Results of Proficiency Test Ethanol (Food / Neutral grade) December 2020

Organized by: Institute for Interlaboratory Studies

Spijkenisse, the Netherlands

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1 Introduction

Since 2007 the Institute for Interlaboratory Studies (iis) organizes a proficiency scheme for the analysis of Ethanol (Food / Neutral grade) every year. During the annual proficiency testing program 2020/2021 it was decided to continue the round robin for the analysis of Ethanol (Food / Neutral grade).

In this interlaboratory study 26 laboratories in 16 different countries registered for participation. See appendix 3 for the number of participants per country. In this report the results of the Ethanol (Food / Neutral grade) proficiency test are presented and discussed. This report is also electronically available through the iis website www.iisnl.com.

2 SET UP

The Institute for Interlaboratory Studies (iis) in Spijkenisse, the Netherlands, was the organizer of this proficiency test (PT). Sample analyzes for fit-for-use and homogeneity testing were subcontracted to an ISO/IEC17025 accredited laboratory. It was decided to send two different samples of Ethanol (Food / Neutral grade): a 0.5L bottle labelled #20247 for the regular analyzes and a 0.25L bottle labelled #20248 for GC determination only. The participants were requested to report rounded and unrounded test results. The unrounded test results were preferably used for statistical evaluation.

2.1 ACCREDITATION

The Institute for Interlaboratory Studies in Spijkenisse, the Netherlands, is accredited in agreement with ISO/IEC17043:2010 (R007), since January 2000, by the Dutch Accreditation Council (Raad voor Accreditatie). This PT falls under the accredited scope. This ensures strict adherence to protocols for sample preparation and statistical evaluation and 100% confidentiality of participant's data. Feedback from the participants on the reported data is encouraged and customer's satisfaction is measured on regular basis by sending out questionnaires.

2.2 PROTOCOL

The protocol followed in the organization of this proficiency test was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of June 2018 (iis-protocol, version 3.5). This protocol is electronically available through the iis website www.iisnl.com, from the FAQ page.

2.3 CONFIDENTIALITY STATEMENT

All data presented in this report must be regarded as confidential and for use by the participating companies only. Disclosure of the information in this report is only allowed by means of the entire report. Use of the contents of this report for third parties is only allowed by written permission of the Institute for Interlaboratory Studies. Disclosure of the identity of one or more of the participating companies will be done only after receipt of a written agreement of the companies involved.

2.4 SAMPLES

For the preparation of the sample for the regular PT Ethanol (Food / Neutral grade) a batch of approximately 35 liters of Ethanol (Food / Neutral grade) was obtained from a local supplier. After homogenization 52 amber glass bottles of 0.5L were filled and labelled #20247.

The homogeneity of the subsamples was checked by determination of Density at 20°C in accordance with ASTM D4052 and Water in accordance with ASTM E203 on 8 stratified randomly selected subsamples.

	Density at 20°C in kg/L	Water in %M/M
Sample #20247-1	0.80563	5.536
Sample #20247-2	0.80564	5.566
Sample #20247-3	0.80565	5.538
Sample #20247-4	0.80565	5.542
Sample #20247-5	0.80563	5.573
Sample #20247-6	0.80565	5.546
Sample #20247-7	0.80566	5.582
Sample #20247-8	0.80564	5.596

Table 1: homogeneity test results of subsamples #20247

From the above test results the repeatabilities were calculated and compared with 0.3 times the corresponding reproducibility of the reference test method or with 0.3 times the estimated reproducibility calculated with the Horwitz equation in agreement with the procedure of ISO13528. Annex B2 in the next table.

	Density at 20°C in kg/L	Water in %M/M
r (observed)	0.00003	0.063
reference test method	ISO12185:96	Horwitz
0.3 x R (reference test method)	0.00015	0.144

Table 2: evaluation of the repeatabilities of subsamples #20247

The calculated repeatabilities are in agreement with 0.3 times the corresponding reproducibility of the reference test method or with 0.3 times the estimated reproducibility calculated with the Horwitz equation. Therefore, homogeneity of the subsamples was assumed.

For the preparation of the GC sample a batch of approximately 13 liters Ethanol (Food / Neutral grade) was separated from the batch for the main round and spiked with Methanol, Acetone, Benzene and Monoethylene glycol (MEG). After homogenization 51 amber glass bottles of 0.25L were filled and labelled #20248.

The homogeneity of the subsamples was checked by determination of Benzene and Isopropanol in accordance with an in-house method on 8 stratified randomly selected subsamples.

	Benzene in mg/kg	Isopropanol in mg/kg
Sample #20248-1	25.6	10.8
Sample #20248-2	25.9	10.8
Sample #20248-3	24.9	10.1
Sample #20248-4	25.3	10.7
Sample #20248-5	24.7	10.1
Sample #20248-6	25.2	10.5
Sample #20248-7	24.9	10.6
Sample #20248-8	24.3	10.1

Table 3: homogeneity test results of subsamples #20248

From the above test results the repeatabilities were calculated and compared with 0.3 times the estimated reproducibilities calculated with the Horwitz equation in agreement with the procedure of ISO13528, Annex B2 in the next table.

	Benzene in mg/kg	Isopropanol in mg/kg
r (observed)	1.4	0.9
reference method	Horwitz	Horwitz
0.3 x R (reference method)	2.1	1.0

Table 4: evaluation of the repeatabilities of subsamples #20248

The calculated repeatabilities are in agreement with 0.3 times the estimated reproducibilities calculated with the Horwitz equation. Therefore, homogeneity of the subsamples was assumed.

To each of the participating laboratories one sample labelled #20247 and one sample labelled #20248 was sent on November 11, 2020. An SDS was added to the sample package.

2.5 STABILITY OF THE SAMPLES

The stability of Ethanol packed in amber glass bottles was checked. The material was found sufficiently stable for the period of the proficiency test.

2.6 ANALYZES

The participants were requested to determine on sample #20247: Appearance, Density at 20°C, Nonvolatile matter, Permanganate Time Test at 20°C, pHe (with LiCl and KCl electrode), Strength (in %M/M and %V/V), Water and UV absorbance at 300, 270, 260, 250, 240, 230 and 220 nm with an evaluation of the UV-scan.

On sample #20248 it was requested to determine: Purity of Ethanol on dry basis, Methanol, Acetal (1,1-diethoxyethane), Acetaldehyde, Acetone, Benzene, Isopropanol, Monoethylene glycol (MEG), Other impurities and Total impurities.

It was explicitly requested to treat the samples as if they were routine samples and to report the test results using the indicated units on the report form and not to round the test results, but report as much significant figures as possible. It was also requested not to report 'less than' test results, which are above the detection limit, because such test results cannot be used for meaningful statistical evaluations.

To get comparable test results a detailed report form and a letter of instructions are prepared. On the report form the reporting units are given as well as the reference test methods (when applicable) that will be used during the evaluation. The detailed report form and the letter of instructions are both made available on the data entry portal www.kpmd.co.uk/sgs-iis/. The participating laboratories are also requested to confirm the sample receipt on this data entry portal. The letter of instructions can also be downloaded from the iis website www.iisnl.com.

3 RESULTS

During five weeks after sample dispatch, the test results of the individual laboratories were gathered via the data entry portal www.kpmd.co.uk/sgs-iis/. The reported test results are tabulated per determination in appendix 1 and 2 of this report. The laboratories are presented by their code numbers.

