

Avantor™ Performance Materials

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Technical Service Department

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Date: February 22, 2024

Re: Removal of Acetic Acid in the Production of Sodium Acetate Trihydrate:

Applicable Products:

J.T.Baker® 3461 Sodium Acetate, Trihydrate, Crystal, U.S.P., Multi-Compendial

J.T.Baker® 3462 Sodium Acetate, Trihydrate, Crystal, U.S.P. - F.C.C.

J.T.Baker® CH06 Sodium Acetate, Trihydrate, Crystal, C.H.P., Multi-Compendial

Background: Acetic acid is listed as a low toxicity Class 3 residual solvent in General Chapter <467> of the United States Pharmacopeia. The chapter states that residual solvents, not being of therapeutic value, be controlled in drug products and drug substances, including excipients. Acetic acid is used as a starting material in the production of sodium acetate trihydrate. If the validated process can be shown to effectively remove acetic acid so it is not expected or likely to be present in the final product, the requirements of General Chapter <467> will be met and unnecessary testing can be avoided.

Product Description: Acetic acid is reacted with sodium hydroxide to produce sodium acetate salt. The stoichiometry of the reaction is designed to effectively neutralize free acetic acid to meet acceptable and consistent yields. Process testing for pH during the early stages of production is conducted to assure correct stoichiometry occurs and that the resulting crystalline product meets the final test requirement for pH. The production process is controlled under current Good Manufacturing Practices. Details of the process are described and recorded utilizing the Batch Production Record.

Conclusions: Free acetic acid is quantitatively neutralized in the pH adjustment step of the process by maintaining a pH range from 7.5-8.5. Subsequent process steps do not add additional acetic acid to the process. Crystalline sodium acetate is recovered from the neutralized process liquors. The resulting sodium acetate trihydrate is required to meet a pH specification of 7.5-9.0 tested on a 5% solution. Typical testing values average about 8.5 within a typical range of 8.2-8.8. Under normal process operations and the specific pH requirements for sodium acetate trihydrate, free acetic acid is effectively removed during processing and is not present in the final crystalline product.

If you have any questions or require additional information, please contact Technical Services.

Prepared by the Avantor
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Revision History:

Rev. 0; August 5, 2020 – New CIQA Document Created (PT)

Rev. 1; February 22, 2024 – Updated to new letterhead