

Kalchem International

Chemicals & Compounding Supplies

SODIUM BICARBONATE - CERTIFICATE OF CONFORMANCE

Grade: USP One
 Date of Manufacture: 02/02/15 Lot Number: WW 5033

USP ANALYSIS

| | | | |
|-----------------------------|----------|--|-------------|
| Sodium Bicarbonate Assay | 100.0% | Description (White Crystalline Powder) | Passes test |
| Carbon Dioxide (calculated) | 52.4% | | |
| Alkali, Total (calculated) | 36.9% | Identity Tests | |
| *Arsenic | ≤ 2 ppm | 1. (Imparts Yellow Flame) | Passes test |
| *Heavy Metals | ≤ 2 ppm | 2. (CO ₂ Evolution in Acid & Precipitates into Calcium Hydroxide) | Passes test |
| *Loss on Drying | ≤ 0.25% | 3. (Cold Solution Uncolored by Phenolphthalein) | Passes test |
| *Chloride | ≤ 0.015% | Insoluble Substances (1:20 Complete and Clear) | Passes test |
| *Limit of Sulfur Compounds | ≤ 0.015% | *Ammonia (Heated Sample Evolves No Odor) | Passes test |
| | | *Normal Carbonate (Clear to Faint Pink with Phenolphthalein) | Passes test |

PARTICLE SIZE DISTRIBUTION

| <u>sieve mesh size:</u> | <u>100</u> | <u>200</u> | <u>325</u> |
|-----------------------------|------------|------------|------------|
| Cumulative Percent Retained | 0 | 38 | 71 |
| Fraction Percent Retained | 0 | 38 | 33 |
| Fraction Percent Through | 100 | 62 | 29 |

P.O. # DA-802900

REMARKS

- 1.) Meets Current USP Specifications. Meets FCC requirements. Stability greater than three years.
- 2.) *Finished Product Testing and Release*: Based on the continuous nature of the manufacturing operation and product history, product is released upon successful completion of Description, Identification, Assay, Insoluble Substances, Particle Size Distribution testing, and batch record review.
 * Starred testing is completed for each lot on the following weekday.
- 3.) *Residual Solvents*: This product does not require Residual Solvents testing, under the USP-NF-(467) stipulation that based on the manufacturer's knowledge of the manufacturing process and controlled handling and storage of the product, there is no potential for the specific toxic solvents to be present if tested.
- 4.) *Additional Remarks*: 0

By: Tracie A Pecheny
 Green River Quality Control Laboratory

Date: 2/2/15

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