

Section A4.1**Analytical Methods for Detection and Identification****Annex Point IIA4.1/4.2 & IIIA-IV.1**

		1 REFERENCE	
1.1 Reference		Iking, M. (2007) Quantification of the total amount of organic acids and ethanol Purac Document no. RDT/A/003 Not GLP, Unpublished Validation: De Jong, V. (2008) Measurement uncertainty for organic acids and oligomers. Purac Document no. VdJ2009058 Not GLP, Unpublished	
1.2 Data protection		Yes	
1.2.1 Data owner		Purac Biochem	
1.2.2 Companies with letter of access		No	
1.2.3 Criteria for data protection		Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		Internal method	
2.2 GLP		No	
2.3 Deviations		Not applicable	
		3 MATERIALS AND METHODS	
3.1 Preliminary treatment			
3.1.1 Enrichment		Not applicable	
3.1.2 Cleanup			
3.2 Detection			
3.2.1 Separation method			
3.2.2 Detector			
3.2.3 Standard(s)			
3.2.4 Interfering substance(s)		Not applicable	
3.3 Linearity			
3.3.1 Calibration range			

Official
use only

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IIIA-IV.1**

		[Redacted]
3.3.2	Number of measurements	[Redacted]
3.3.3	Linearity	[Redacted]
3.4	Specificity: interfering substances	Not relevant [Redacted]
3.5	Recovery rates at different levels	[Redacted]
3.5.1	Relative standard deviation	[Redacted]
3.6	Limit of determination	[Table with redacted content]
3.7	Precision	
3.7.1	Repeatability	[Redacted]

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		[REDACTED]
		[REDACTED]
3.7.2	Independent laboratory validation	Not applicable
4 APPLICANT'S SUMMARY AND CONCLUSION		
4.1	Materials and methods	[REDACTED]
4.2	Conclusion	The method is suitable as in-house method for quality control. Method is suitable as method to determine impurities in lactic acid samples.
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	2008/08/21
Materials and methods	
Conclusion	Adopt applicant's version
Reliability	1
Acceptability	acceptable
Remarks	

COMMENTS FROM ...

Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>

Section A4.1

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III A-IV.1**

Conclusion

Discuss if deviating from view of rapporteur member state

Reliability

Discuss if deviating from view of rapporteur member state

Acceptability

Discuss if deviating from view of rapporteur member state

Remarks
