

## Certificate of Analysis

**Productname:** Anetholum (synth)

**Inspection No:** I09970/1221/536  
**Batchnumber:** 21K08-T06-093032  
**Expiration date:** 18.10.2024  
**Analysed according to:** DAB  
**Original Manuf. Date:** 19.10.2021

**Sample Unit:** 1 x 10 ml  
**Batch Size:** 528 x 100 ml

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

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	White, crystalline mass, >23 °C clear liquid.	Conform			Fagron CZ
Odour	Strong, characteristic.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
<b>IDENTIFICATION</b>					
Identification B	20 - 22	20	°C	Freezing point	Fagron CZ
Identification C	Conform	Conform		IR-spectrum	Fagron CZ
<b>TESTS</b>					
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 <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

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		<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:** 13.12.2021

**Conclusion:** **APPROVED**

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

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