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TECHNICALLY UNAVOIDABLE PARTICLE PROFILE (TUPP) – SODIUM DECANOATE

PROCESS ROOM E06

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1. PURPOSE:

- 1.1. The purpose of this document is to provide the user of this product with a Technically Unavoidable Particle Profile (TUPP) for Process Room E06 at BioSpectra's Bangor, PA facility used in the manufacture of cGMP Sodium Decanoate Bio Excipient grade.

2. SCOPE:

- 2.1. This TUPP applies to the manufacturing and packaging process of Sodium Decanoate manufactured at BioSpectra's Bangor, PA facility in Process Room E06.

3. REFERENCES:

- 3.1. IPEC; Technically Unavoidable Particle Profile (TUPP) Guide

4. DEFINITIONS:

- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all potential known Technically Unavoidable Particles (TUP) for an excipient process that can be shared with a customer or end user.
- 4.3. Atypical Particles – particles not consistent with the typical particulate profile; not previously encountered or identified.
- 4.4. Reprocessing: A system of improving an intermediate or finished product that does not conform to established specification by repeating a step or series of steps that are a part of the approved manufacturing process. The reprocessing of a batch of Sodium Decanoate was approved as part of the validation of the Sodium Decanoate manufacturing process.

5. TECHNICALLY UNAVOIDABLE PARTICLES (TUP):

- 5.1. The construction of a technically unavoidable particle profile assumes that GMPs are followed and possible mitigation strategies are taken, the remaining particles, if they pose no risk to safety, are deemed technically unavoidable.
- 5.2. Technically unavoidable particles could originate from any of the following parts of the manufacturing process: Material of Construction of the manufacturing equipment that is product contacting, consumable process equipment, Material of Construction of the packaging components and any materials that are involved in the manufacturing process that may come into contact with the product that are the lowest risk scenarios. Scenarios that are considered to be the lowest risk are situations in which no mitigation strategies exist or cannot be implemented within reason.

6. PROCESS FLOW DIAGRAM:

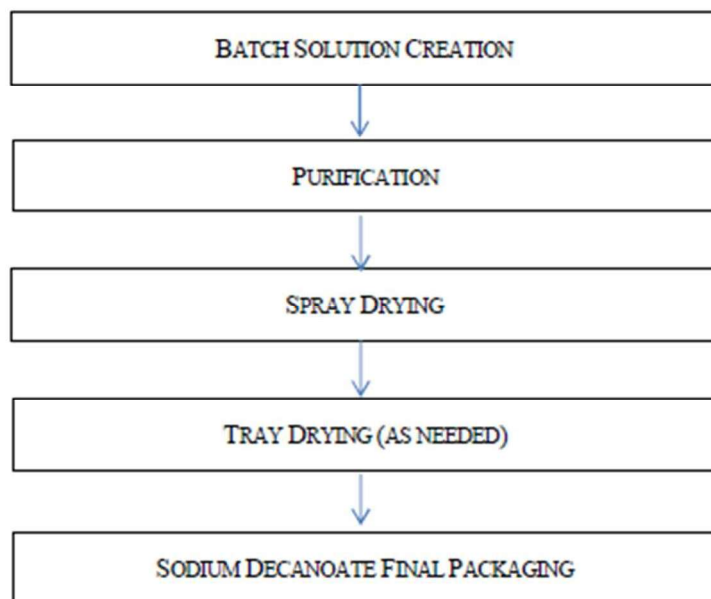


Figure 1: cGMP Sodium Decanoate Manufacturing Process Flow Diagram

7. PROFILE:







7.1. Manufacturing Location:

7.1.1. Bangor, PA Facility

7.2. Applicable Product Codes:




7.2.1. NDEC-3200 through NDEC-33XX, NDEC-4201-NDEC-42XX

7.3. TUPPs originating from product contacting surfaces in the manufacturing process:

Table 1: Originating from the Manufacturing Process					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
Glass	Glass Fragments	Process Tanks Process Tank Agitators	Filtration Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	Not Available
PTFE	Opaque White Plastic	Process Tanks	Filtration Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
Tantalum	Metallic Shavings	Process Tanks	Filtration Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
Hastelloy	Metallic Shavings	Process Tank Agitator Seals	Filtration Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
Polypropylene	Natural Colored Opaque Off- White Plastic	Process Tank Fittings	Filtration Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
Hastelloy C276	Metallic Shavings	Filter Housings	Filtration Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
316 Stainless Steel	Metallic Shavings	Spray Dryer Chamber Spray Dryer Atomizer Spray Dryer Cyclone Spray Dryer Bag House Collection Drums 12 Mesh Sieve Process Piping (P01 P04 Po7)	Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	

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Table 1: Originating from the Manufacturing Process

Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
304 Stainless Steel	Metallic Shavings	Spray Dryer Chamber	Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
HDPE	White Plastic	Drying Trays	Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	
PVC	White, Clear, or Gray Opaque Plastic	Milk Hoses	Inspection Reprocess	Pre-Process Inspection Preventative Maintenance	

7.4. TUPPs originating from product contacting surfaces of the packaging components:

7.4.1. The following TUPPs are dependent on the packaging type.




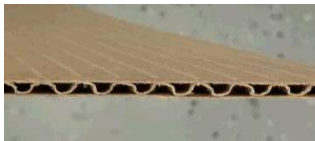

Table 2: Originating from the Packaging components

Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
Hexene LLDPE	Clear Plastic	Liner (Packaging)	Reprocessing	Inspection at time of use	
HDPE	White Plastic	Bottle (Packaging)	Reprocessing	Inspection at time of use	
Polypropylene	Blue Plastic	Tamper Evident lid (Packaging)	Reprocessing	Inspection at time of use	

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7.5. Atypical particles originating from non-product contacting surfaces of the packaging components:

7.5.1. The following Atypical particles are dependent on the packaging type.

Table 3: Atypical particles: originating from the packaging components					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
HMW-HDPE	Blue Plastic	Drum (Packaging)	Reprocessing	Inspection at time of use and Product Care Procedure	
HDPE	Blue or White Plastic	Pail and Lid (Packaging)	Reprocessing	Inspection at time of use and Product Care Procedure	
Fiber	Brown cardboard	Drum (Packaging) Drum (Desiccant Storage)	Reprocessing	Inspection at time of use and Product Care Procedure	
Cardboard	Brown	Pallet Liner	Reprocessing	Inspection at time of use and Product Care Procedure	
Wood	Wood Shaving	Pallet	Reprocessing	Inspection at time of use and Product Care Procedure	

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