

**ERREGIERRE**

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CERTIFICATE OF ANALYSIS N°

48423

CICLOPIROX OLAMINE USP - Ph.Eur.

CAS N. 41621-49-2

CODE 1441

BATCH 0614014

MAN. DATE 06/2014 EXPIRY DATE 06/2017

TEST FOR	SPECIFICATIONS	RESULTS
Description	white or pale yellow crystalline powder	Complies
Identification		
· IR	positive	Complies
Appearance of solution	according to Ph.Eur.	Complies
pH	$\geq 8.0 \leq 9.0$	8.3
Heavy metals	NMT 10 ppm (Ph.Eur. spec.: NMT 20 ppm)	Complies
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.04
Loss on drying	≤ 1.5 %	0.41
Assay (content of Ciclopirox Olamine, volumetric on as is basis) - USP	$\geq 97.5 \leq 101.5$ %	99.3
Assay (content of 2-aminoethanol, volumetric, mg per g of Ciclopirox Olamine found in the assay USP) - USP	$\geq 223 \leq 230$ mg/g	228
Assay (content of 2-aminoethanol, volumetric, on dried basis) - Ph.Eur.	$\geq 22.2 \leq 23.3$ %	22.7
Assay (content of Ciclopirox, volumetric, on dried basis) - Ph.Eur.	$\geq 76.0 \leq 78.5$ %	77.0
Related substances (HPLC)		
· Impurity A at 220 nm ((RS)-2-(3-cyclohexyl-5-methyl-4,5-dihydroisoxazol-5-yl)acetic acid)	≤ 0.5 %	Non quantifiable
· Impurity B at 298 nm (6-cyclohexyl-4-methyl-2H-pyran-2-one)	≤ 0.5 %	Non quantifiable
· Impurity C at 298 nm (6-cyclohexyl-4-methylpyridin-2(1H)-one)	≤ 0.5 %	Non quantifiable
· any other impurity at 298 nm	NMT 0.10% ≤ 0.5 %	Complies
· total at 298 nm	(Ph.Eur. spec.: sum of impurities other than B)	Non quantifiable
<u>Additional specifications</u>		
Residual solvents (GC)		
· ethyl acetate	≤ 2000 ppm	296

OBSERVATIONS:

- Protect from moisture (packaged in double polyethylene bag and PET/ALU/LLDPE)
- Store between 5°C and 25°C

Copies of this CoA are not valid**APPROVED**

on Jun 09, 2014

QUALITY CONTROL

Dr. R. Poli

Jun 19, 2014