### Section A4.1

# **Analytical Methods for Detection and Identification**

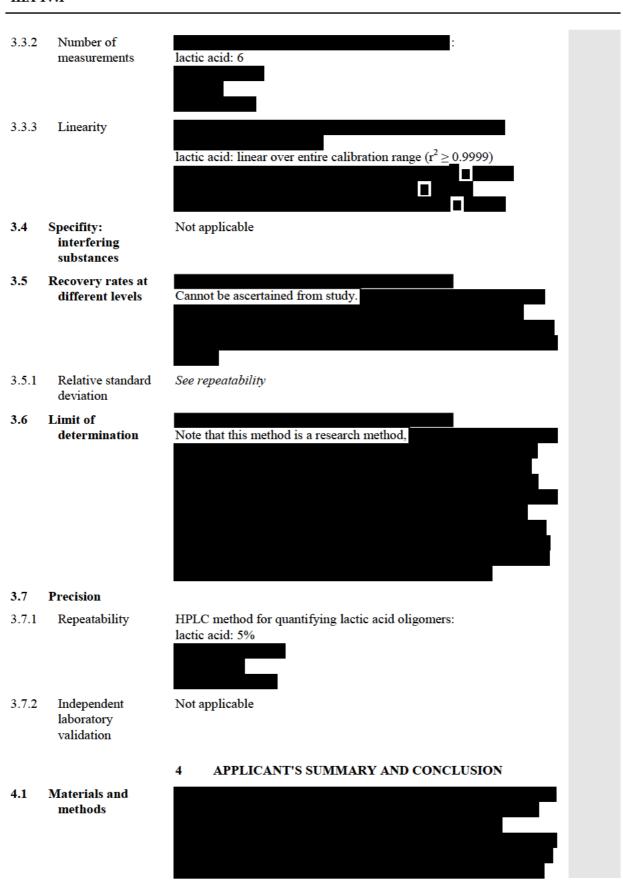
Annex Point IIA4.1/4.2 & IIIA-IV.1

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		1 REFERENCE	Official use only
1.1	Reference	Lieuwen, R. (2008) Determination of lactide,	
		Purac Document no. RDT/A/0036 Not GLP, Unpublished	
		De Jong, V. (2008)  Measurement uncertainty for organic acids  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 VdJ2009058  Not GLP, Unpublished	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)	Lactic acid,	
3.2.4	Interfering substance(s)	Not applicable	
3.3	Linearity		
3.3.1	Calibration range		

#### **Section A4.1**

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### Section A4.1

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**4.2 Conclusion** The methods are suitable as an in-house quality control method.

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	2009/08/21
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
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	