

RESIDUAL SOLVENTS STATEMENT

Sodium Decanoate GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Sodium Decanoate, Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra does not intentionally add or use any Class 1, 2, 3, or other solvents in the manufacturing process of Sodium Decanoate, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 3 solvent Ethanol is used in the manufacture of the raw material supplied to BioSpectra. BioSpectra has additionally analyzed Sodium Decanoate finished good for residual solvents during process validation, and confirmed that the product complies with the limit of 5000 ppm max Ethanol.

| Current Product Number |
|------------------------|
| NDEC-4201 |

For further information, please contact info@biospectra.us

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