

Sodium Bicarbonate, Powder, USP
Multi-Compendial



Material No.: 3510-05
Batch No.: 0000170164
Manufactured Date: 2016/03/01
Retest Date: 2021/02/28

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
USP – Identification	Passes Test	PT
USP – Limit of Sulfur Compounds	$\leq 0.015 \%$	< 0.015
USP – Loss on Drying	$\leq 0.25 \%$	< 0.05
USP – Insoluble Matter	Passes Test	PT
USP – Normal Carbonate	Passes Test	PT
USP – Limit of Ammonia	$\leq 20 \text{ ppm}$	< 20
USP – Chloride (Cl)	$\leq 0.015 \%$	< 0.015
USP – Arsenic (As)	$\leq 2 \text{ ppm}$	< 2
USP – Heavy Metals (as Pb)	$\leq 5 \text{ ppm}$	< 5
USP – Assay (NaHCO_3) (dried basis)	99.0 – 100.5 %	100.0
USP – Endotoxin Concentration (EU/g)	≤ 2.5	< 1.0
EP/BP – Assay (NaHCO_3)	99.0 – 101.0 %	100.2
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 – Carbonate (CO_3)	Passes Test	PT
EP/BP – Chloride (Cl)	$\leq 150 \text{ ppm}$	< 150
EP/BP – Sulfate (SO_4)	$\leq 150 \text{ ppm}$	< 150
EP/BP – Ammonium (NH_4)	$\leq 20 \text{ ppm}$	< 20
EP/BP – Arsenic (As)	$\leq 2 \text{ ppm}$	< 2
EP/BP – Calcium (Ca)	$\leq 100 \text{ ppm}$	< 100

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.

3477 Corporate Parkway, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Test	Specification	Result
EP/BP – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Iron (Fe)	<= 20 ppm	< 20
JP – Assay (NaHCO ₃)	99.0 – 101.0 %	100.0
JP – Identification	Passes Test	PT
JP – pH (1 in 20)	7.9 – 8.4	8.0
JP – Clarity and Color of Solution	Passes Test	PT
JP – Chloride (Cl)	<= 0.040 %	< 0.040
JP – Carbonate (CO ₃)	Passes Test	PT
JP – Ammonium (NH ₄)	Passes Test	PT
JP – Heavy Metals (as Pb)	<= 5 ppm	< 5
JP – Arsenic (As)	<= 2 ppm	< 2

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.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0040001
Manufacturer source batch: FF6061



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

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Jamie Ethier
Vice President Global Quality

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