

CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : 1325/24

Issue Date: December 11, 2024

Lot. n°: C010524005

Manufacturing date: December 05, 2024

Expiry date: December 05, 2029

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		European Pharmacopoeia
Appearance of the solution		: According to Ph. Eur.		European Pharmacopoeia
Solubility in alcohol		: According to Ph. Eur.		European Pharmacopoeia
Organic volatile impurities		: According to Ph. Eur.		European Pharmacopoeia
pH of 3,3 % solution		: 4,1	3,8 4,8	pH-Meter
Sulphate SO ₄	ppm	< 20	- 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 Results	Specific	Analytical chemistry procedure employed
ISO 3310			Min. Max.	
> 300 µm	%	3,8	- 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