Directly after the deadline, a reminder was sent to those laboratories that had not reported test results at that moment. Shortly after the deadline, the available test results were screened for suspect data. A test result was called suspect in case the Huber Elimination Rule (a robust outlier test) found it to be an outlier. The laboratories that produced these suspect data were asked to check the reported test results (no reanalyzes). Additional or corrected test results are used for data analysis and the original test results are placed under 'Remarks' in the result tables in appendix 1. Test results that came in after the deadline were not taken into account in this screening for suspect data and thus these participants were not requested for checks.

3.1 STATISTICS

The protocol followed in the organization of this proficiency test was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of June 2018 (iis-protocol, version 3.5).

For the statistical evaluation the *unrounded* (when available) figures were used instead of the rounded test results. Test results reported as '<...' or '>...' were not used in the statistical evaluation.

First, the normality of the distribution of the various data sets per determination was checked by means of the Lilliefors-test, a variant of the Kolmogorov-Smirnov test and by the calculation of skewness and kurtosis. Evaluation of the three normality indicators in combination with the visual evaluation of the graphic Kernel density plot, lead to judgement of the normality being either 'unknown', 'OK', 'suspect' or 'not OK'. After removal of outliers, this check was repeated. If a data set does not have a normal distribution, the (results of the) statistical evaluation should be used with due care.

The assigned value is determined by consensus based on the test results of the group of participants after rejection of the statistical outliers and/or suspect data.

According to ISO13528 all (original received or corrected) results per determination were submitted to outlier tests. In the iis procedure for proficiency tests, outliers are detected prior to calculation of the mean, standard deviation and reproducibility. For small data sets, Dixon (up to 20 test results) or Grubbs (up to 40 test results) outlier tests can be used. For larger data sets (above 20 test results) Rosner's outlier test can be used. Outliers are marked by D(0.01) for the Dixon's test, by G(0.01) or DG(0.01) for the Grubbs' test and by F(0.01) for the Rosner's test. Stragglers are marked by F(0.01) for the Dixon's test, by F(0.01) for the Rosner's test. Both outliers and stragglers were not included in the calculations of averages and standard deviations.

For each assigned value the uncertainty was determined in accordance with ISO13528. Subsequently the calculated uncertainty was evaluated against the respective requirement based on the target reproducibility in accordance with ISO13528. In this PT, the criterion of ISO13528, paragraph 9.2.1. was met for all evaluated tests, therefore, the uncertainty of all assigned values may be negligible and need not be included in the PT report.

Finally, the reproducibilities were calculated from the standard deviations by multiplying them with a factor of 2.8.

3.2 GRAPHICS

In order to visualize the data against the reproducibilities from literature, Gauss plots were made, using the sorted data for one determination (see appendix 1). On the Y-axis the reported test results are plotted. The corresponding laboratory numbers are on the X-axis. The straight horizontal line presents the consensus value (a trimmed mean). The four striped lines, parallel to the consensus value line, are the +3s, +2s, -2s and -3s target reproducibility limits of the selected reference test method. Outliers and other data, which were excluded from the calculations, are represented as a cross. Accepted data are represented as a triangle.

Furthermore, Kernel Density Graphs were made. This is a method for producing a smooth density approximation to a set of data that avoids some problems associated with histograms. Also, a normal Gauss curve (dotted line) was projected over the Kernel Density Graph (smooth line) for reference.

3.3 Z-SCORES

To evaluate the performance of the participating laboratories the z-scores were calculated. As it was decided to evaluate the performance of the participants in this proficiency test (PT) against the literature requirements, e.g. ISO reproducibilities, the z-scores were calculated using a target standard deviation. This results in an evaluation independent of the variation in this interlaboratory study.

The target standard deviation was calculated from the literature reproducibility by division with 2.8. In case no literature reproducibility was available, other target values were used, like Horwitz or an estimated reproducibility based on former iis proficiency tests.

When a laboratory did use a test method with a reproducibility that is significantly different from the reproducibility of the reference test method used in this report, it is strongly advised to recalculate the z-score, while using the reproducibility of the actual test method used, this in order to evaluate whether the reported test result is fit-for-use.

The z-scores were calculated according to:

```
z_{\text{(target)}} = \text{(test result - average of PT)} / \text{target standard deviation}
```

The $z_{(target)}$ scores are listed in the test result tables in appendix 1.

Absolute values for z<2 are very common and absolute values for z>3 are very rare. Therefore, the usual interpretation of z-scores is as follows:

```
|z| < 1 good
1 < |z| < 2 satisfactory
2 < |z| < 3 questionable
3 < |z| unsatisfactory
```

4 EVALUATION

Some problems were encountered with the dispatch of the samples due to COVID-19 pandemic. Therefore, the reporting time on the data entry portal was extended with another three weeks. When considering the test results of the two samples together one participant reported test results after the final reporting date and two participants did not report any test result. Not all participants were able to perform all analyzes requested. In total 24 participants reported 315 numerical test results. Observed were 19 outlying test results, which is 6.0%. In proficiency tests outlier percentages of 3% - 7.5% are quite normal.

Not all data sets proved to have a normal Gaussian distribution. These are referred to as "not OK" or "suspect". The statistical evaluation of these data sets should be used with due care, see also paragraph 3.1.

4.1 EVALUATION PER SAMPLE AND PER TEST

In this section the reported test results are discussed per sample and per test. The test methods which were used by the various laboratories were taken into account for explaining the observed differences when possible and applicable. These test methods are also in the tables together with the original data. The abbreviations, used in these tables, are explained in appendix 4.

Unfortunately, a suitable reference test method, providing the precision data, is not available for all determinations. For these tests the calculated reproducibility was compared against the estimated reproducibility calculated with the Horwitz equation.

In the iis PT reports ASTM test methods are referred to with a number (e.g. D1363) and an added designation for the year that the test method was adopted or revised (e.g. D1363:06). If applicable, a designation in parentheses is added to designate the year of reapproval (e.g. D1363:06(2019)). In the test results tables of appendix 1 only the method number (sub) and year of adoption or revision (e.g. D1363:06) will be used.

- <u>Appearance:</u> This determination was not problematic. All reporting participants agreed on a test result of Clear and Bright / Pass.
- <u>Density at 20°C:</u> This determination was not problematic. One statistical outlier was observed. The calculated reproducibility after rejection of the statistical outlier is in agreement with the requirements of ISO12185:96.
- Nonvolatile matter: This determination was not problematic. Almost all reporting participants agreed on a test result of <1 mg/100mL. Therefore, no z-scores were calculated.
- <u>Permanganate Time Test at 20°C:</u> This determination was problematic. No statistical outliers were observed. However, the calculated reproducibility is not in agreement with the requirements of ASTM D1363:06(2019).
- <u>pHe with LiCl electrode:</u> This determination was problematic. No statistical outliers were observed. However, the calculated reproducibility is not in agreement with the requirements of EN15490:07.
- <u>pHe with KCl electrode:</u> This determination was problematic. No statistical outliers were observed. However, the calculated reproducibility is not in agreement with the requirements of D6423:20a.
- <u>Strength (%M/M):</u> This determination was problematic. No statistical outliers were observed. However, the calculated reproducibility is not in agreement with the reproducibility derived from the OIML table.
- <u>Strength (%V/V):</u> This determination was not problematic. Two statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is in agreement with the reproducibility derived from the OIML table.
- Water: This determination was not problematic. One statistical outlier was observed. The calculated reproducibility after rejection of the statistical outlier is in agreement with the estimated reproducibility calculated with the Horwitz equation.

