Section A4.1 Analytical Methods for Detection and Identification

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

Official use only

1 REFERENCE

1.1	**Reference**	Rodriguez, E. (2001) Manual of analytical procedures of lactic acid; Determination of lactic acid content (PSP). Purac Document no. LA008C Not GLP, Unpublished Escribà, J. (2001) Validation report of the method for determination of lactic acid content (PSP method) LA008 Purac Document no. VAL-LA008(I) and VAL-LA008-1(I) Not GLP, Unpublished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	Not applicable
3.2	**Detection**	
3.2.1	Separation method	Not applicable. [redacted]
		[redacted]
3.2.2	Detector	[redacted]
3.2.3	Standard(s)	[redacted]
3.2.4	Interfering substance(s)	Other acids; not relevant since the composition of the sample is under strict control.

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3.3	**Linearity**		
3.3.1	Calibration range	0.77 – 1.19 g total lactic acid with [redacted] method; 0.86 – 1.0 g total lactic acid with single-step method (only total acid).	
3.3.2	Number of measurements	Not mentioned	
3.3.3	Linearity	r = 0.999991 with [redacted] method.	
3.4	**Specifity: interfering substances**	Other acids; not relevant since the composition of the sample is under strict control.	
3.5	**Recovery rates at different levels**	Recovery 100.02% @ 90.03% acid content with [redacted] method; recovery 99.98% @ 90.03% acid content with single-step method (only total acid).	
3.5.1	Relative standard deviation	*0.078% with [redacted] method; 0.044% with single step method.*	
3.6	**Limit of determination**	Not relevant.	
3.7	**Precision**		
3.7.1	Repeatability	90.05 ± 0.078% @ 90.% acid content with [redacted] method; 90.013 ± 0.044% @ 90.03% acid content with single-step method (only total acid).	
3.7.2	Independent laboratory validation	Not relevant	
	4	**APPLICANT'S SUMMARY AND CONCLUSION**	
4.1	**Materials and methods**	[redacted]. Note that this is a method for determining content; as such samples can always be pretreated to contain an amount that falls within the limits of the method. Linearity, recovery at different levels, and LoQ of such a method are therefore not relevant.	x
4.2	**Conclusion**	The method is based on the method used by the QC laboratory of PURAC Biochem bv, Gorinchem.	
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	2009/08/21

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Materials and methods	[redacted]
Conclusion	Adopt applicant´s version
Reliability	2
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	