



100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

TECHNICALLY UNAVOIDABLE PARTICLE PROFILE
(TUPP) – SODIUM CHLORIDE 5M SOLUTION
PROCESS ROOM L08

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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 L08 at Bio Spectra's Bangor, PA facility used in the manufacturing of cGMP Sodium Chloride 5M Solution Bio Excipient and below compliance grade material.

2. SCOPE:

- 2.1. This TUPP applies to the manufacturing and packaging process of Sodium Chloride 5M Solution manufactured at BioSpectra's Bangor, PA facility in Process Room L08.

3. REFERENCES:

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

4. DEFINITIONS:

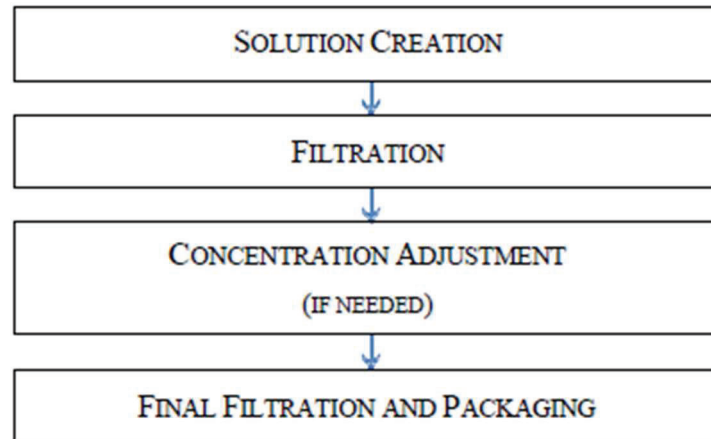
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all 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 Chloride 5M Solution was approved as part of the validation of the Sodium Chloride 5M Solution 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:

cGMP Sodium Chloride 5M Solution Manufacturing Process Flow Diagram



7. PROFILE:

7.1. Manufacturing Location:

7.1.1. Bangor, PA Facility

7.2. Applicable Product Codes:

7.2.1. Sodium Chloride 5M Solution, NACL-3100 and below compliance grades

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

Originating from the Manufacturing Process					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
Polyethylene	Opaque White Plastic	Process Tanks Basket Filters	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
Hastelloy C276	Metallic Shavings	Process Tank Agitators	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
Viton	Black Elastomer Fragment	Basket Filters	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
Carbon	Black or Gray Fragments	Centrifugal Pump	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	Not Available
Ceramic	Ceramic Fragments	Centrifugal Pump	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	

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Originating from the Manufacturing Process

Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
Fluorosint PTFE	Opaque White Plastic	Centrifugal Pump	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
Kalrez	Black Plastic	Centrifugal Pump	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
Polypropylene	Opaque Off-White Plastic	Basket Filters Centrifugal Pump	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
PTFE	Opaque White Plastic	Centrifugal Pump	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	
PVC	Clear, White, or Gray Opaque Plastic	Milk Hoses	Filtration Reprocessing Inspection	Pre-Process Inspection Preventative Maintenance	

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

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

Originating from the Packaging Components					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
TepoFlex	Clear Opaque Plastic	1000L TepoFlex Biocontainer	Reprocessing	Inspection at Time of Use	
TPE	Clear Opaque Plastic	1000L TepoFlex Biocontainer	Reprocessing	Inspection at Time of Use	
Silicone	Clear Opaque Plastic	1000L TepoFlex Biocontainer	Reprocessing	Inspection at Time of Use	

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