



## Certificate of Analysis

**Productname:** Anetholum (synth)

**Inspection No:** J00038/0122/536

**Batchnumber:** 21K08-T06-093435

**Expiration date:** 18.10.2024

**Analysed according to:** DAB

**Original Manuf. Date:** 19.10.2021

**Sample Unit:** 1 x 10 ml

**Batch Size:** 69 x 100 ml

**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	Comform	Conform			Fagron CZ
Heavy metals	<=40	Conform	µg/g		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	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

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

**Performed by:** Ing. Petra Drábková

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

**Date:** 19.01.2022

**Conclusion:** **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.