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## TECHNICALLY UNAVOIDABLE PARTICLE PROFILE (TUPP) – WATER FOR INJECTION

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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 packaging of cGMP Water for Injection Bio Excipient and below compliance grade material.

**2. SCOPE:**

- 2.1. This TUPP applies to the packaging process of Water for Injection at BioSpectra's Bangor, PA facility in Process Room L08.

**3. REFERENCES:**

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

**4. DEFINITIONS:**

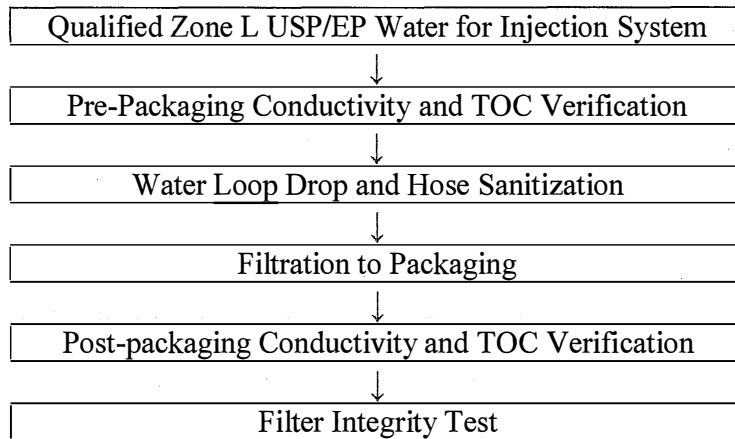
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all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

**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 Water for Injection Bio Excipient Grade Process Flow Diagram



**7. PROFILE:**

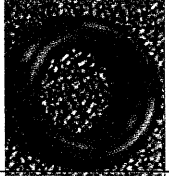
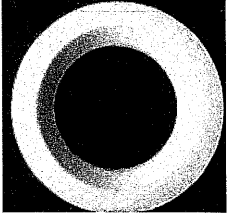
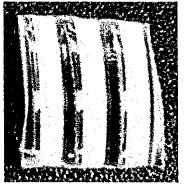
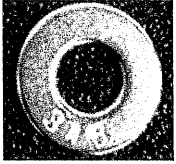
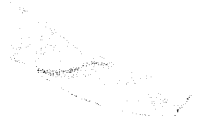
7.1. Packaging Location:

7.1.1. Bangor, PA Facility




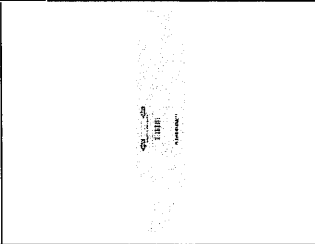
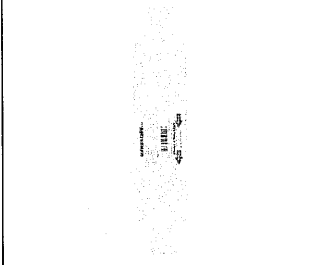

7.2. Applicable Product Codes:

7.2.1. Water for Injection, WAFI-31XX and below compliance grades



7.3. TUPPs originating from product contacting surfaces during the packaging process:

Originating from the Packaging Process					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
Viton	Black Elastomer Fragment	Gaskets	Filtration Inspection	Pre-Process Inspection Preventative Maintenance	
PTFE	Opaque White Plastic	Gaskets	Filtration Inspection	Pre-Process Inspection Preventative Maintenance	
PVC	Clear, White, or Gray Opaque Plastic	Milk Hoses	Filtration Inspection	Pre-Process Inspection Preventative Maintenance	
316L Stainless Steel	Metal shavings	Water for Injection loop	Filtration Inspection	Pre-Process Inspection Preventative Maintenance	
PTFE / Teflon	White strand	Process piping connections / Pressure gauge connection	Filtration Inspection	Pre-Process Inspection Preventative Maintenance	

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

<b>Originating from the Product Contact Packaging Components</b>				
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Prevented</b>	<b>Picture (Example of Source)</b>
TepoFlex	Clear Opaque Plastic	200L & 1000L TepoFlex Biocontainer	Inspection at Time of Use	
TPE	Clear Opaque Plastic	1000L TepoFlex Biocontainer	Inspection at Time of Use	
Silicone	Clear Opaque Plastic	1000L TepoFlex Biocontainer tubing	Inspection at Time of Use	
Polyethersulfone (PES) / STyLUX	Clear Opaque Plastic	1000L TepoFlex Biocontainer filter	Inspection at Time of Use	
Polypropylene / SteriLUX	Clear Opaque Plastic	200L TepoFlex Biocontainer filter 1-1/2" Sanitary Connection	Inspection at Time of Use	
PVC	Clear Opaque Plastic	200L TepoFlex Biocontainer tubing	Inspection at Time of Use	

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

<b>Originating from the Non-Product Contact Packaging Components</b>				
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Prevented</b>	<b>Picture (Example of Source)</b>
ABS or Acrylonitrile Butadiene Styrene	Tan rigid plastic	FlexStation 1000L	Inspection	
HMW-HDPE	Blue Plastic	Drum	Inspection	
Polyethylene	White foam	Dunnage	Inspection	