume expansion coefficient of acetonitrile is 1370 * 10^{-6}/°C [6], volume expansion term (rectangular distribution) was divided by $\sqrt{3}$

[f,j,m] All contributions are combined to give the u (V) = $\sqrt{u(cal)^2 + u(rep)^2 + u(Vol. \exp.)^2}$

Calculation of the combined uncertainty u_c and the expanded standard uncertainty U

$$c_{Toxin} = \frac{10 \times m_{ws} \times P \times V_p}{V_{f1} \times V_{f2}} = \frac{10 \times 2.536 \times 99 \times 25}{250 \times 500} = 0.502 \; mg/L$$

$$\frac{u_c(c_{Toxin})}{c_{Toxin}} = \sqrt{\left[\frac{u(P)}{P}\right]^2 + \left[\frac{u(m)}{m_{ws}}\right]^2 + \left[\frac{u(V1)}{V_{f1}}\right]^2 + \left[\frac{u(V2)}{V_{f2}}\right]^2 + \left[\frac{u(V3)}{V_p}\right]^2} = \sqrt{\left[\frac{0.6}{99}\right]^2 + \left[\frac{0.001}{2.536}\right]^2 + \left[\frac{0.59}{250}\right]^2 + \left[\frac{1.2}{500}\right]^2 + \left[\frac{0.06}{25}\right]^2} = 0.007$$

$$u_c(c_{Toxin}) = c_{Toxin} \times 0.007 = 0.502 \times 0.007 = 0.004 \, mg/L$$

Calculation of expanded standard uncertainty U using a coverage factor k = 2

$$U(c_{Toxin}) = u_c(c_{Toxin}) \times 2 = 0.004 \times 2 = 0.008 \, mg/L = 0.01 \, \mu g/mL$$

4. Discussion of traceability

This calibrant is certified on the basis of gravimetric preparation [5]. Thus the certified value (mass concentration of Aflatoxin M1) is based on the weighed amount of the starting material and is therefore traceable to the stated purity of the solid raw material. High purity material represents a practical realization of concentration units, through conversion of mass to molar quantity.

5. Confirmation of certified value by HPLC-UV

The certified concentration of Aflatoxin M1 of the gravimetric prepared solution was confirmed by HPLC-UV against an independently prepared reference batch of Aflatoxin M1.

column	Phenomenex Kinetex C18, 100x 3mm, 2.6µmm
injection volume	25 µL sample
solvent A	water / acetonitrile / methanol 57/17/26
oven	35°C
flow rate	0.5 mL / min
DAD settings	365 nm
sample dilution	1:5 with solvent A

Figure 1: HPLC-UV chromatogram of Aflatoxin M1 calibrant

	time	area	height	concentration [a]
Aflatoxin M1	3.147	0.489	2.741	0.510 ± 0.015 µg/mL

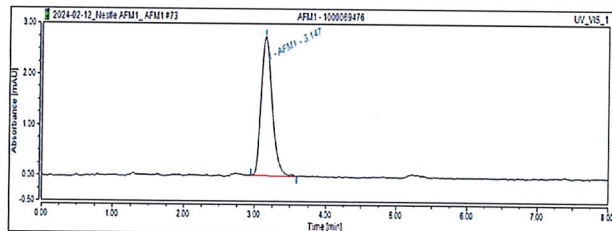[a] Mean of 6 replicate measurements against reference batch, confidence interval with P = 95 %

6. Further information

The purchaser must determine the suitability of this product for its particular use. Romer Labs Division Holding GmbH makes no warranty of any kind, express or implied, other than its products meet all quality control standards set by Romer Labs Division Holding GmbH. We do not guarantee that the product can be used for a special application.

approved for release by: Michaela Streicher

date: 15.02.2024

This document has been computer generated and is valid without a signature.

References:

[1] ISO Guide 31:2015 - 1-18, "Reference materials – contents of certificates, labels and accompanying documentation"
[2] Eurachem / CITAC Guide, 1-37, (2003), *"Traceability in Chemical Measurement"*
[3] Eurachem / CITAC Guide CG-4, 1-133, (QUAM:2012.P1), *"Quantifying Uncertainty in Analytical Measurement"*, *3rd Ed.*
[4] International Organization for Standardization (ISO), (2008), *"Guide to the expression of uncertainty in measurement"*, (GUM 1995 with minor corrections) 1st Ed. Geneva, Switzerland
[5] R.D. Josephs, R. Krska, S. MacDonald, P. Wilson, H. Pettersson, J. AOAC Int. 86, 50-60, (2003), *"Preparation of a Calibrant as Certified Reference Material for Determination of the Fusarium Mycotoxin Zearalenone"*
[6] E.W. Flick, (1998), *"Industrial Solvents Handbook"*, 5th Ed., Noyes Data Corp. Westwood NJ