

Section A4.1

Analytical Methods for Detection and Identification

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

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 RDT/A/0036 Not GLP, Unpublished De Jong, V. (2008) Measurement uncertainty for organic acids [REDACTED] Purac Document no. VdJ2009058 Not GLP, Unpublished	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

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- 3.3.2 Number of measurements [redacted]:
lactic acid: 6
[redacted]
- 3.3.3 Linearity [redacted]
lactic acid: linear over entire calibration range ($r^2 \geq 0.9999$)
[redacted]
- 3.4 **Specificity:
interfering
substances** Not applicable
- 3.5 **Recovery rates at
different levels** [redacted]
Cannot be ascertained from study. [redacted]
- 3.5.1 Relative standard deviation *See repeatability*
- 3.6 **Limit of
determination** [redacted]
Note that this method is a research method, [redacted]
- 3.7 **Precision**
- 3.7.1 Repeatability HPLC method for quantifying lactic acid oligomers:
lactic acid: 5%
[redacted]
- 3.7.2 Independent laboratory validation Not applicable

4 APPLICANT'S SUMMARY AND CONCLUSION

- 4.1 **Materials and
methods** [redacted]

