

NATRIUM PRODUCTS, INC.

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RESIDUAL SOLVENTS STATEMENT

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According to General Chapter <467> in the U.S. Pharmacopeia (USP), "Testing of drug substances, excipients, and drug products for residual solvents should be performed when production or purification processes are known to result in the presence of such residual solvents. It is only necessary to test for residual solvents that are used or produced in the manufacture or purification of drug substances, excipients, or products."

In the manufacture of sodium bicarbonate, Natrium Products Inc. does not use any of the Class 1, 2, or 3 solvents listed in General Chapter <467>. Furthermore, based on our knowledge of the raw materials and processes used, there is no potential for any residual solvents to be present in Natrium's products. Accordingly, Sodium Bicarbonate USP produced by Natrium Products, Inc. does not require testing for Residual Solvents under USP <467>.



Andrew F. Hoffmann
Regulatory Manager