



Certificate of Analysis

Productname: TRANSCUTOL P

Inspection No: K02269/0623/536

Batchnumber: 22K02-T09-103309

Expiration date: 31.03.2025

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

Original Manuf. Date: 31.3.2022

Sample Unit: 1 x 1 ml

Batch Size: 5 x 100 ml

Identification of producer: V00752

Batch no. of vendor: 189234

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless, hygroscopic liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
Relative density	About 0,991	0,9892			Contract Lab
IDENTIFICATION					
Identification A	1,426 - 1,428	1,426		Refractive index	Contract Lab
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Acid value	<=0,1	<0,1			Contract Lab
Peroxide value	<=8,0	1,7			Contract Lab
Related substances	Conform	Conform		GC	Contract Lab
ethylene glycol monomethyl ether	<=50	<50	ppm		Contract Lab
ethylene glycol monoethyl ether	<=160	4	ppm		Contract Lab
ethylene glycol	<=620	6	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	<0,1	%		Contract Lab
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: Ekocentrum

Responsible: Mgr. Zdeňka Šinclová, QC
PharmDr. Ivana Urbánková, QP

Date: 19.06.2023

Conclusion: **APPROVED**

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