Section A4.1

Analytical Methods for Detection and Identification

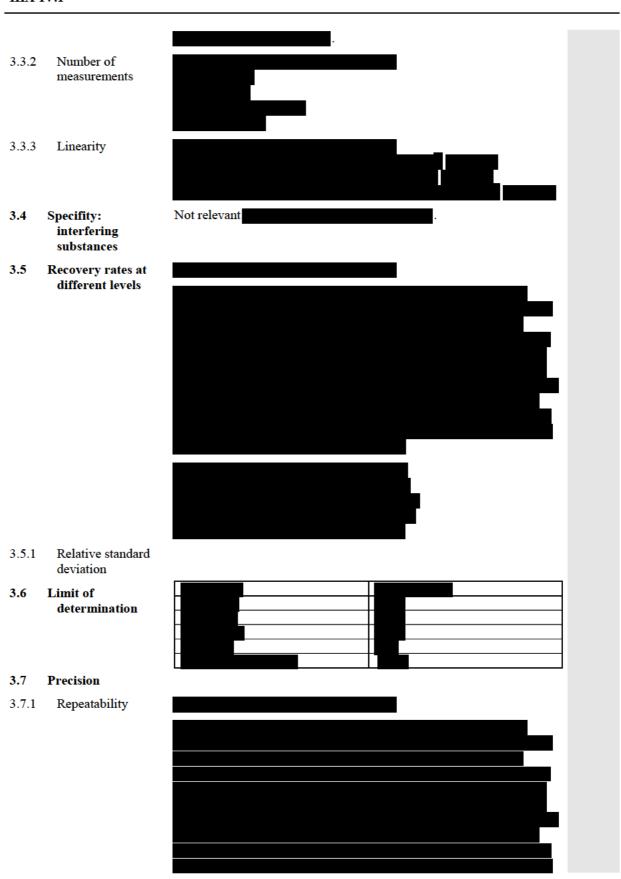
Annex Point IIA4.1/4.2 & IIIA-IV.1

			Official
		1 REFERENCE	use only
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 RDT/A/003 Not GLP, Unpublished	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 VdJ2009058 Not GLP, Unpublished	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		

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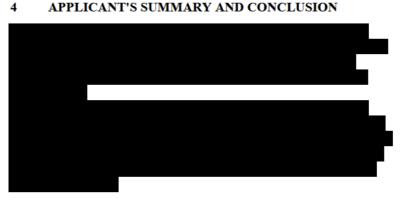
Annex Point IIA4.1/4.2 & IIIA-IV.1



3.7.2 Independent laboratory validation

Not applicable

4.1 Materials and methods



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 14.2.2 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	Give date of comments submitted	
Results and discussion	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

Purac Biochem	L(+) Lactic Acid	June/2009
Section A4.1	Analytical Methods for Detection and Identification	
Annex Point IIA4.1/4.2 & IIIA-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		