

Certificate of analysis: Aqua purificata

Test method: Ph. Eur. 04/2018:0008

Batch: 20H18-H500130135 (BIB 5L)

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect:		
Appearance	Clear, colourless, odourless and tasteless liquid	Complies
Other tests:		
Nitrates (limit test)	NMT 0,2 ppm	Complies
Oxidizable substances (colour reaction)	The solution remains faintly pink	Complies
Chlorides (reaction)	No change in appearance for at least 15 minutes.	Complies
Sulfates (reaction)	The solution shows no change in appearance for at least 1 hour.	Complies
Ammonium (limit test)	NMT 0,2 ppm	Complies
Calcium & magnesium (colour reaction)	A pure blue colour is produced.	Complies
Acidity or alkalinity		
Acidity or alkalinity 1 (colour reaction)	The solution is not coloured red.	Complies
Acidity or alkalinity 2 (colour reaction)	The solution is not coloured blue	Complies
Conductivity		
Conductivity	Complies with Ph. Eur.	1,2 µS/cm
Temperature		23,2°C
Residue on evaporation:		
Residue on evaporation (mg)	NMT 1 mg	0,1 mg
Residue on evaporation (%)	NMT 0,001%	0,0001%
Microbial contamination		
Total viable aerobic count	NMT 100 CFU/ mL	< 10 CFU/ mL

BATCH RELEASED BY:

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Responsible Pharmacist

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