Sodium Borate, 10-Hydrate, N.F. Multi-Compendial

(Borax)



Material No.: 3575-07 Batch No.: 0000221513

Manufactured Date: 2018/05/24 Retest Date: 2023/05/23 Release Date: 2019/02/14

Revision No: 1

## Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets N.F. Requirements, GMP Manufactured Product

Test	Specification	Result
NF - Assay	99.0 - 105.0 %	101.4
NF - Identification	Passes Test	PT
NF - Carbonate and Bicarbonate	Passes Test	PT
NF - Endotoxin Concentration (EU/g)	<= 2.5	< 0.3
EP/BP - Assay (Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> ·10H <sub>2</sub> O)	99.0 - 103.0 %	101.8
EP/BP – Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Identification C	Passes Test	PT
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - pH of 4% Solution at 25°C	9.0 - 9.6	9.2
EP/BP - Sulfate (SO <sub>4</sub> )	<= 50 ppm	< 50
EP/BP – Ammonium (NH <sub>4</sub> )	<= 10 ppm	< 10
EP/BP - Arsenic (As)	<= 5 ppm	< 5
EP/BP - Calcium (Ca)	<= 100 ppm	< 100
JP – Assay (Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> · 10H <sub>2</sub> O)	99.0 - 103.0 %	101.4
JP – Identification	Passes Test	PT
JP - pH (1 in 20)	9.1 - 9.6	9.3
JP - Clarity and Color of Solution	Passes Test	PT
JP – Carbonate and Bicarbonate	Passes Test	PT
JP – Heavy Metals (as Pb)	<= 20 ppm	< 20
JP – Arsenic (As)	<= 5 ppm	< 5

**Bulk Pharmaceutical Chemical** 

CAUTION: For Manufacturing, processing or repackaging No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Material No.: 3575-07 Batch No.: 0000221513

Elemental Impurities (USP 232, EP 5.20) – Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Country of Origin: IT

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0078001

Manufacturer source batch: C020218006



Phillipsburg, NJ 9001:2015, FSSC22000
Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Gliwice, Poland 9001:2015, 13485:2012
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2015, 17025:2005
Panoli, India 9001:2015

Jamie Ethier
Vice President Global Quality