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**	Klein, J. (2001) Assay of Lactic acid. Purac Document no. AMLAC009 Not GLP, Unpublished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	Lactic acid is neutralized by an excess of a sodium hydroxide solution. The excess is titrated back with hydrochloric acid. (Standardization of these solutions is described in Documents IV A4.1-03a and IV A4.1-03b)
3.2.2	Detector	Phenolphtalein is used as indicator.
3.2.3	Standard(s)	Not applicable
3.2.4	Interfering substance(s)	Not applicable
3.3	**Linearity**	
3.3.1	Calibration range	Not applicable
3.3.2	Number of measurements	Not applicable
3.3.3	Linearity	Not applicable
3.4	**Specifity: interfering substances**	Not applicable
3.5	**Recovery rates at different levels**	Not mentioned

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3.5.1	Relative standard deviation	
3.6	**Limit of determination**	Not applicable
3.7	**Precision**	DOC IV A 4.1_11; Solution with a theoretical concentration of 91.3% lactic acid total. Determination of the content using method AMLAC009 by 7 independent technicians, all in duplicate.
3.7.1	Repeatability	Mean concentration (91.288 ± 0.12) %
3.7.2	Independent laboratory validation	Duplicate repeatability RSD 0.03 % Reproducibility RSD 0.06 %

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Lactic acid is neutralized by an excess of a sodium hydroxide solution. The excess is titrated back with hydrochloric acid. Phenolphtalein is used as the indicator.
4.2	**Conclusion**	The method is based on the method used by the QC laboratory of PURAC Biochem bv, Gorinchem. Method is intended to determine the actual (acid) concentration in solutions with a nominal concentration of 90-93% lactic acid. Due to the intended application of the method, no interferences are expected, and no analytical identification is required. The method has an acceptable repeatability and reproducibility.
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	2009/12/14
Materials and methods	The given titration method is not specific, only in addition to the chromatographically methods it is acceptable to be used. Because of the validation of the chromatographically method no further information is required.
Conclusion	Adopt applicant´s version
Reliability	2
Acceptability	acceptable (because of further analytical methods)
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*

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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	