



ERREGIERRE

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CERTIFICATE OF ANALYSIS N°

38897

AMBROXOL HYDROCHLORIDE EP

CAS N. 23828-92-4 CODE 486

BATCH S0513038

MAN. DATE 05/2013 RETEST DATE 05/2019

TEST FOR	SPECIFICATIONS	RESULTS
Description	white to yellowish crystalline powder	Complies
Identification		
· IR	positive	Complies
· Chlorides	positive	Complies
Appearance of solution	according to EP	Complies
pH	$\geq 4.5 \leq 6.0$	5.3
Heavy metals	NMT 10 ppm (EP spec.: NMT 20ppm)	Complies
Loss on drying	≤ 0.5 %	0.02
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.01
Assay (volumetric, on dried basis)	$\geq 99.0 \leq 101.0$ %	100.4
Related substances (HPLC)		
· any impurity (highest)	≤ 0.10 %	Non quantifiable
· total	≤ 0.3 %	Non quantifiable
<u>Additional specifications</u>		
Residual solvents (GC)		
· ethyl acetate	≤ 500 ppm	106

OBSERVATIONS:

Copies of this CoA are not valid

APPROVED

on May 24, 2013

QUALITY CONTROL

Dr. G.Lorenzi

May 27, 2013