

Certificate of Analysis

Productname: Anetholum (synth)

Inspection No: I03323/0421/536

Batchnumber: 20H26-F01-086106

Expiration date: 16.08.2023

Analysed according to: DAB

Original Manuf. Date: 17.8.2020

Sample Unit: 1 x 10 ml

Batch Size: 100 x 100 ml

Identification of producer: V00201

Batch no. of vendor: 1219097

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	White, crystalline mass, >23 °C clear liquid.	Conform			Fagron CZ
Odour	Strong, characteristic.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification B	20 - 22	21	°C	Freezing point	Fagron CZ
Identification C	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Freezing point	20 - 22	21	°C		Fagron CZ
Anisaldehyde and oth. rel.subs.	Conform	Conform		GC	Fagron
cis-anethole	<=0,5	0	%		Fagron
anisaldehyde	<=1	0	%		Fagron
other impurities	<=0,5	0,1	%		Fagron
total impurities	<=1	0			Fagron
Phenols	Conform	Conform			Fagron
Heavy metals	<=40	<40	µg/g		Fagron
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 17.05.2021

Conclusion: **APPROVED**

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