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# TECHNICALLY UNAVOIDABLE PARTICLE PROFILE (TUPP) – UREA 6M SOLUTION

## PROCESS ROOM L09

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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 L09 at BioSpectra's Bangor, PA facility used in the manufacturing of cGMP Urea 6M Solution Bio Excipient and below compliance grade material.

**2. SCOPE:**

- 2.1. This TUPP applies to the manufacturing and packaging process of Urea 6M Solution manufactured at BioSpectra's Bangor, PA facility in Process Room L09.

**3. REFERENCES:**

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

**4. DEFINITIONS:**

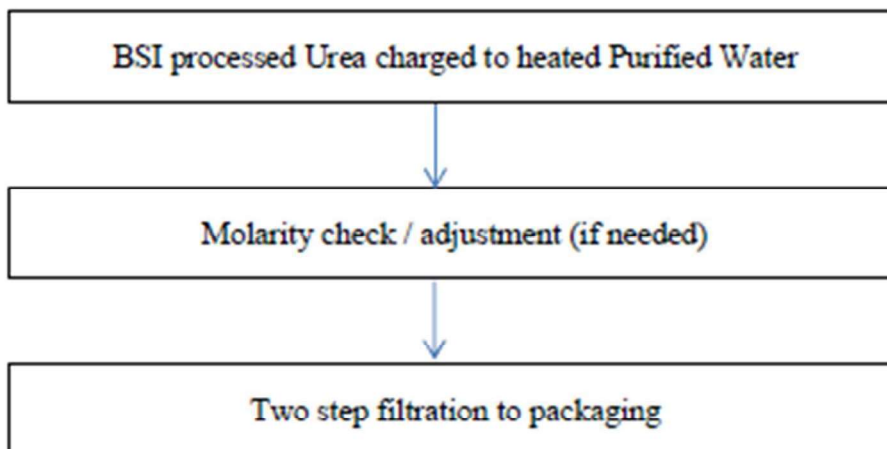
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all 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 Urea 6M Solution was approved as part of the validation of the Urea 6M 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 Urea 6M 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. Urea 6M Solution, UREA-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)
Polypropylene	Natural Colored Opaque Off-White Blue Plastic	Basket Filter Centrifugal Pump Diaphragm Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Hastelloy C-276	Metallic Shaving	Process Tank Agitator	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Viton	Black Elastomer Fragment	Basket Filter	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
316 Stainless Steel	Metallic Shaving	Heat Exchanger	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Fluorosint Polytetra- fluoroethylene (PTFE)	Opaque White Plastic	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Carbon	Black or Gray Fragments	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	Not Available
Ceramic	Ceramic Fragments	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Kalrez	Plastic	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	


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Polytetrafluoroethylene (PTFE)	Opaque White Plastic	Centrifugal Pump Diaphragm Pump Piping Threads (Teflon)	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Polyethylene	Opaque White Plastic	Process Tank Chemical Hoses	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
CPVC	Gray Plastic	Carbon Chamber (Housing and Piping) Cartridge Filter (Piping) Hand Valves and Piping Packaging Line	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Kynar	White / Off-White Plastic	Carbon Chamber (Piping)	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	Not Available
PVC	White, Clear, or Gray Opaque Plastic	Milk Hoses	Filtration Reprocessing	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.

<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>
HDPE	Opaque White Plastic  Black Plastic	55 Gallon Drum  1135 Liter Tote	Reprocessing	Inspection at time of use  Product Care Procedure	

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 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>
Wood	Wood Shaving	Pallet	Reprocessing	Inspection at time of use and Product Care Procedure	

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