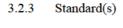
Analytical Methods for Detection and Identification

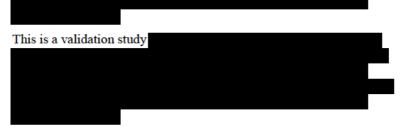
Annex Point IIA4.1/4.2 & IIIA-IV.1

		1 REFERENCE	Official use only
1.1	Reference	De Jong, V. (2008)	
		Measurement uncertainty for organic acids and oligomers.	
		Purac Document no. VdJ2008097	
		Not GLP, Unpublished	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	This is a validation study	
3.1.2	Cleanup	This is a validation study	
3.2	Detection		
3.2.1	Separation method		
		This is a validation study	
3.2.2	Detector		
		This is a validation study	

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3.2.4 Interfering substance(s)

Not applicable

3.3 Linearity

3.3.1 Calibration range

Relevant range; note that this is a method for quantifying impurities in a technical product; as such, samples can be prepared to always fall within the required calibration range.

Relevant range; note that this is a method for quantifying impurities in a technical product; as such, samples can be prepared to always fall within the required calibration range.

3.3.2 Number of measurements

formic acid: 11
acetic acid: 11

lactic acid: 6 lactoyl-lactide: 6 lactide: 6 meso-lactide: 6

3.3.3 Linearity

formic acid: linear over entire calibration range ($r^2 = 0.9999$) acetic acid: linear over entire calibration range ($r^2 = 0.9994$)

lactic acid: linear over entire calibration range $(r^2 \ge 0.9999)$ lactoyl-lactide: linear over entire calibration range $(r^2 \ge 0.9999)$ lactide: linear over entire calibration range $(r^2 \ge 0.9999)$ meso-lactide: linear over entire calibration range $(r^2 \ge 0.9999)$

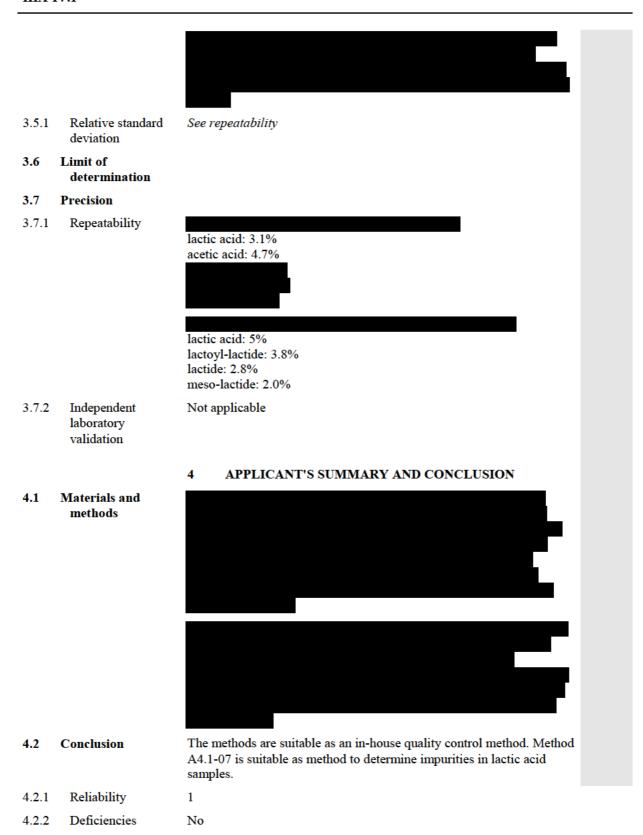
3.4 Specifity: interfering substances Not applicable

3.5 Recovery rates at different levels

lactic acid: 100.7% at method concentration acetic acid: 101.0% at method concentration

Analytical Methods for Detection and Identification

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



Analytical Methods for Detection and Identification

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Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 30/10/2014

Materials and methods

Conclusion The information given above is only in addition to the analytical methods for

detection and identification presented in the DOC III A 4.1.07 and Doc III

A4.1.08 documents.

It would be more useful and comprehensible to merge all information on one

analytical method for detection and identification and their validation in one

DOC III A 4.1 document

Reliability

Acceptability

Remarks Additional information.

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