



Certificate of Analysis

Productname: Anetholum (synth)

Inspection No: K09964/0424/536

Batchnumber: 23A27-T08-110219

Expiration date: 16.01.2026

Analysed according to: DAB

Original Manuf. Date: 17.1.2023

Sample Unit: 1 x 10 ml

Batch Size: 31 x 100 ml

Identification of producer: V00201

Batch no. of vendor: 1339708

	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	20	°C	Freezing point	Fagron CZ
Identification C	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Freezing point	20 - 22	20	°C		Fagron CZ
Anisaldehyde and oth. rel.subs.	Conform	Conform		GC	Contract Lab
cis-anethole	<=0,5	<0,05	%		Contract Lab
anisaldehyde	<=1	<1	%		Contract Lab
other impurities	<=0,5	0,1	%		Contract Lab
total impurities	<=1	<1	%		Contract Lab
Phenols	Comform	Conform			Fagron CZ
Heavy metals	<=40	<40	ppm		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	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

Quality: Excipient

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ludmila Burianová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 17.01.2024

Conclusion: **APPROVED**

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