UV absorbance: Regretfully, no reference test method for this determination exists. Some participants reported test results obtained with a 50 mm cuvette, others with a 10 mm cuvette. In order to determine a Pass or Fail based on the sample UV-graph, it is important that even the smallest deviation is detected visually. Therefore, the use of a 50 mm cuvette is preferable. Eleven laboratories used a 50 mm cuvette and seven laboratories used a 10 mm cuvette. Both groups were evaluated separately.

- UV 50 mm cuvette: In total over seven parameters (UV absorbance in nm) six statistical outliers were observed and one other test result was excluded. Seven participants evaluated the sample as 'Fail' while two other evaluated as 'Pass'.
- UV 10 mm cuvette: In total over seven parameters (UV absorbance in nm) no statistical outliers were observed. Two participants evaluated the sample as 'Fail' while four other evaluated as 'Pass'.
- Purity of Ethanol on dry basis: Regretfully, no reference test method is available that gives a clear definition of purity in Ethanol (Food / Neutral grade). Therefore, no z-scores could be calculated. Two statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is in line with the calculated reproducibility in the previous proficiency tests iis19C17 and iis18C11.

Methanol:

This determination may be problematic. No statistical outliers were observed. However, the calculated reproducibility is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

Acetone:

This determination may be problematic. One statistical outlier was observed. The calculated reproducibility after rejection of the statistical outlier is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

Benzene:

This determination may be problematic. No statistical outliers were observed. However, the calculated reproducibility is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

Isopropanol:

This determination may be problematic. Two statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

Monoethylene glycol: Five laboratories reported a numeric test result and two other laboratories reported a "less than" test result. Therefore, no z-scores were calculated.

Other impurities: This determination may be problematic. Two statistical outliers were observed. No z-scores were calculated due to a large variation in the test results.

<u>Total impurities:</u> This determination was not problematic. Two statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is in agreement with the estimated reproducibility calculated with the Horwitz equation for 6 components.

Impurities where the majority of participants agreed on a concentration near or below the limit of detection are mentioned in appendix 2. No z-scores were calculated because of the low concentrations of these impurities.

4.2 PERFORMANCE EVALUATION FOR THE GROUP OF LABORATORIES

A comparison has been made between the reproducibility as declared by the reference test method or as declared by the estimated target reproducibility calculated with the Horwitz equation and the reproducibility as found for the group of participating laboratories. The number of significant test results, the average, the calculated reproducibility (2.8 * standard deviation) and the target reproducibility derived from literature reference test methods (in casu ASTM and ISO test methods) or based on previous proficiency tests or the target reproducibility derived from the official test method or estimated using the Horwitz equation are presented in the next tables.

Parameter	unit	n	average	2.8 * sd	R(target)
Appearance		16	C&B/Pass	n.a.	n.a.
Density at 20°C	kg/L	21	0.8057	0.0001	0.0005
Nonvolatile matter	mg/100mL	12	<1	n.e.	n.e.
Permanganate Time Test at 20°C	minutes	11	32.6	13.2	8.2
pHe with LiCl electrode		6	7.8	0.9	0.7
pHe with KCl electrode		4	7.8	1.4	1.0
Strength	%M/M	14	94.46	0.07	0.06
Strength	%V/V	19	96.43	0.03	0.06
Water	%M/M	16	5.52	0.26	0.48
UV – 50 mm cuvette:					
UV-absorbance 300 nm		9	0.026	0.032	n.a.
UV-absorbance 270 nm		9	0.108	0.029	n.a.
UV-absorbance 260 nm		9	0.289	0.043	n.a.
UV-absorbance 250 nm		10	0.506	0.036	n.a.
UV-absorbance 240 nm		10	0.612	0.046	n.a.
UV-absorbance 230 nm		9	0.800	0.109	n.a.
UV-absorbance 220 nm		9	1.53	0.137	n.a.
Conclusion UV-scan	Pass/Fail	7	Fail	n.a.	n.a.
UV – 10 mm cuvette:					
UV-absorbance 300 nm		7	-0.002	0.031	n.a.

Parameter	unit	n	average	2.8 * sd	R(target)
UV-absorbance 270 nm		7	0.012	0.035	n.a.
UV-absorbance 260 nm		7	0.047	0.034	n.a.
UV-absorbance 250 nm		7	0.089	0.036	n.a.
UV-absorbance 240 nm		7	0.109	0.041	n.a.
UV-absorbance 230 nm		7	0.140	0.050	n.a.
UV-absorbance 220 nm		7	0.281	0.063	n.a.
Conclusion UV-scan	Pass/Fail	2	Fail	n.a.	n.a.

Table 5: reproducibilities of tests on sample #20247

Parameter	unit	n	average	2.8 *sd	R(target)
Purity of Ethanol on dry basis	%M/M	12	99.99	0.004	(5.600)
Methanol	mg/kg	15	25.4	12.9	7.0
Acetone	mg/kg	12	48.2	13.9	12.1
Benzene	mg/kg	13	15.9	6.4	4.7
Isopropanol	mg/kg	10	9.0	4.2	2.9
Monoethylene glycol (MEG)	mg/kg	5	23.1	49.3	(6.4)
Other impurities	mg/kg	6	17.6	50.1	(8.9)
Total impurities	mg/kg	9	104.8	50.9	57.1

Table 6: reproducibilities of tests on sample #20248

Without further statistical calculations, it can be concluded that for many tests there is not a good compliance of the group of participants with the reference test methods. The problematic tests have been discussed in paragraph 4.1.

4.3 COMPARISON OF THE PROFICIENCY TEST OF DECEMBER 2020 WITH PREVIOUS PTS

	December 2020	December 2019	December 2018	December 2017	December 2016
Number of reporting laboratories	24	25	25	29	26
Number of test results	315	337	303	301	329
Number of statistical outliers	19	19	20	22	16
Percentage of statistical outliers	6.0%	5.6%	6.6%	7.3%	4.9%

Table 7: comparison with previous proficiency tests

In proficiency tests, outlier percentages of 3% - 7.5% are quite normal.

The performance of the determinations of the proficiency tests was compared to the requirements of the reference test methods. The conclusions are given in the following table.

Parameter	December 2020	December 2019	December 2018	December 2017	December 2016
Density at 20°C	++	++	++	++	++
Nonvolatile matter	n.e.	-	++	++	++
Permanganate Time Test at 20°C	-	+	-	-	(+)
pHe with LiCl electrode	-	-	++	-	(-)
pHe with KCl electrode	-				
Strength %M/M	-	+	++	++	(+/-)
Strength %V/V	+	+/-	+	++	++
Water	+	+	-	-	-
Purity Ethanol on dry basis	(+/-)	(++)	(+)	(+)	(+)
Methanol	-	-		-	++
Acetal (1,1-diethoxyethane)	n.e.	+	n.e.	n.e.	+/-
Acetaldehyde	n.e.	n.a.	n.a.	n.a.	n.a.
Acetone	-	+	+/-		n.e.
Benzene	-	-		n.e.	++
Isopropanol	-	-	+	+	n.e.
Monoethylene glycol (MEG)	()	n.e.	n.e.	n.e.	+/-
Other impurities	()	n.a.	n.a.	n.a.	n.a.
Total impurities	+	-	-	-	n.e.

