

*gh* 09/07/2024

**CERTIFICATE OF ANALYSIS**

Certificate of Analysis n° : 661/24

Issue Date: June 24, 2024

Lot. n°: C010524002

Manufacturing date: June 19, 2024

Expiry date: June 19, 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		:	<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		:	<b>4,2</b>	3,8 4,8	pH-Meter
Sulphate	SO <sub>4</sub>	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 <sub>3</sub> BO <sub>3</sub>	%	: 100,0	99,0 100,5	Potentiometric Titration

**Particle Size Distribution (% Progressive Residue)**

Characteristics	Units	Test Results	Specific		Analytical chemistry procedure employed
			Min.	Max.	
ISO 3310					
> 300 µm	%	2,9	-	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*