Sodium Carbonate, Anhydrous, N.F. Multi-Compendial



Material No.: 3606-09

Revision No.: 0

Product Specification

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

| Test | Specification |
|---|----------------|
| NF - Identification A | Passes Test |
| NF - Identification B | Passes Test |
| NF - Water (H ₂ O) | ≤ 0.5 % |
| NF - Assay (Na ₂ CO ₃) (anhydrous basis) | 99.5 - 100.5 % |
| EP/BP - Assay (Na ₂ CO ₃) (dried basis) | 99.5 - 100.5 % |
| EP/BP - Identification A | Passes Test |
| EP/BP - Identification B | Passes Test |
| EP/BP - Identification C | Passes Test |
| EP/BP - Identification D | Passes Test |
| EP/BP - Appearance of Solution | Passes Test |
| EP/BP - Alkali Hydroxides and Bicarbonates | Passes Test |
| EP/BP - Chloride (CI) | ≤ 125 ppm |
| EP/BP - Sulfate (SO ₄) | ≤ 250 ppm |
| EP/BP - Iron (Fe) | ≤ 50 ppm |
| EP/BP - Loss on Drying | ≤ 1.0 % |
| JP - Identification A | Passes Test |
| JP - Identification B | Passes Test |
| JP - Clarity and Color of Solution | Passes Test |
| JP - Chloride (CI) | ≤ 0.071 % |
| JP - Heavy Metals (as Pb) | ≤ 20 ppm |
| JP - Arsenic (As) | ≤ 3.1 ppm |
| JP - Loss on Drying | ≤ 0.5 % |
| JP - Assay (Na₂CO₃) (dried basis) | 99.0 - 101.0 % |

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Test Specification

GMP Manufactured Product 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. 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.

Packaging Site: Phillipsburg Mfg Ctr & DC

