



Certificate of Analysis

Productname: Anisi stellati aetheroleum

Inspection No: J01980/0322/536
Batchnumber: 22A19-T03-093450
Expiration date: 04.01.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 5.1.2022

Sample Unit: 1 x 1 ml
Batch Size: 121 x 30 ml

Identification of producer: V00201
Batch no. of vendor: 1294092

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless or pale yellow liquid.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,979 - 0,985	0,980			Fagron CZ
Refractive index	1,553 - 1,556	1,554			Fagron CZ
Teplota tuhnutí	15 - 19	15	°C		Fagron CZ
Fenchon	<=0,01	<0,01	%	GC	Contract Lab
Pseudoisoeugenyl-2-methylbutyrate	<=0,01	<0,01	%	GC	Contract Lab
Fatty oils and resini.essen.oils	Conform	Conform			Contract Lab
Chromatographic profile	Conform	Conform		GC	Contract Lab
linalol	0,2 - 2,5	0,8	%		Contract Lab
estragole	0,5 - 6,0	2,1	%		Contract Lab
alfa-terpineol	<=0,3	0,1	%		Contract Lab
cis-anethole	0,1 - 0,5	0,3	%		Contract Lab
trans-anethole	86 - 93	90	%		Contract Lab
anisaldehyde	0,1 - 0,5	0,4	%		Contract Lab
foeniculin	0,1 - 3,0	0,5	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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: Ing. Petra Drábková

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

Date: 30.03.2022

Conclusion: **APPROVED**

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