Table 8: comparison determinations against the reference test methods

Results in brackets should be used with due care and/or are compared with the observed reproducibility of the previous proficiency test

The following performance categories were used:

- ++ : group performed much better than the reference test method
- + : group performed better than the reference test method
- +/- : group performance equals the reference test method
- : group performed worse than the reference test method
- -- : group performed much worse than the reference test method
- n.e. : not evaluated

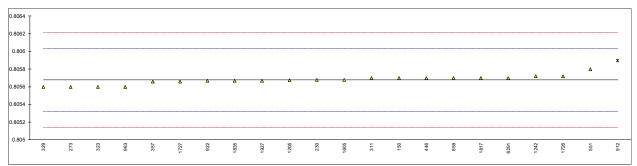
APPENDIX 1

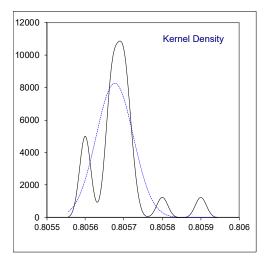
Determination of Appearance on sample #20247;

lab	method	value	mark	z(targ)	remarks
150	Visual	C&B			
230	Visual	C&B			
273					
311	E2680	pass			
323	Visual	c&b			
329	Visual	clear liquid			
357	Visual	CFSM			
446	Visual	Pass			
541					
551	Visual	Pass			
859	Visual	Pass			
912					
913					
922	Visual	Clear and Bright			
963	Visual	Pass			
1205					
1242					
1574					
1605					
1726	Visual	Clear&Colorless			
1727	Visual	Clear&Colorless			
1817	Visual	PASS			
1835	Visual	C&C			
1927					
6224					
6291	Visual	clear and bright			
	n	16			
	mean (n)	Clear and Bright / Pass			

Determination of Density at 20°C on sample #20247; results in kg/L

lah	- math a d	value	no o uls	=/towa\	vomovico.
lab	method	value	mark	z(targ)	remarks
150	D4052	0.8057		0.13	
230	D4052	0.80568		0.02	
273	D4052	0.8056		-0.43	
311	D4052	0.8057		0.13	
323	D4052	0.8056		-0.43	
329	D4052	0.8056		-0.43	
357	D4052	0.80566		-0.09	
446	D4052	0.8057		0.13	
541	D 40-0				
551	D4052	0.8058		0.69	
859	D4052	0.8057		0.13	
912	ISO12185	0.8059	R(0.01)	1.25	
913					
922	D4052	0.80567		-0.04	
963	ISO12185	0.8056		-0.43	
1205	In house	0.805678		0.01	
1242	In house	0.805720		0.24	
1574					
1605	D4052	0.805681		0.02	
1726	D4052	0.80572		0.24	
1727	D4052	0.80566		-0.09	
1817	Table OIML	0.80570		0.13	
1835	ISO12185	0.80567		-0.04	
1927	D4052	0.80567		-0.04	
6224					
6291	ISO12185	0.8057		0.13	
	n armality	augnost.			
	normality	suspect			
	n outliers	21 1			
	mean (n)	0.805677			
	st.dev. (n)	0.0000482			
	R(calc.)	0.000135			
	st.dev.(ISO12185:96)	0.0001786			
	R(ISO12185:96)	0.0005			



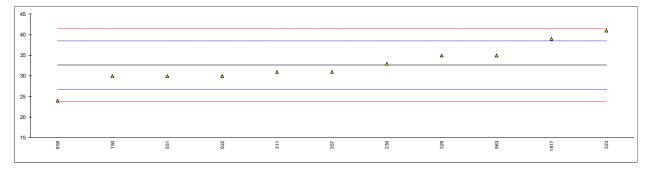


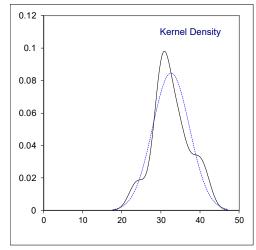
Determination of Nonvolatile matter on sample #20247; results in mg/100mL

lab	method	value	mark	z(targ)	remarks
150	D1353	0.5	С		first reported 3.8
230	D1353	1.4			
273					
311	D1353	<1			
323	D1353	1.2			
329	D1353	<1			
357	D1353	<1			
446	D1353	0			
541					
551	D1353	0.4			
859	D1353	<1			
912	D1353	<1.0			
913					
922	D1353	<0.1			
963	D1353	0.3			
1205					
1242					
1574					
1605					
1726	EN15691	0.7			
1727	EN15691	<10			
1817	In house	0			
1835					
1927					
6224					
6291					
		40			
	n	12			
	mean (n)	<1			

Determination of Permanganate Time Test at 20°C on sample #20247; results in minutes

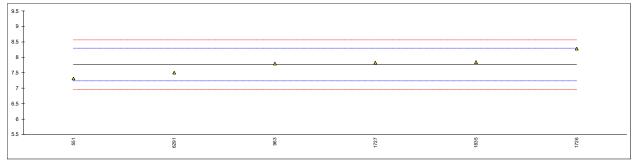
lab	method	value	mark z(targ)	remarks
150	D1363	30	mark z(targ) -0.90	Iciliaiva
230	D1363	33	0.12	
273	D1303			
311	D1363	31	-0.56	
323	D1363	41	2.85	
329	D1363	35	0.80	
357	D1363	31	-0.56	
446	INH-6392	>20	-0.30	
541	11111-0332			
551	D1363	30	-0.90	
859	D1363	24	-2.94	
912	D 1000		-2.54	
913				
922	D1363	30	-0.90	
963	D1363	35.0	0.80	
1205	2.000			
1242				
1574				
1605				
1726				
1727				
1817	In house	39	2.17	
1835				
1927				
6224				
6291				
	normality	OK		
	n	11		
	outliers	0		
	mean (n)	32.64		
	st.dev. (n)	4.717		
	R(calc.)	13.21		
	st.dev.(D1363:06)	2.937		
	R(D1363:06)	8.22		





Determination of pHe with LiCl electrode on sample #20247;

lab	method	value	mark	z(targ)	remarks
150					
230					
273					
311					
323					
329					
357					
446					
541					
551	NBR10891	7.32		-1.68	
859					
912					
913					
922					
963	D6423	7.8		0.13	
1205					
1242					
1574					
1605					
1726	EN15490	8.29		1.97	
1727	EN15490	7.83		0.24	
1817	B0400				
1835	D6423	7.85		0.31	
1927					
6224					
6291		7.51		-0.96	
	normality	unknown			
	n	6			
	outliers	0			
	mean (n)	7.767			
	st.dev. (n)	0.3321			
	R(calc.)	0.930			
	st.dev.(EN15490:07)	0.2663			
	R(EN15490:07)	0.746			

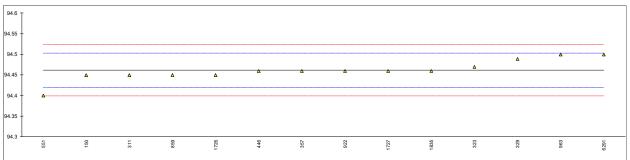


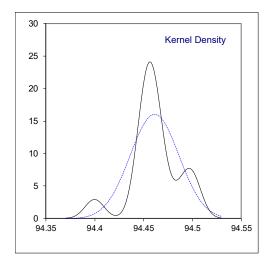
Determination of pHe with KCI electrode on sample #20247;

lab	method	value	mark	z(targ)	remarks	
150	D6423	8.1		0.73		
230						
273	D6423	7.39		-1.17		
311						
323						
329						
357						
446						
541	DC400	0.40		4.50		
551 859	D6423	8.42		1.59		
912						
912						
922	D6423	7.4		-1.15		
963	D0423	7.4		-1.13		
1205						
1242						
1574						
1605						
1726						
1727						
1817						
1835						
1927						
6224						
6291						
	normality	unknown				
	n	4				
	outliers	0				
	mean (n)	7.827 0.5162				
	st.dev. (n) R(calc.)	0.5162 1.445				
	st.dev.(D6423:20a)	0.3725				
	R(D6423:20a)	1.043				
	11(D0420.20a)	1.040				
9.5 T						
8.5 -					Δ	Δ
8 -					Δ	
7.5 -	Δ		Δ			
7 -						
6.5 -						
6						
5.5 -						
5	Ф.		8		•	
	273		922		150	152

