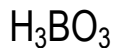


3 Compendials (EP, NF, JP)

Granular

Orthoboric Acid



CAS No. 10043-35-3

Optibor[®] 3 Compendials Granular is a white, crystalline product manufactured in France by Borax Français S.A.S. to conform to the current editions of the:

- U.S. Pharmacopeia/National Formulary
- European Pharmacopeia
- Japanese Pharmacopeia (translated into English)

U.S. Pharmacopeia/National Formulary

Chemical Specification

Analyte	Guarantee	Sieve Specification		
		U.S. Sieve	Mesh Size (mm)	% Retained Guarantee
H ₃ BO ₃ %	99.5 - 100.5	8	2.36	≤0.1
Loss on drying	≤ 0.5			
Solubility in alcohol	Completely dissolves			
Solubility in water	Clear solution			
Identification Test Borate A	Pass the test			

European Pharmacopeia

Chemical Specification

Analyte	Guarantee	Sieve Specification		
		U.S. Sieve	ISO Sieve (mm)	% Retained Guarantee
H ₃ BO ₃ %	99.0 - 100.5	N/A	1.00	≤ 2.0
pH of 33 g/l aqueous solution	3.8 - 4.8			
Sulphates (SO ₄) ppm	< 450			
Appearance of aqueous solution	Solution S is clear (2.2.1) and colorless (2.2.2, Method II)			
Organic matter	Does not darken on heating			
Solubility in alcohol	Solution is not more opalescent than reference suspension II (2.2.1) and is colorless (Method II, 2.2.2)			
Identification Tests A, B	Pass the tests			

Japanese Pharmacopeia

Chemical Specification

Analyte	Guarantee	Sieve Specification		
		U.S. Sieve	Mesh Size (mm)	% Retained Guarantee
H ₃ BO ₃ %	≥ 99.5	8	2.36	≤0.1
B ₂ O ₃ %	≥ 56.0			
Arsenic ppm	≤ 5			
Heavy metals ppm	≤ 10			
pH of 50 g/l aqueous solution	3.5 – 4.1			
Loss on drying %	≤ 0.5			
Clarity and color of solution	Pass the test			
Identification Tests A, B	Pass the tests			

Notes:

- All data in the above specifications are determined by NF, EP, and JP analytical methods.
- Product is only available in 200kg drums.