



100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

TECHNICALLY UNAVOIDABLE  
PARTICLE PROFILE(TUPP)– URIDINE  
PROCESS ROOM N05

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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 N05 at BioSpectra's Bangor, PA facility used in the manufacturing of cGMP Uridine Bio Excipient grade material.

**2. SCOPE:**

- 2.1. This TUPP applies to the manufacturing and packaging process of Uridine manufactured at BioSpectra's Bangor, PA facility in Process Room N05.

**3. REFERENCES:**

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

**4. DEFINITIONS:**

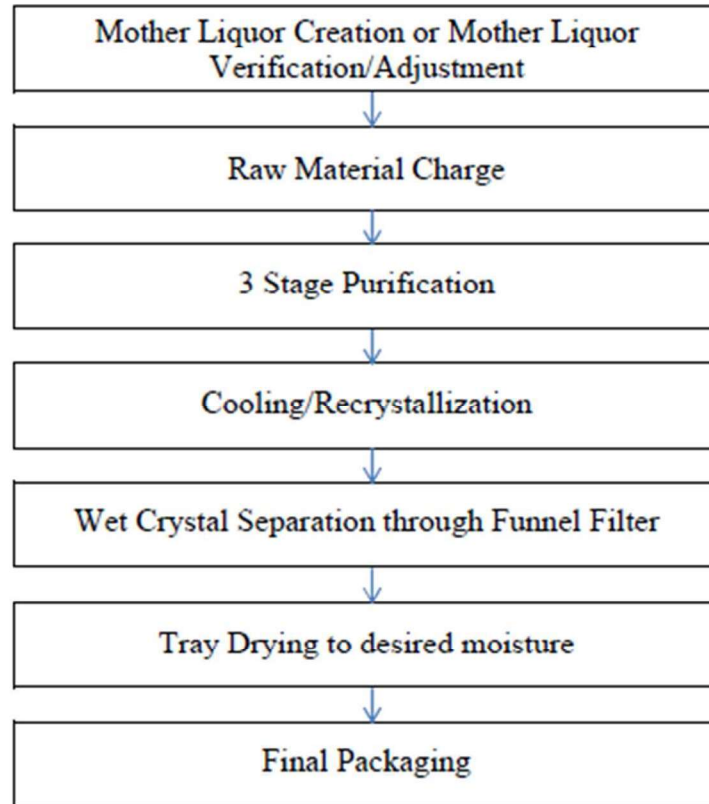
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all 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 Uridine has not yet been approved as part of the validation of the Uridine 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 Uridine Manufacturing Process Flow Diagram



## 7. PROFILE:





7.1. Manufacturing Location:

7.1.1. Bangor, PA Facility






7.2. Applicable Product Codes:

7.2.1. Uridine, URID-3200 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)
PTFE	Opaque White Plastic	Process Tank Gaskets Centrifugal Pump	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
Tantalum	Metallic Shavings	Process Tanks	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
Hastelloy	Metallic Shavings	Process Tank Agitator Seals	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
Hastelloy C-276	Metallic Shavings	Cuno Filter Housings Zeta Filter Housings	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
Glass	Glass Fragments	Process Tank Agitators (Glass Coated) Process Tanks (Glass Coated Interiors)	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	Not Available




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Polypropylene	Natural Colored Opaque Off White Plastic	Process Tanks Piping and fittings 5 Micron Cartridge Filter	Filtration Inspection of product post- filtration	Pre-Process Inspection  Preventative Maintenance	
		Funnel Filter Shell  Funnel Filter Perforated Plate  Funnel Filter's Filter Cloth	Inspection of product post- filtration	Replacement of Filters	
PVDF	Opaque Plastic	Centrifugal Pump	Filtration Inspection of product post- filtration	Pre-Process Inspection  Preventative Maintenance	
Kalrez	Black Plastic	Centrifugal Pump	Filtration Inspection of product post- filtration	Pre-Process Inspection  Preventative Maintenance	
Alumina Ceramic	Ceramic Fragments	Centrifugal Pump	Filtration Inspection of product post- filtration	Pre-Process Inspection  Preventative Maintenance	
USP Silicon	Clear Elastomer	Pipe Gasket	Filtration Inspection of product post- filtration	Pre-Process Inspection  Preventative Maintenance	

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Viton	Black Elastomer Fragment	Pipe Gasket	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
PVC	White, Clear, or Gray Opaque Plastic	Milk Hoses	Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
Polyethylene	Opaque White Plastic	Chemical Hoses	Filtration Reprocess Inspection	Pre-Process Inspection Preventative Maintenance	
Active Carbon	Black or Gray Fragments	0.7-2 Micron Zeta Filter	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance Replacement of Filters	Not available
Cellulose	Fiber	0.7-2 Micron Zeta Filter	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance Replacement of Filters	
Polyethersulfone	Opaque White Plastic	0.2 Micron Filter Capsule	Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance Replacement of Filters	Not Available

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316 Stainless Steel	Metallic Shavings	Funnel Filter Fittings Drum Sifter	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
HDPE	White Plastic	Funnel Filter Support Structure Drying Trays Drum Sifter	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	
CPVC	Gray Plastic	Funnel Filter Fittings	Filtration Inspection of product post-filtration	Pre-Process Inspection Preventative Maintenance	

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




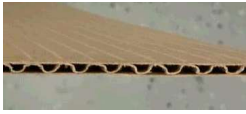

## 7.4.1. The following TUPPs are dependent on the packaging type.

<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>
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.

<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>
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 Shavings	Pallet	Reprocessing	Inspection at Time of Use and Product Care Procedure	

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