

## CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : **692/21**

Issue Date: **July 08, 2021**

Lot. n°: **C010521002**

Manufacturing date: **July 05, 2021**

Expiry date: **July 05, 2026**

Print date: **July 08, 2021**

### **BORIC ACID EP POWDER**

The product is in accordance with the European Pharmacopoeia 10.0 for Boric Acid

#### Analysis:

<u>Characteristics</u>	Units	Test	Specific		<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		:	<b>4,0</b>	3,8 4,8	pH-Meter
Chloride	Cl	ppm <	<b>0,8</b>	- -	Ion Chromatography
Sulphate	SO <sub>4</sub>	ppm <	<b>5</b>	- 450	Ion Chromatography
Heavy metals	as Pb	ppm <	<b>1</b>	- 15	Colorimetry after concentration
Iron	Fe	ppm <	<b>1</b>	- -	Colorimetry (Tripyridil Triazine)
Boric Acid	H <sub>3</sub> BO <sub>3</sub>	% :	<b>100,0</b>	99,0 100,5	Potentiometric Titration

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

<u>Characteristics</u>	Units	Test Results	Specific		<u>Analytical chemistry procedure employed</u>
			Min.	Max.	
<u>ISO 3310</u>					
> 300 µm	%	<b>1,6</b>	-	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  
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