Determination of Strength on sample #20247; results in %M/M

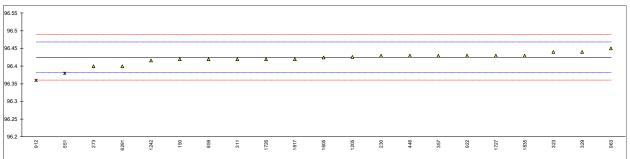
lab	method	value	mark	z(targ)	remarks
150	Table OIML	94.45		-0.55	
230					
273					
311	Table OIML	94.45		-0.55	
323	Table OIML	94.47		0.42	
329	Table OIML	94.489		1.33	
357	Table OIML	94.46		-0.07	
446	Table OIML	94.46		-0.07	
541					
551	NBR15639	94.40		-2.96	
859	Table OIML	94.45		-0.55	
912					
913					
922	Table OIML	94.46		-0.07	
963	Table OIML	94.50		1.87	
1205					
1242					
1574					
1605					
1726	Table OIML	94.45		-0.55	
1727	Table OIML	94.46		-0.07	
1817					
1835	Table OIML	94.46		-0.07	
1927					
6224					
6291		94.5	С	1.87	first reported 77.6
	normality	not OK			
	n	14			
	outliers	0			
	mean (n)	94.461			
	st.dev. (n)	0.0250			
	R(calc.)	0.070			
	st.dev.(OIML table)	0.0207			
	R(OIML table)	0.058			OIML R022-e75
	()				

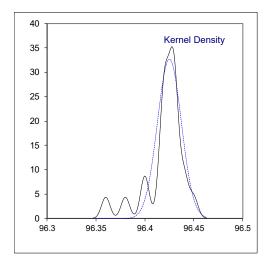




Determination of Strength on sample #20247; results in %V/V

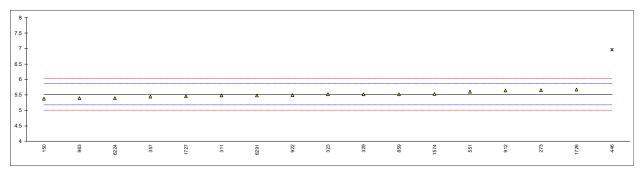
lab	method	value	mark	z(targ)	remarks
150	Table OIML	96.42		-0.24	
230	Table OIML	96.43		0.23	
273	Table OIML	96.4		-1.17	
311	Table OIML	96.42		-0.24	
323	Table OIML	96.44		0.69	
329	Table OIML	96.44		0.69	
357	Table OIML	96.43		0.23	
446	Table OIML	96.43		0.23	
541					
551	NBR15639	96.38	R(0.05)	-2.11	
859	Table OIML	96.42		-0.24	
912	Table OIML	96.36	R(0.05)	-3.04	
913					
922	Table OIML	96.43		0.23	
963	Table OIML	96.45		1.16	
1205	Table OIML	96.426		0.04	
1242		96.416		-0.43	
1574					
1605	Table OIML	96.425		-0.01	
1726	Table OIML	96.42		-0.24	
1727	Table OIML	96.43		0.23	
1817	Table OIML	96.42		-0.24	
1835	Table OIML	96.43		0.23	
1927					
6224					
6291		96.4		-1.17	
	normality	OK			
	n	19			
	outliers	2			
	mean (n)	96.425			
	st.dev. (n)	0.0122			
	R(calc.)	0.034			
	st.dev.(OIML table)	0.0214			
	R(OIML table)	0.060			OIML R022-e75

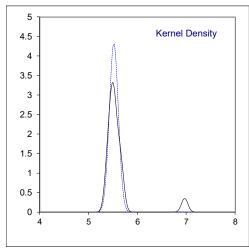




Determination of Water on sample #20247; results in %M/M

lab	method	value	mark	z(targ)	remarks
150	E203	5.38		-0.80	
230					
273	E1064	5.66	С	0.84	first reported 3.48
311	E203	5.487		-0.18	
323	E203	5.5247		0.04	
329	E203	5.526		0.05	
357	E203	5.447		-0.41	
446	D1364	6.97	G(0.01)	8.51	
541					
551	E203	5.612		0.56	
859	D1364	5.530		0.07	
912	E203	5.645		0.75	
913					
922	E203	5.50		-0.10	
963	D1364	5.40		-0.69	
1205					
1242					
1574		5.5356		0.11	
1605	ENIAECOO	 		0.05	
1726 1727	EN15692	5.6789		0.95 -0.34	
1817	EN15692	5.46			
1835					
1927					
6224	In house	5.40		-0.69	
6291	III IIOuse	5.49	С	-0.09	first reported 4.94
0231		3.43	O	-0.10	ilist reported 4.94
	normality	OK			
	n	16			
	outliers	1			
	mean (n)	5.5173			
	st.dev. (n)	0.09271			
	R(calc.)	0.2596			
	st.dev.(Horwitz)	0.17066			
	R(Horwitz)	0.4779			
Compa					
	R(E203:16)	0.0780			range 660 – 960 mg/kg



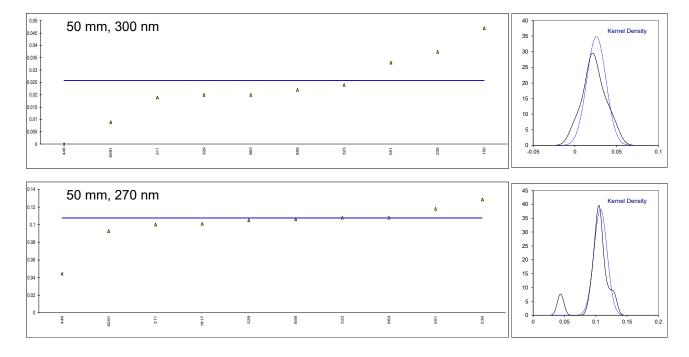


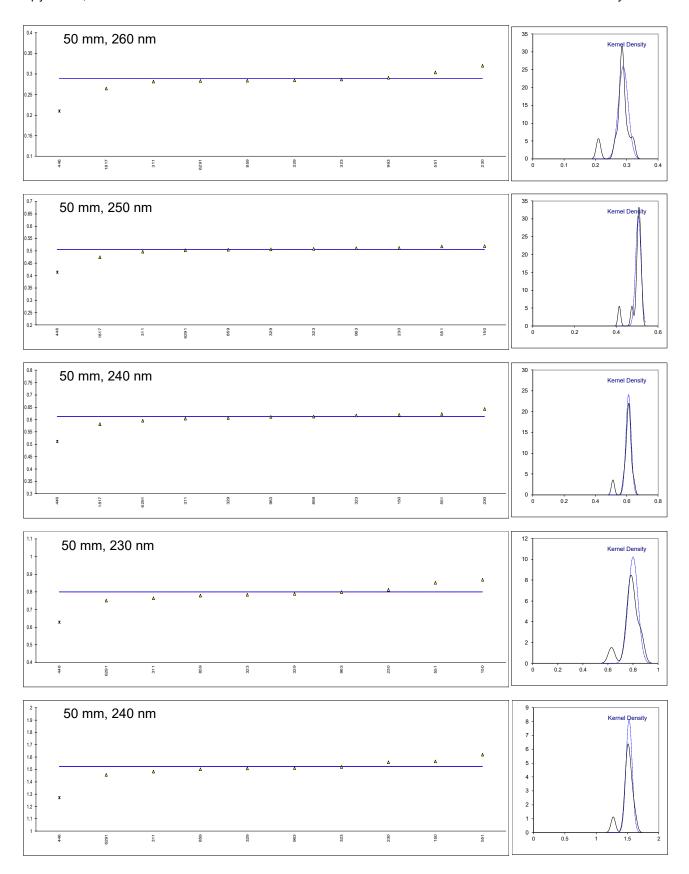
Determination of UV absorbance (50 mm cuvette) on sample #20247;

