

CERTIFICATE OF ANALYSIS

Product name: ENOXOLONE EP **Product Code:** 1002-ACT
Botanical name: **Part Used:**
Batch: 10020005035-FP **Manufacturing date:** 26/08/2015 **Exp. date:** 25/08/2020
Storage: Keep container tightly sealed and store in a cool place in closed original container
Comment: 5 years in original packaging

ANALYSIS	METHODS	SPECIFICATIONS	RESULTS
Description			
Appearance	Visual	White or almost white crystalline powder	Complies
Physico-Chemical			
Solubility Loss on drying (% w/w) Sulphated ash (%) Appearance of solution Specific optical rotation Identification IR	Eur.Ph.current ed. 2.2.32 Eur.Ph.current ed.2.4.14 Eur.Ph.current ed.2.2.1 and 2.2.2 Method II Eur.Ph.current ed.2.2.7 Eur.Ph.current ed.2.2.24	Soluble in ethanol, practically insoluble in water, Sparingly soluble in methylene chloride $\leq 0,5$ $\leq 0,2$ solution is clear and < Y6 +145,0 to +154,0 Complies	Complies 0.02 0.06 Complies 151.1 Complies
Related substances			
Total impurities (%) Any impurity (%)	HPLC HPLC	$\leq 2,0$ $\leq 0,7$	0.9 0.4
Assay			
Assay (% (dried substance))	Potentiometry-Eur.Ph.current edition	98,0-101,0	100.5
Residual solvents			
Ethanol (%)	GC (Acc.CPMP/ICH/283/95 guidelines)	$\leq 0,5$	0.04
Microbiology			
Total aerobic microbial count (TAMC) (CFU/g) Total combined yeasts/moulds count (TYMC) (CFU/g) Escherichia coli (g) Salmonella (g) Staphylococcus aureus (g)	Eur.Ph.current ed.2.6.12 Eur.Ph.current ed.2.6.12 Eur.Ph.current ed.2.6.31 Eur.Ph.current ed.2.6.31 Eur.Ph.current ed.2.6.13	≤ 1000 ≤ 100 Absence 1 Absence 1 Absence 1	<1000 <100 Absence Absence Absence
Contaminants			
Heavy metals (ppm)	ICP	≤ 20	<20

Acc.to the monograph "1511:Enoxolone" of Eur.Ph. current edition

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