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**	Anonymous (1968) Milchsäure, Acidium lacticum. In: Deutsches Arzneibuch, 7th edition, Deutscher Apotheker-Verlag, Stuttgart, Govi-Verlag GmbH, Frankfurt, p. 680-681. Not GLP, published.	x
1.2	**Data protection**	No	
1.2.1	Data owner	Not applicable	
1.2.2	Companies with letter of access	Not applicable	
1.2.3	Criteria for data protection	No data protection claimed	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Pharmacopoeia 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 heated with 25 mL sodium hydroxide. Phenolphthalein is added and sodium hydroxide is titrated until the turning point is reached. Then, 2 mL hydrochloric acid is added and the solution is heated again. The excess is titrated back with sodium hydroxide.	
3.2.2	Detector	The total amount of sodium hydroxide used minus the total amount of hydrochloric acid equals the amount of lactic acid.1 mL of sodium hydroxide corresponds with 90.08 mg lactic acid.	
3.2.3	Standard(s)	Not applicable	
3.2.4	Interfering substance(s)	Not applicable	
3.3	**Linearity**		
3.3.1	Calibration range	Not mentioned (Pharmacopeia method)	
3.3.2	Number of measurements	Not mentioned (Pharmacopeia method)	
3.3.3	Linearity	Not mentioned (Pharmacopeia method)	

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3.4	**Specifity: interfering substances**	Not applicable
3.5	**Recovery rates at different levels**	Not mentioned (Pharmacopeia method)
3.5.1	Relative standard deviation	Not mentioned (Pharmacopeia method)
3.6	**Limit of determination**	Not mentioned (Pharmacopeia method)
3.7	**Precision**	
3.7.1	Repeatability	Not mentioned (Pharmacopeia method)
3.7.2	Independent laboratory validation	Not mentioned (Pharmacopeia method)

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Lactic acid is heated with 25 mL sodium hydroxide. Phenolphthalein is added and sodium hydroxide is titrated until the turning point is reached. Then, 2 mL hydrochloric acid is added and the solution is heated again. The excess is titrated back with sodium hydroxide. The total amount of sodium hydroxide used minus the total amount of hydrochloric acid equals the amount of lactic acid.1 mL of sodium hydroxide corresponds with 90.08 mg lactic acid.
4.2	**Conclusion**	Pharmacopoeia methods meet the EU requirements for specificity, accuracy, precision and linearity. This method is suitable for analysis and identification of the active ingredient.
4.2.1	Reliability	1
4.2.2	Deficiencies	No

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Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2009/03/01
Materials and methods	No validation of the titration - method is described. No specify requirements are considered. Further analytical methods are described in Subsection A-4.1.
Conclusion	
Reliability	4
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	