lab	method	300 nm	270 nm	260 nm	250 nm	240 nm	230 nm	220 nm	Pass/Fail
150	IMPCA004	0.047			0.520 C	0.620 C	0.869	1.565	Fail
230	INH-13	0.0374	0.12865	0.3201	0.5127 C	0.6439	0.8129	1.5600	Pass
273									
311	INH-13	0.019	0.100	0.282	0.497	0.604	0.764	1.484	Fail
323	IMPCA004	0.024	0.108	0.287	0.509	0.617	0.785	1.521	Fail
329	INH-CM	0.020	0.105	0.285	0.507	0.607	0.790	1.510	Fail
357	15111 4040								
446	INH-1318	0 ex	0.044 D(1)	0.210 D(1)	0.414 D(1)	0.512 D(1)	0.629 D(1)	1.272 D(1)	Fail
541	1811 1 0000	0.000	0.440	0.004	0.540	0.000	0.050	4.000	
551	INH-3063	0.033	0.118	0.304	0.519	0.623	0.853	1.620	Fail
859	IMPCA004	0.022	0.106	0.284	0.505	0.613	0.779	1.502	Fail
912 913									
913									
963	IMPCA004	0.020	0.108	0.291	0.511	0.612	0.799	1.512	Pass
1205	IIVII CAUU4	0.020	0.100	0.231	0.511	0.012	0.133	1.512	1 033
1242									
1574									
1605									
1726									
1727									
1817			0.101	0.265	0.475	0.582			
1835									
1927									
6224									
6291		0.009	0.093	0.283	0.503	0.596	0.751	1.457	
	normality	OK	suspect	suspect	not OK	suspect	OK	OK	
	n	9	9	9	10	10	9	9	7
	outliers	0 +1ex	1	1	1	1	1	1	•
	mean (n)	0.0257	0.1075	0.2890	0.5059	0.6118	0.8003	1.5257	Fail
	st.dev. (n)	0.01145	0.01046	0.01542	0.01290	0.01658	0.03905	0.04885	
	R(calc.)	0.0321	0.0293	0.0432	0.0361	0.0464	0.1093	0.1368	
	1 1(0010.)	0.0021	0.0200	5.070L	0.0001	0.0707	3.1000	3.1000	

Lab 150 first reported 0.565 and 0.683 for UV absorbance at 250 nm and 240 nm respectively Lab 230 first reported 0.5427 for UV absorbance at 250 nm $\,$

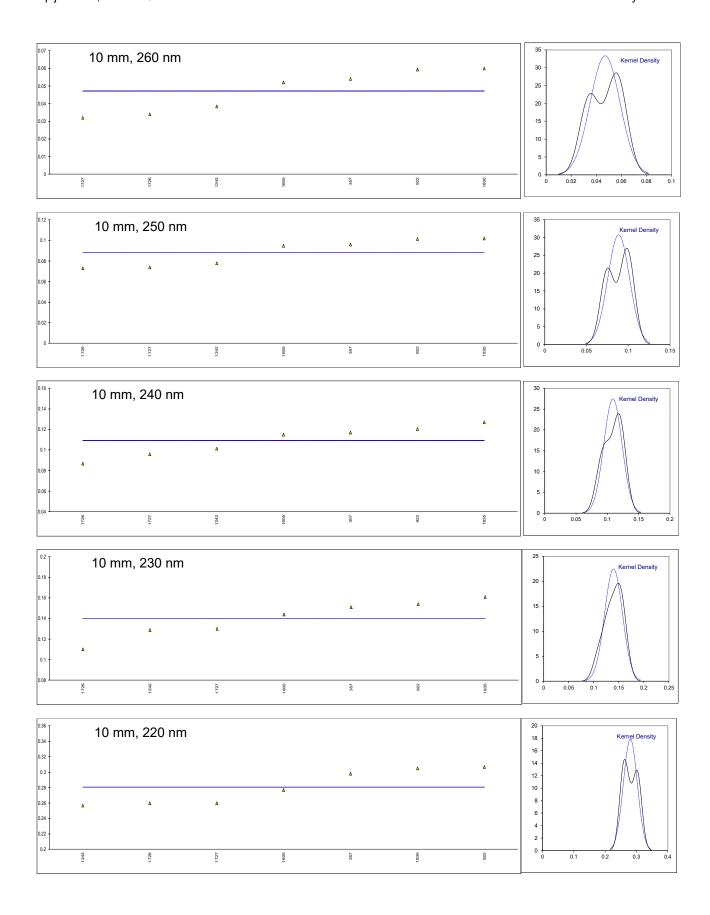
Lab 446 test result excluded at 300 nm as statistical outliers in related parameters





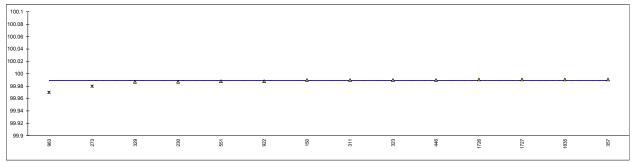
Determination of UV absorbance (10 mm cuvette) on sample #20247;

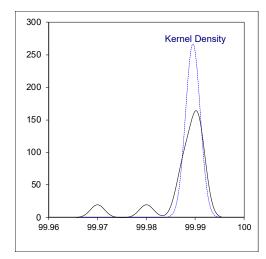
lab	method	300 nm	270 nm	260 nm	250 nm	240 nm	230 nm	220 nm	Pass/Fail
150									
230 273									
311									
323									
329									
357	INH-13	0.002	0.018	0.054	0.096	0.117	0.151	0.298	Fail
446									
541 551									
859									
912									
913									
922	INH-13	0.0067	0.0228	0.0593	0.1015	0.1205	0.1539	0.3067	Fail
963 1205									
1203		0.0000	0.0035	0.0385	0.0780	0.1015	0.1290	0.2570	
1574									
1605		0.001	0.016	0.052	0.095	0.115	0.144	0.277	Pass
1726	IMPCA004	-0.014	-0.002	0.034	0.073	0.087	0.11	0.26	Pass
1727	IMPCA004	-0.020000	-0.004900	0.032	0.074	0.096	0.13	0.26	Pass
1817 1835		0.01	0.027	0.06	0.102	 0.127	 0.161	0.305	 Pass
1927									
6224									
6291									
	normality	unknown	unknown	unknown	unknown	unknown	unknow	n unknown	
	n	7	7	7	7	7	7	7	2
	outliers	0	0	0	0	0	0	0	
	mean (n)	-0.0020 0.01093	0.0115 0.01255	0.0471 0.01198	0.0885 0.01298	0.1091 0.01452	0.1398 0.01776	0.2805 0.02235	Fail
	st.dev. (n) R(calc.)	0.01093	0.01255	0.01196	0.01298	0.01432	0.01770	0.0626	
	r ((oaio.)	0.0000	0.0002	0.0000	0.0000	0.0101	0.0101	0.0020	
0.02	10 mm, 30	0 nm						40	Kernel Density
0.01	, , , , , ,						Δ	35 -	xernel Density
				Δ	Δ	Δ		30 -	//\\
0 †			Δ				-	25 -	/ / \\
-0.01								20 -	′/ \\
-0.02	Δ	Δ						15	∫
0.02	•							10 - //	1
-0.03								//	\
-0.04									
	17271	1726	1242	1605	357	922	1835	-0.06 -0.04 -0.02	0 0.02 0.04
0.04 T	10 mm, 2	70 nm						35	Kernel Density
0.03 -	10 111111, 21	0 11111					Δ	30 -	Kernel Density
0.02				Δ	Δ	Δ		25 -	λ
0.01							-		<u> </u>
0 +		Δ	Δ					20 -	· \\
-0.01	Δ							15	\\
-0.02								10 -	\\
-0.03								5.	\\
-0.04									
111	727	726	1242	909	357	922	1835	-0.04 -0.02 0	0.02 0.04 0.06



