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TECHNICALLY UNAVOIDABLE PARTICLE PROFILE (TUPP) – D-GALACTOSE, PLANT DERIVED

PROCESS ROOM N02/E06

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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 N02 and E06 at BioSpectra's Bangor, PA facility used in the manufacturing of cGMP D-Galactose, Plant Derived, Bio Excipient grade product.

2. SCOPE:

2.1. This TUPP applies to the manufacturing and packaging process of D-Galactose, Plant Derived manufactured at BioSpectra's Bangor, PA facility in Process Room N02 and E06.

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 D-Galactose Plant Derived was approved as part of the validation of the D-Galactose Plant Derived manufacturing process.

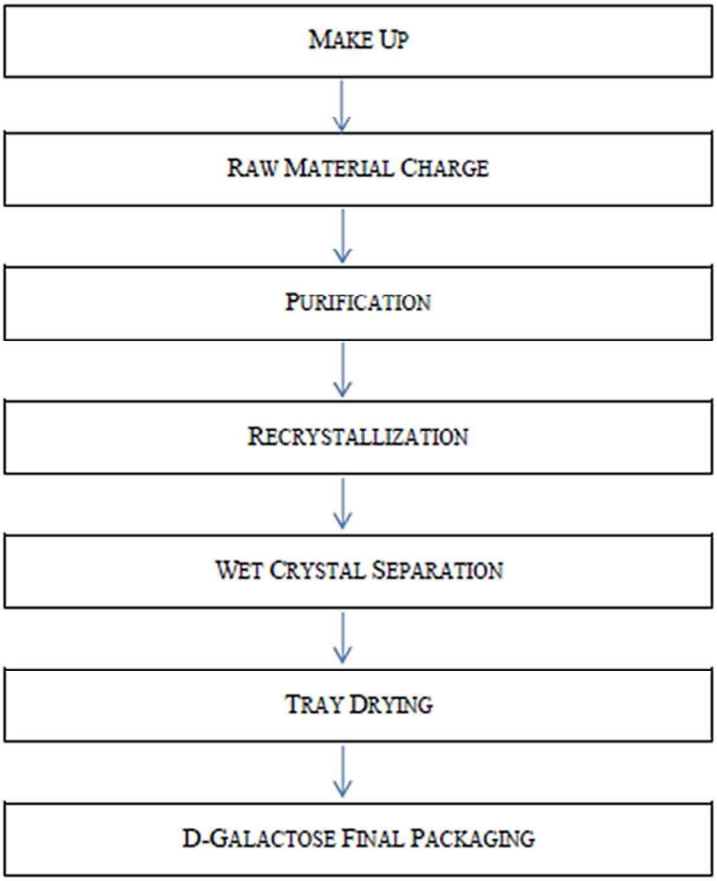
5. TECHNICALLY UNAVOIDABLE PARTICLES (TUP):

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 D-Galactose Plant Derived Manufacturing Process Flow Diagram



7. PROFILE:

7.1. Manufacturing Location:

7.1.1. Bangor, PA Facility

7.2. Applicable Product Codes:

7.2.1. D-Galactose, Plant Derived, GALP-3200 and below compliance grades

Table 1: 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)**
Tantalum	Metallic Shavings	Process Tanks	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
PTFE	Opaque White Plastic	Process Tanks Process Tank Burst Disks Process Tank Pressure Gauges	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
		Centrifugal Pump Centrifuge Diaphragm Pump	Inspection of the product Reprocess		
Glass	Glass Fragments	Process Tanks Process Tank Agitators	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	Not Available
Hastelloy	Metallic Shavings	Process Tanks	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Hastelloy C276	Metallic Shavings	Filter Housings	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Hastelloy C22	Metallic Shavings	Centrifuge	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	

Originating from the Manufacturing Process					
Identity	**Characterization**	**Origin**	**How Removed**	**How Prevented**	**Picture (Example of Source)**
Polypropylene	Natural Colored Opaque Off-White Plastic	Process Tanks Process Tank Pressure Gauges Basket Filter Filtration(N02)	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Polypropylene Conductive	Natural Colored Opaque Off-White Plastic	Diaphragm Pump	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
PVDF	Opaque Plastic	Centrifugal Pump Basket Filter Filtration (E06)	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Kalrez	Plastic	Centrifugal Pump	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Alumina Ceramic	Ceramic Fragment	Centrifugal Pump	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Halar	Polymer Lining	Centrifuge Mother Liquor Trap Tank	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
316 Stainless Steel	Metallic Shaving	Tray Sifter Diaphragm Pump	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	

Originating from the Manufacturing Process					
Identity	**Characterization**	**Origin**	**How Removed**	**How Prevented**	**Picture (Example of Source)**
HDPE	White Plastic	Mother Liquor Holding Tank Drying Trays	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
LLDPE	Opaque Plastic	Sifting Bin	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Teflon	Opaque Plastic	Piping Threads	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	Not Available
PVC	White, Clear, or Gray Opaque Plastic	Milk Hoses	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
UHMV-PE (Polyethylene)	Opaque White Plastic	Chemical Hoses	Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	
Resin	Proprietary	Purification	Filtration Reprocess	Pre-Process Inspection Preventative Maintenance	Not Available
Active Carbon	Black or Gray Fragments	Filtration	Filtration Inspection of the product Reprocess	Pre-Process Inspection Preventative Maintenance	Not Avaiable

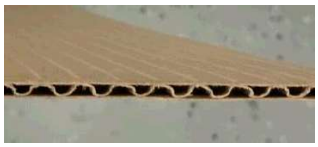
7.3. The following TUPPs are dependent on the packaging type.

Table 2: TUPPs originating from product contacting surfaces of the packaging components:

Originating from the Packaging Components					
Identity	**Characterization**	**Origin**	**How Removed**	**How Prevented**	**Picture (Example of Source)**
Hexene LLDPE	Clear Plastic	Liner (Packaging)	Inspection at time of use	Inspection at time of use	
HDPE	White Plastic	Bottle (Packaging)	Inspection at time of use	Inspection at time of use	
Polypropylene	Blue Plastic	Tamper Evident lid (Packaging)	Inspection at time of use	Inspection at time of use	

7.4. The following Atypical particles are dependent on the packaging type.

Table 3: Atypical particles originating from non-product contacting surfaces of the packaging components:

Atypical Particles: Originating from the Packaging Components					
Identity	**Characterization**	**Origin**	**How Removed**	**How Prevented**	**Picture (Example of Source)**
HMW-HDPE	Blue Plastic	Drum (Packaging)	Inspection at time of use	Inspection at time of use and Product Care Procedure	
HDPE	Blue or White Plastic	Pail and Lid (Packaging)	Inspection at time of use	Inspection at time of use and Product Care Procedure	
Cardboard	Brown	Pallet Liner	Inspection at time of use	Inspection at time of use and Product Care Procedure	
Wood	Wood Shaving	Pallet	Inspection at time of use	Inspection at time of use and Product Care Procedure