

Certificate of Analysis

PRODUCT : Water purified ERBapharm-According to pharmacopoeia: Ph.Eur.-FU-Ph.Franc.-BP-DAB-USP-JP
CODE : 307602
LOT N° : V5C404265C **METHOD** : 7339
EXPIRING DATE : 2016/03 **EDITION** 5

TEST	U.M.	SPECIFICATION	RESULT
Description	-	Clear colourless liquid	Conform
Identification	-	Positive	Positive
pH	-	5.0 ÷ 7.0	6.7
Acidity or alkalinity	Ph.Eu.	Conform	Conform
Oxidizable substances	Ph.Eu.	Conform	Conform
Chloride	-	Pass test	Conform
Sulphate	-	Pass test	Conform
Calcium	-	Conform	Conform
Calcium + Magnesium	Ph.Eu.	Conform	Conform
Carbon dioxide	-	Conform	Conform
Residue on evaporation	ppm	<=10	0.4
Ammonium	ppm	<=0.2	< 0.2
Nitrate	ppm	<=0.2	< 0.2
Heavy metals (Pb)	ppm	<=0.1	< 0.1
Total aerobic bacteria	Ph.Eu.	Conform	Conform
Origin (BSE/TSE)	-	Mineral	Conform

Produced according Pharmacopoeia requirements
Total aerobic bacteria conform to European Pharmacopoeia
Not to be used for dialysis solutions or sterile and apyrogenic preparations

Statistical sampling executed in conformity with $\sqrt{n} + 1$ and CER CQ000 procedure

Approve Date : 22/04/2015

Not signed electronically issued document

QUALITY CONTROL RESPONSIBLE

B. COULANGE (VDR)