Determination of Purity of Ethanol on dry basis on sample #20248; results in %M/M

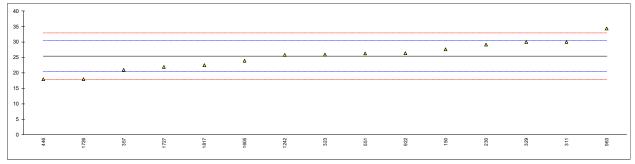
lab	method	value	mark	z(targ)	remarks
150	INH-02	99.99			
230	INH-0001	99.9873			
273	IMPCA004	99.98	G(0.01)		
311	INH933	99.99			
323	INH-001	99.99			
329	INH-02	99.987			
357	INH-02	99.991			
446	INH-043	99.99			
541					
551	INH-1313	99.988			
859					
912					
913					
922	INH-02	99.988			
963	D5501	99.97	C,G(0.01)		first reported 94.63
1205					
1242					
1574					
1605					
1726	In house	99.9909			
1727		99.9909			
1817					
1835	In house	99.9909			
1927					
6224					
6291			W		test result withdrawn, first reported 94.94
	normality	OK			
	n	12			
	outliers	2			
	mean (n)	99.9895			
	st.dev. (n)	0.00150			
	R(calc.)	0.0042			
	st.dev.(Horwitz)	(1.99982)			
	R(Horwitz)	(5.5995)			
Compa	are	(0.0000)			
Jonipe	R(iis19C17)	0.0024			
	R(iis18C11)	0.0024			
	11(11310011)	0.0070			

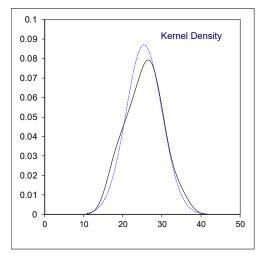




Determination of Methanol on sample #20248; results in mg/kg

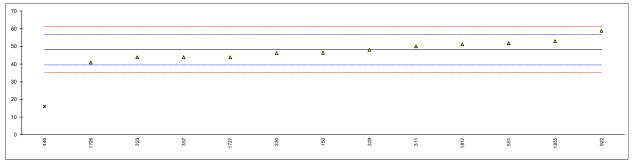
lab	method	value	mark	z(targ)	remarks
150	INH-02	27.7		0.91	
230	INH-0001	29.1638		1.49	
273					
311	INH933	30		1.83	
323	INH-001	26		0.23	
329	INH-02	30		1.83	
357	INH-02	21		-1.77	
446	INH-043	18		-2.97	
541					
551	INH-1313	26.33		0.36	
859					
912					
913					
922	INH-02	26.44		0.41	
963	D5501	34.35		3.57	
1205					
1242		25.9023		0.19	
1574					
1605		24.0		-0.57	
1726	In house	18		-2.97	
1727		22		-1.37	
1817	In house	22.5251		-1.16	
1835	In house	<25			
1927					
6224					
6291			W		test result withdrawn, first reported 60
	normality	OK			
	n	15			
	outliers	0			
	mean (n)	25.427			
	st.dev. (n)	4.5911			
	R(calc.)	12.855			
	st.dev.(Horwitz)	2.4998			
	R(Horwitz)	6.999			
	(. /5//	0.000			

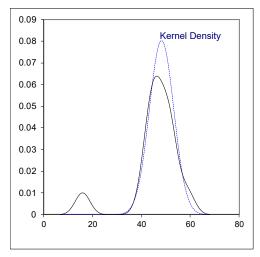




Determination of Acetone on sample #20248; results in mg/kg

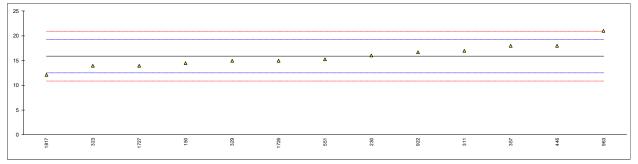
lab	method	value	mark	z(targ)	remarks
150	INH-02	46.4		-0.42	
230	INH-0001	46.3249		-0.44	
273					
311	INH933	50		0.41	
323	INH-001	44		-0.98	
329	INH-02	48		-0.05	
357	INH-02	44		-0.98	
446	INH-043	16	D(0.01)	-7.48	
541					
551	INH-1313	51.83		0.84	
859					
912					
913					
922	INH-02	58.79		2.45	
963	D5501	<50			
1205					
1242					
1574					
1605					
1726	In house	41		-1.68	
1727		44		-0.98	
1817	In house	51.3123		0.72	
1835	In house	53		1.11	
1927					
6224					
6291			W		test result withdrawn, first reported <0.1
	normality	OK			
	n	12			
	outliers	1			
	mean (n)	48.221			
	st.dev. (n)	4.9803			
	R(calc.)	13.945			
	st.dev.(Horwitz)	4.3053			
	R(Horwitz)	12.055			
	, ·-···,				

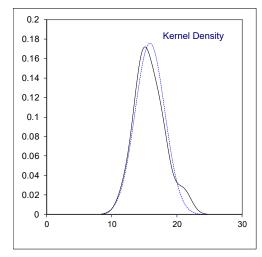




Determination of Benzene on sample #20248; results in mg/kg

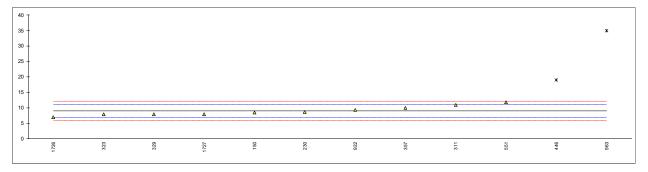
lab	method	value	mark	z(targ)	remarks
150	INH-02	14.5		-0.83	
230	INH-0001	16.0234		0.08	
273					
311	INH933	17		0.66	
323	INH-001	14		-1.13	
329	INH-02	15		-0.53	
357	INH-02	18		1.25	
446	INH-043	18		1.25	
541					
551	INH-1313	15.25		-0.38	
859					
912					
913					
922	INH-02	16.70		0.48	
963	D5501	21	С	3.04	first reported 23
1205					
1242					
1574					
1605					
1726	In house	15		-0.53	
1727		14		-1.13	
1817	In house	12.1674		-2.22	
1835	In house	<15			
1927					
6224					
6291			W		test result withdrawn, first reported <0.1
	normality	OK			
	n	13			
	outliers	0			
	mean (n)	15.895			
	st.dev. (n)	2.2703			
	R(calc.)	6.357			
	st.dev.(Horwitz)	1.6772			
	R(Horwitz)	4.696			
	, ,				

