

CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : 763/23

Issue Date: August 02, 2023

28/08/2023

Lot. n°: C010523003

Manufacturing date: July 21, 2023

Expiry date: July 21, 2028

BORIC ACID EP POWDER

The product is in accordance with the European Pharmacopoeia 11.0 for Boric Acid

Analysis:

Characteristics	Units	Test	Specific	Analytical chemistry procedure employed
		Results	Min. Max.	
Description		Powder, white granules		
Identification		Positive		
Appearance of the solution		According to Ph. Eur.		
Solubility in alcohol		According to Ph. Eur.		
Organic volatile impurities		According to Ph. Eur.		
pH of 3,3 % solution		4,1	3,8 4,8	pH-Meter
Chloride Cl	ppm	< 0,8	- -	Ion Chromatography
Sulphate SO ₄	ppm	< 5	- 450	Ion Chromatography
Heavy metals as Pb	ppm	< 1	- 15	Colorimetry after concentration
Iron Fe	ppm	< 1	- -	Colorimetry (Tripyridil Triazine)
Boric Acid H ₃ BO ₃	%	100,0	99,0 100,5	Potentiometric Titration

Particle Size Distribution (% Progressive Residue)

Characteristics	Units	Test	Specific	Analytical chemistry procedure employed
		Results	Min. Max.	
ISO 3310				
> 300 µm	%	0,9	- 5,0	Laser diffraction

► **Shelf life statement/Date Limite d'Utilisation Optimale**

- The product stored in its original and properly sealed containers is chemically stable for at least 5 years from the manufacturing date indicated in the documents.
- Store cool, dry and well-ventilated place, away from strong reducing agents; keep preferably at a temperature between 20°C and 35°C; To avoid:
 - high air humidity
 - sunlight exposure
 - temperatures under -5°C and over 40°C

Laboratory / Quality Control
Michele Ciampoli