PRODUCT IN FOCUS

EXSYN®
ESSENTIAL CHEMISTRY

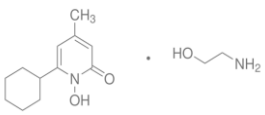
Ciclopirox Olamine Ph.Eur.

INTRODUCTION

Ciclopirox Olamine (CPO) is the N-oxide of a 2 -hydroxy pyridine derivative that carries antifungal, antibacterial, and anti-inflammatory properties. It is composed of 6-cyclohexyl-1-hydroxy-4-methyl-2(1H)-pyridone combined with 2 aminoethanol (olamine) in a 1:1 ratio. It works through a multifaceted mechanism of action that primarily disrupts the fungal cell's metabolic function by inhibiting essential enzymes through its ability to create large polyvalent cation through chelation.
It exhibits antibacterial, anti-inflammatory and antifungal properties, hence often formulated as cream, lotion, or nail lacquer.

Manufacture

CPO is manufactured by reacting Ciclopirox base with equimolar ethanolamine in a suitable solvent under controlled temperature to form the salt.The product is then crystallized, filtered, washed, and dried to obtain the final active pharmaceutical ingredient.

Synonyms	2(1H)-Pyridinone, 6-cyclohexyl-1-hydroxy-4-methyl- compound with 2-aminoethanol (1:1)
CAS no.	41621-49-2
EINECS no.	255-464-9
Molecular formula	$C_{12}H_{17}NO_2 \cdot C_2H_7NO$
Molecular weight	268.35
Structure	

Applications

CPO is a versatile and effective antifungal agent with a well-established safety profile. Its ability to disrupt fungal cell metabolism and membrane integrity makes it a valuable treatment option for a range of fungal infections.

- It is commonly formulated in creams, lotions, gels, shampoos, and nail lacquers.
- It is used primarily in treatment of fungal infections of the skin, including tinea corporis (ringworm), tinea cruris(jock itch), tinea pedis (athlete's foot), and the nails (onychomycosis).
- Clinically, ciclopirox 1% cream, lotion, and 0.77% topical suspension are indicated for the treatment of cutaneous candidiasis.
- In dosage of 0.7 %– 1.6% it provides relief of symptoms such as itching, redness.
- It exerts its anti-inflammatory activity by inhibiting 5-lipoxygenase and cyclooxygenase (COX).
- Ciclopirox Olamine can be used to study the regulatory mechanisms of metal homeostasis in cells and its effects on cellular processes.

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SPECIFICATIONS

Test	Unit	Specification
Appearance	-	White or Pale-yellow crystalline powder
Solubility	-	Sparingly soluble in water, very soluble in Ethanol (96%) & in Methylene Dichloride , slightly soluble in Ethyl Acetate, practically insoluble in Cyclohexanone
Identification (IR)	%	Should match with standard
Thin layer chromatography	-	Should pass test
Appearance of the solution	-	Should pass test
pH (In mixture with water 1:1000)	-	8.0 – 9.0
Loss on drying	%	Max 1.5
Residue on Ignition	%	Max 0.1
Related substance		
Impurity A at 220 nm	%	NMT 0.5
Impurity B at 220 nm	%	NMT 0.5
Impurity C at 220 nm	%	NMT 0.5
Unspecified Impurities	%	NMT 0.5
Sum of impurities other than B at 298 nm	%	NMT 0.5
Assay (Potentiometry)		
2- Aminoethanol	%	22.2 -23.3
Ciclopirox	%	76.0 -78.5
Residual Solvents		
Ethyl Acetate	ppm	NMT 5000

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Test	Unit	Specification
Ethylene Dichloride (EDC)	ppm	NMT 5
Hexane	ppm	NMT 290
Methanol	ppm	NMT 3000

STORAGE & PRECAUTION
Store at ambient conditions

PACKING
25 kg drum

REACH Status
REACH registered

ExSyn offers Ciclopirox Olamine Ph.Eur. on commercial scales and welcomes enquiries. No matter the quantity you need, our exceptional quality and service will make ExSyn your supplier of choice! If you need any additional information or SDS, please contact us.