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

(Borax)



Material No.: 3575-07 Batch No.: 0000166150 Manufactured Date: 2016/10/06

Retest Date: 2021/10/05

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 %	101.7
NF – Identification	Passes Test	PT
NF – Carbonate and Bicarbonate	Passes Test	PT
NF – Heavy Metals (as Pb)	<= 0.002 %	< 0.002
NF – Endotoxin Concentration (EU/g)	<= 2.5	2.5
EP/BP – Assay (Na2B4O7·10H2O)	99.0 - 103.0 %	102.1
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 ₄)	<= 50 ppm	< 50
EP/BP – Ammonium (NH ₄)	<= 10 ppm	< 10
EP/BP – Arsenic (As)	<= 5 ppm	< 5
EP/BP – Calcium (Ca)	<= 100 ppm	< 100
EP/BP – Heavy Metals (as Pb)	<= 25 ppm	< 25
P – Assay (Na2B4O7 · 10H2O)	99.0 - 103.0 %	101.7
P – Identification	Passes Test	PT
P – pH (1 in 20)	9.1 - 9.6	9.3
P – Clarity and Color of Solution	Passes Test	PT
P – Carbonate and Bicarbonate	Passes Test	PT
P – Heavy Metals (as Pb)	<= 20 ppm	< 20
P – Arsenic (As)	<= 5 ppm	< 5

Bulk Pharmaceutical Chemical

Material No.: 3575-07 Batch No.: 0000166150

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.

Country of Origin: IT

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0078001
Manufacturer source batch: C020216019



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000
Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003
Gliwice, Poland 9001:2008, 13485:2012
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008
Panoli, India 9001:2008

Jamie Ethier
Vice President Global Quality