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TECHNICALLY UNAVOIDABLE PROFILE (TUPP) –  
TRIS BIO FUISA/ACTIVE  
PROCESS ROOM E04

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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 API Suite 3 Process Room E04 at BioSpectra's Majestic, PA facility used in the manufacture of cGMP Tris Bio FUIISA/Active grade.

**2. SCOPE:**

- 2.1. This TUPP applies to the manufacturing and packaging process of Tris Bio FUIISA/Active manufactured at BioSpectra's Bangor, PA facility in Process Room E04.

**3. REFERENCES:**

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

**4. DEFINITIONS:**

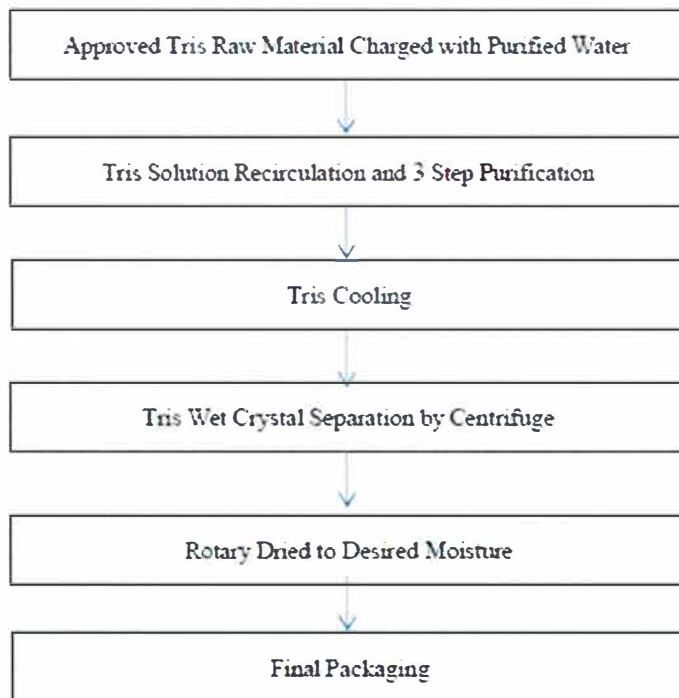
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all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

**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:

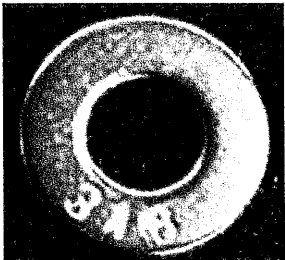
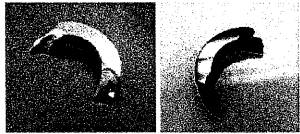
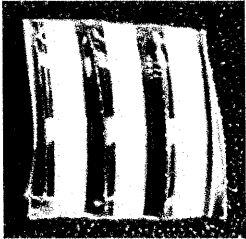
cGMP Tris Manufacturing Process Flow Diagram

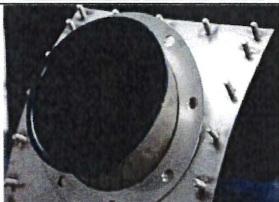
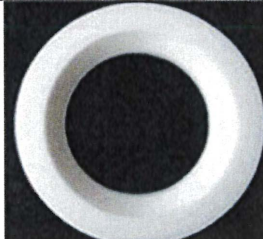

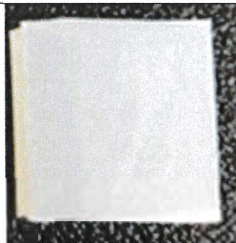
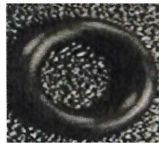



## 7. PROFILE:

- 7.1. Manufacturing Location:
  - 7.1.1. Bangor, PA Facility
- 7.2. Applicable Product Codes:
  - 7.2.1. TRIS, TRIS-12XX
  - 7.2.2. TRIS, TRIS-22XX




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

<b>Originating from the Manufacturing Process</b>					
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Removed</b>	<b>How Prevented</b>	<b>Picture (Example of Source)</b>
316 Stainless Steel	Metallic Shavings	Hot Tank Hot Tank Agitator Cold Tank Cold Tank Agitator Cartridge Filter Zeta Filter Polishing Filter	Filtration Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
		Centrifugal Pump Wall Supply Wall Return Centrifuge Rotary Dryer (Body and Shoot)	Reprocess Inspection		
Carbon	Black or Gray Fragments	Centrifugal Pump (Rotating Carbon Seal)	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	Not Available
Silicon Carbide	Ceramic Fragment	Centrifugal Pump (Stationary Seat)	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
PVC	White, Clear, or Gray Opaque Plastic	Zeta Filter	Filtration Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
		Milk Hoses	Reprocess Inspection		

<b>Originating from the Manufacturing Process</b>					
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Removed</b>	<b>How Prevented</b>	<b>Picture (Example of Source)</b>
Halar	Polymer Lining	Centrifuge	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
PTFE / Teflon	Opaque White Plastic	Centrifuge Rotary Dryer	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
Hastelloy C22	Metallic Shavings	Centrifuge	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
Silicone	Clear or White Elastomer	Rotary Dryer	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
Viton	Black Elastomer Fragment	Rotary Dryer (Gaskets)	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
Polyethylene	Opaque White Plastic	Chemical Hoses	Reprocess Inspection	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.

<b>Originating from the Packaging Components</b>					
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Removed</b>	<b>How Prevented</b>	<b>Picture (Example of Source)</b>
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	

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.

<b>Atypical particles: Originating from the packaging</b>					
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Removed</b>	<b>How Prevented</b>	<b>Picture (Example of Source)</b>
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	
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	