

May 28, 2026

**Suitable for Human Use Statement**

**Sodium Decanoate, GMP**

BioSpectra's Sodium Decanoate, product code: NDEC-3201, is manufactured for the intended use in pharmaceuticals as a novel parenteral excipient. Therefore, it is suitable for use in human parenteral and oral drugs. It is manufactured in accordance with ICH Q7 Good Manufacturing Practice Guide in our FDA registered cGMP facility in Bangor PA, USA. BioSpectra maintains an active TYPE IV Drug master file for this product with the USFDA.

Respectfully submitted,



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