



## Certificate of Analysis

**Productname:** TRANSCUTOL P

**Inspection No:** K03961/0823/536  
**Batchnumber:** 23E03-T04-104779  
**Expiration date:** 30.11.2025  
**Analysed according to:** Ph.Eur.11.0  
**Original Manuf. Date:** 30.11.2022

**Sample Unit:** 1 x 1 ml  
**Batch Size:** 20 x 100 ml

**Identification of producer:** V00752  
**Batch no. of vendor:** 193045

	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	0,990			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	0,0			Fagron CZ
Peroxide value	<=8,0	0,098			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
ethylene glycol monomethyl ether	<=50	<50	ppm		Contract Lab
ethylene glycol monoethyl ether	<=160	3	ppm		Contract Lab
ethylene glycol	<=620	2	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	0,02	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
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**Performed by:** Ing. Petra Drábková

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 05.09.2023

**Conclusion:** **APPROVED**

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