

Section A4.1/02-07**Analytical Methods for Detection and Identification****Annex Point IIA, IV.4.1***Analytical method for detection of impurities 1-6*

Note: Details of the methods for determination of impurities in the active substance are confidential to THOR GmbH. The methods for determination of impurities are presented in the confidential attachment.

	1	REFERENCE	Official use only
1.1		Reference	
1.2		Data protection	
1.2.1		Data owner	
1.2.2		Companies with letter of access	
1.2.3		Criteria for data protection	
	2	GUIDELINES AND QUALITY ASSURANCE	
2.1		Guideline study	
2.2		GLP	
2.3		Deviations	
	3	MATERIALS AND METHODS	
3.1		Preliminary treatment	
3.1.1		Extraction	
3.1.2		Cleanup	
3.2		Detection	
3.2.1		Separation method	
3.2.2		Detector	
3.2.3		Standard(s)	
3.2.4		Interfering substance(s)	
3.3		Linearity	
3.3.1		Calibration range	
3.3.2		Number of measurements	
3.3.3		Linearity	
3.4		Specificity: interfering substances	
3.5		Recovery rates at different levels	
3.5.1		Relative standard deviation	

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3.6 Limit of determination**3.7 Precision**

3.7.1 Repeatability

3.7.2 Independent laboratory validation

4 APPLICANT'S SUMMARY AND CONCLUSION**4.1 Materials and methods****4.2 Conclusion**

4.2.1 Reliability

4.2.2 Deficiencies

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE**Date** 12/06/14**Materials and methods** -**Conclusion** Adopt applicant's version**Reliability** N/A**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**