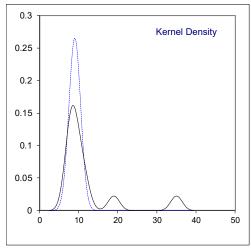




Determination of Isopropanol on sample #20248; results in mg/kg

lab	method	value	mark	z(targ)	remarks
150	INH-02	8.5		-0.52	
230	INH-0001	8.7057		-0.32	
273					
311	INH933	11		1.89	
323	INH-001	8	С	-1.00	first reported <5
329	INH-02	8		-1.00	
357	INH-02	10		0.92	
446	INH-043	19	D(0.01)	9.59	
541					
551	INH-1313	11.83		2.69	
859					
912					
913					
922	INH-02	9.36		0.31	
963	D5501	35	C,D(0.01)	25.00	first reported 41
1205					
1242					
1574					
1605					
1726	In house	7		-1.96	
1727		8		-1.00	
1817					
1835	In house	<25			
1927					
6224			147		
6291			W		test result withdrawn, first reported <0.1
	normality	OK			
	n	10			
	outliers	2			
	mean (n)	9.040			
	st.dev. (n)	1.5077			
	R(calc.)	4.222			
	st.dev.(Horwitz)	1.0384			
	R(Horwitz)	2.907			
	` '				



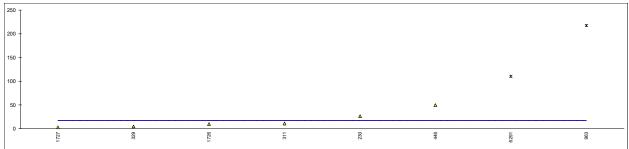


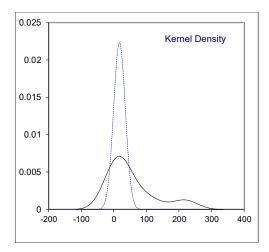
Determination of Monoethylene glycol (MEG) on sample #20248; results in mg/kg

lab	method	value	mark	z(targ)	remarks	
150						
230	INH-0001	0			possibly a false negative test result?	
273						
311	INH933	18				
323						
329	INH-02	19				
357	INH-02	<30				
446						
541	INII 1 4070	47.74				
551	INH-1379	47.71				
859						
912						
913 922	INILI OO	20.72				
922 963	INH-02	30.72				
1205						
1205						
1574						
1605						
1726						
1727						
1817						
1835						
1927						
6224						
6291		<0.1			possibly a false negative test result?	
	normality	unknown				
	n	5				
	outliers	0				
	mean (n)	23.086				
	st.dev. (n)	17.6078				
	R(calc.)	49.302				
	st.dev.(Horwitz)	(2.3028)				
	R(Horwitz)	(6.448)				
60 T						
50 -						Δ.
						_
40 -						
30 -					Δ	
						_
20 -		Δ		Δ		
10 -						
0	 82	311		329	825	

Determination of Other impurities on sample #20248; results in mg/kg

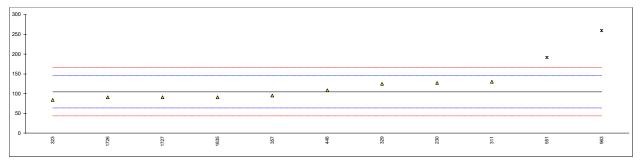
lab	method	value	mark	z(targ)	remarks
150					
230	INH-0001	26.5683			
273					
311	INH933	11			
323					
329	INH-02	5			
357	INH-02	<5			
446	INH-043	50			
541					
551	INH-1313	<6			
859					
912					
913					
922					
963	D5501	217.36	G(0.05)		
1205					
1242					
1574					
1605					
1726	In house	10			
1727		3			
1817	In house	<300			
1835	In house	<25			
1927					
6224					
6291		110	G(0.05)		
	normality	unknown			
	n	6			
	outliers	2			
	mean (n)	17.595			
	st.dev. (n)	17.9077			
	R(calc.)	50.142			
	st.dev.(Horwitz, comp:3)	(3.1668)			
	R(Horwitz, comp:3)	(8.867)			

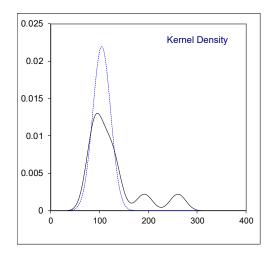




Determination of Total impurities on sample #20248; results in mg/kg

lab	method	value	mark	z(targ)	remarks
150					
230	INH-0001	126.7860		1.08	
273	1411.1000			4.04	
311	INH933	130		1.24	
323	INH-001	84		-1.02	
329	INH-02	125		0.99	
357	INH-02	95		-0.48	
446	INH-043	109		0.21	
541 551	INH-1313	191.59	G(0.05)	4.26	
859	IIVII-1313	191.59	G(0.05)	4.20	
912					
913					
922					
963	D5501	260	C,G(0.05)	7.62	first reported 315
1205	20001		0,0(0.00)		mot reported one
1242					
1574					
1605					
1726	In house	91		-0.67	
1727		91		-0.67	
1817					
1835	In house	91		-0.67	
1927					
6224					
6291			W		test result withdrawn, first reported 50580
	normality	OK			
	n	9			
	outliers	2			
	mean (n)	104.754			
	st.dev. (n)	18.1800			
	R(calc.)	50.904			
	st.dev.(Horwitz, comp:6)	20.3845			
	R(Horwitz, comp:6)	57.077			





APPENDIX 2

Other reported impurities in sample #20248; results in mg/kg

lab	Acetal (1,1-diethoxyethane)	Acetaldehyde	
150	<2	<2	
230	0	0	
273			
311	<5	<5	
323	< 5	< 5	
329	<5	<5	
357	<5	<5	
446	<5	<5	
541			
551	<6	<6	
859			
912			
913			
922	<2.0	<2.0	
963		<50	
1205			
1242			
1574			
1605			
1726	ND	ND	
1727	<10	<10	
1817	ND	ND	
1835	<25	<10	
1927			
6224			
6291	<0.1		W

Lab 6291 test result withdrawn, first reported 21

APPENDIX 3

Number of participants per country

- 1 lab in ARGENTINA
- 4 labs in BELGIUM
- 1 lab in BRAZIL
- 1 lab in CHINA, People's Republic
- 1 lab in FINLAND
- 1 lab in HONG KONG
- 2 labs in INDIA
- 1 lab in MAURITIUS
- 4 labs in NETHERLANDS
- 1 lab in PAKISTAN
- 1 lab in SAUDI ARABIA
- 1 lab in SOUTH AFRICA
- 3 labs in SPAIN
- 2 labs in THAILAND
- 1 lab in UNITED KINGDOM
- 1 lab in UNITED STATES OF AMERICA

APPENDIX 4

Abbreviations

DG(0.05)

C = final test result after checking of first reported suspect test result

 $\begin{array}{ll} D(0.01) &= \text{outlier in Dixon's outlier test} \\ D(0.05) &= \text{straggler in Dixon's outlier test} \\ G(0.01) &= \text{outlier in Grubbs' outlier test} \\ G(0.05) &= \text{straggler in Grubbs' outlier test} \\ DG(0.01) &= \text{outlier in Double Grubbs' outlier test} \\ \end{array}$

R(0.01) = outlier in Rosner's outlier test R(0.05) = straggler in Rosner's outlier test

E = calculation difference between reported test result and result calculated by iis

W = test result withdrawn on request of participant ex = test result excluded from statistical evaluation

= straggler in Double Grubbs' outlier test

fr. = first reported
n.a. = not applicable
n.e. = not evaluated
n.d. = not detected
SDS = Safety Data Sheet

Literature

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