

Certificate of Analysis

Productname: **Anetholum (synth)**

Inspection No: 109969/1221/536
 Batchnumber: **21K08-T06-092552**
 Expiration date: 18.10.2024
 Analysed according to: DAB
 Original Manuf. Date: 19.10.2021

Sample Unit: 1 x 10 ml
 Batch Size: 323 x 1 l

Identification of producer: V00201
 Batch no. of vendor: 1282165

	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	<0,1	%		Contract Lab
anisaldehyde	<=1	0,07	%		Contract Lab
other impurities	<=0,5	<0,1	%		Contract Lab
total impurities	<=1	<1	%		Contract Lab
Phenols	Conform	Conform			Fagron CZ
Heavy metals	<=40	Conform	µg/g		Fagron CZ
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

Quality: Excipient

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 13.12.2021

Conclusion: **APPROVED**

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