



100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

TECHNICALLY UNAVOIDABLE PARTICLE PROFILE (TUPP) – 6N HCl IN IPA

PROCESS ROOM N02

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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 at BioSpectra's Bangor, PA facility used in the manufacturing of cGMP 6N HCl in IPA, Bio Pharma grade.

2. SCOPE:

- 2.1. This TUPP applies to the manufacturing and packaging process of 6N HCl in IPA manufactured at BioSpectra's Bangor, PA facility in Process Room N02.

3. REFERENCES:

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

4. DEFINITIONS:

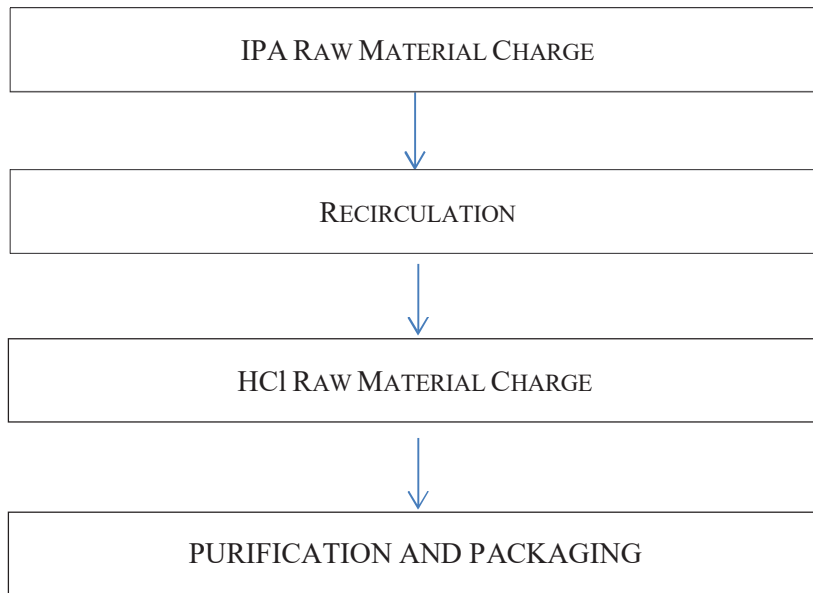
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all 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 6N HCl in IPA was approved as part of the validation of the 6N HCl in IPA 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 6N HCl in IPA Manufacturing Process Flow Diagram



7. PROFILE:

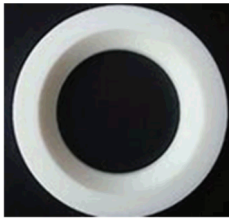




7.1. Manufacturing Location:

7.1.1. Bangor, PA Facility

7.2. Applicable Product Codes:

7.2.1. 6N HCl in IPA, IHCL-4101

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)
Glass	Glass Fragments	Process Tanks and Agitators	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	Not Available
PTFE	Opaque White Plastic	Process Tanks Process Tank Burst Disks Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Tantalum	Metallic Shavings	Process Tanks	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Hastelloy	Metallic Shavings	Process Tank Agitator Seals Dip Tube	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Polypropylene	Natural Colored Opaque Off-White Plastic	Process Tank Fittings	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
PVDF	Opaque Plastic	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	


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Kalrez	Plastic	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Alumina Ceramic	Ceramic Fragments	Centrifugal Pump	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
Polyethylene	Opaque White Plastic	Chemical Hoses Gas Lines	Filtration Reprocessing	Pre-Process Inspection Preventative Maintenance	
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.

Originating from the Packaging Components					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
HDPE	Black Plastic	55 Gallon Drum	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.

Atypical Particles: Originating from the Packaging Components					
Identity	Characterization	Origin	How Removed	How Prevented	Picture (Example of Source)
Wood	Wood Shavings	Pallet	Reprocessing	Inspection at time of use Product Care Procedure	

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