

**SCL Italia**

Larderello Group

METAPHARMACEUTICAL

N DE LOTE:

0130722

CERTIFICATE OF ANALYSIS

21/07/2022

Certificate of Analysis n° : 729/22

Issue Date: June 17, 2022

Lot. n°: C010522003

Manufacturing date: June 13, 2022

Expiry date: June 13, 2027

BORIC ACID EP POWDER

The product is in accordance with the European Pharmacopoeia 10.0 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			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			4,0	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)

<u>Characteristics</u>	<u>Units</u>	<u>Test Results</u>	<u>Specific</u>		<u>Analytical chemistry procedure employed</u>
			Min.	Max.	
<u>ISO 3310</u>					
> 300 µm	%	2,4	-	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

SCL Italia SpA

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