

**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:

<u>Characteristics</u>	<u>Units</u>	<u>Test</u>	<u>Specific</u>		<u>Analytical chemistry procedure employed</u>
			Results	Min. Max.	
Description		:	<b>Powder, white granules</b>		
Identification		:	<b>Positive</b>		European Pharmacopoeia
Appearance of the solution		:	<b>According to Ph. Eur.</b>		European Pharmacopoeia
Solubility in alcohol		:	<b>According to Ph. Eur.</b>		European Pharmacopoeia
Organic volatile impurities		:	<b>According to Ph. Eur.</b>		European Pharmacopoeia
pH of 3,3 % solution		:	4,1	3,8 4,8	pH-Meter
Sulphate	SO <sub>4</sub>	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 <sub>3</sub> BO <sub>3</sub>	%	: 100,0	99,0 100,5	Potentiometric Titration

Particle Size Distribution (% Progressive Residue)

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			Results	Min. Max.	
<u>ISO 3310</u>					
> 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

*[Signature]*  
Michele Ciampoli