



Certificate of Analysis

Productname: TRANSCUTOL P

Inspection No: J09323/0223/536

Batchnumber: 22D12-T03-100074

Expiration date: 31.12.2024

Analysed according to: ČL 2017-Dopl.2020, Ph.Eur.10.0

Original Manuf. Date: 31.12.2021

Sample Unit: 1 x 1 ml

Batch Size: 21 x 100 ml

Identification of producer: V00752

Batch no. of vendor: 188042

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless, hygroscopic liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,991	0,989			Fagron CZ
IDENTIFICATION					
Identification A	1,426 - 1,428	1,427		Refractive index	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Acid value	<=0,1	0,01			Fagron CZ
Peroxide value	<=8,0	0,0			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
ethylene glycol monomethyl ether	<=50	<50	ppm		Contract Lab
ethylene glycol monoethyl ether	<=160	31	ppm		Contract Lab
ethylene glycol	<=620	14	ppm		Contract Lab
diethylene glycol	<=250	<250	ppm		Contract Lab
Total impurities	<=0,2	<0,2	%		Contract Lab
Ethylene oxide	<=1	<0,4	ppm	GC	Contract Lab
Water	<=0,1	0,04	%		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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

Performed by: Bc. Andrea Šmídová

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

Date: 10.11.2022

Conclusion: **APPROVED**

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