

Section A4.1

Analytical Methods for Detection and Identification

Annex Point IIA4.1/4.2 &
IIIA-IV.1Official
use only

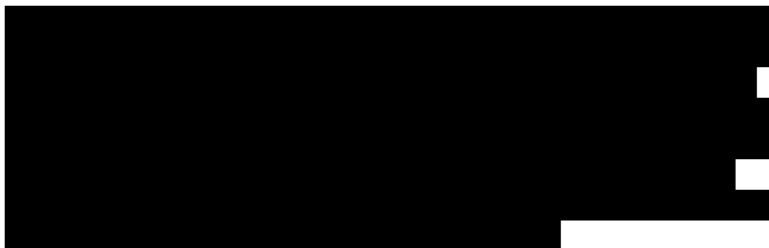
	1 REFERENCE	
1.1 Reference	Huntink, T.B. (2005) Determination of the chiral purity [REDACTED] Purac Document no. RDT/A/0003 Not GLP, Unpublished Van Nieuwenhuizen, S. (1999) Determination of the chiral purity of lactic acid and derivatives [REDACTED] Thesis, Hogeschool van Rotterdam Not GLP, Unpublished Method validation	
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	[REDACTED]	
3.2 Detection		
3.2.1 Separation method	[REDACTED]	
3.2.2 Detector	[REDACTED]	
3.2.3 Standard(s)	Lactic acid with a known S-to-L lactate ratio, in the 0.1 to 1.5% range.	
3.2.4 Interfering substance(s)	None; [REDACTED]	
3.3 Linearity		
3.3.1 Calibration range	A normal calibration range is not applicable. Note that the method is not intended for quantitation of an amount, but only of a ratio. As such the method can be done at a single, appropriate response point, and has its	

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own internal standard.



3.3.2 Number of measurements

9

3.3.3 Linearity

$r^2 = 0.9996$

3.4 **Specificity:
interfering
substances**

None:

[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

3.5 **Recovery rates at
different levels**

3.5.1 Relative standard deviation

95.3 ± 1.5 % @ 0.5% chiral impurity
101.1 ± 0.5 % @ 1.25% chiral impurity
101.6 ± 0.6 % @ 3.1% chiral impurity

3.6 **Limit of
determination**

0.04% chiral impurity.

3.7 **Precision**

3.7.1 Repeatability

0.38%

3.7.2 Independent laboratory validation

Not applicable.

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		4	APPLICANT'S SUMMARY AND CONCLUSION
4.1	Materials and methods		[REDACTED]
4.2	Conclusion		[REDACTED]
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
Materials and methods	
Conclusion	Adopt applicant's version
Reliability	1
Acceptability	acceptable
Remarks	
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>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</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	