BIOSPECTRA
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TECHNICALLY UNAVOIDABLE PARTICLE PROFILE(TUPP) – SODIUM HYDROXIDE 10N SOLUTION

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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 10N Sodium Hydroxide manufactured in BioSpectra's Bangor, PA facility.

2. **SCOPE:**

   2.1. This TUPP applies to the manufacturing and packaging process of 10 N Sodium Hydroxide manufactured at BioSpectra's Bangor, PA facility.

3. **REFERENCES:**

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

4. **DEFINITIONS:**

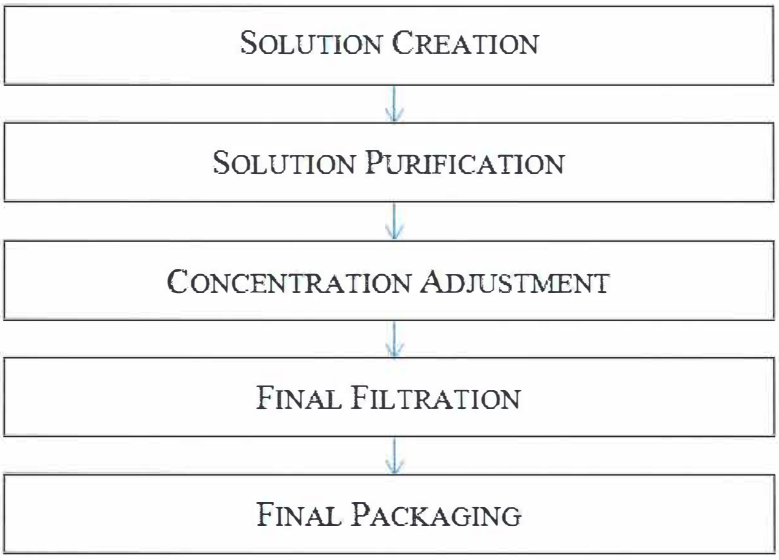
   4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed withthe naked eye that is inherent to the raw material, manufacturing process or product and doesnot pose risk to patient safety.
   4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all potential 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.

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.

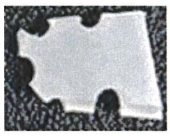
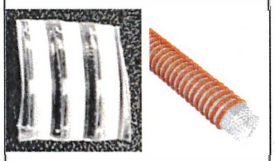
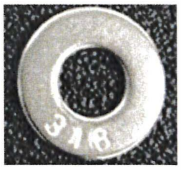
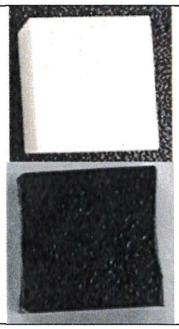
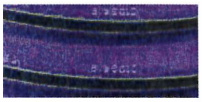
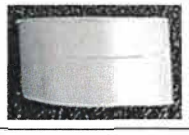
6. PROCESS FLOW DIAGRAM:

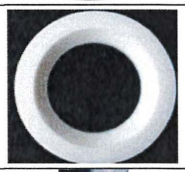
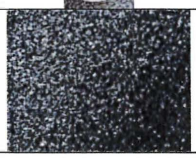
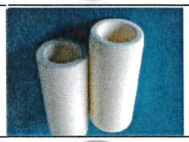
Sodium Hydroxide Solution Manufacturing Process Flow Diagram



7. PROFILE:

7.1. Manufacturing Location:
  7.1.1. Bangor, PA Facility
7.2. Applicable Product Codes:
  7.2.1. NAHY-41XX and below compliance grades
7.3. TUPPs originating from product contacting surfaces in the manufacturing process and packaging components are detailed in the tables below:

Originating the Manufacturing Process					
Identity	**Characterization**	**Origin**	**How Removed**	**How Prevented**	**Picture**
Polypropylene	Blue Plastic, black plastic	Centrifugal Pump, Fill Valve, pipe fittings, Purification	Filtration	Pre-Process Inspection, Preventative Maintenance,	
Proprietary Resin	Proprietary	Purification	Filtration	Pre-Process Inspection, Preventative Maintenance,	Not Applicable
PVC	White, Gray, Orange Opaque plastic	Storage Tanks, Process Piping, Supply Hose for Liquid Fillers	Filtration	Pre-Process Inspection, Preventative Maintenance	
Silicone	Orange or white elastomer	Process Tank manway o- ring	Filtration	Pre-Process Inspection, Preventative Maintenance	
Stainless Steel 316	Metallic shaving	Centrifugal Pump, Purification Equipment, Process Pipes, Process Tanks, Tank Agitators, Filling Lance & Filling Valve (Liquid Fillers)	Filtration	Pre-Process Inspection, Preventative Maintenance	
HDLPE	Off-White, White, Opaque plastic	Storage Tanks	Filtration	Pre-Process Inspection, Preventative Maintenance	
U.H.M.W. PE	Clear Plastic	Chemical Hoses	Filtration	Pre-Process Inspection, Preventative Maintenance	
CPVC	Gray, Opaque plastic	Storage Tanks	Filtration	Pre-Process Inspection, Preventative Maintenance	

Originating the Manufacturing Process					
Identity	**Characterization**	**Origin**	**How Removed**	**How Prevented**	**Picture**
EPDM	Black Elastomer	Storage Tanks, gaskets, Hand Valves	Filtration	Pre-Process Inspection, Preventative Maintenance	
PTFE	White Plastic	Centrifugal Pump, Hose and Piping Gaskets, Hand Valves, Wiper Ring (Liquid Fillers)	Filtration	Pre-Process Inspection, Preventative Maintenance	
FEP	Clear Plastic	Tank Agitator O-ring, Fill Valve O-ring	Filtration	Pre-Process Inspection, Preventative Maintenance	
Silicon Carbide	Metallic Ceramic	Tank Agitators	Filtration	Pre-Process Inspection, Preventative Maintenance	
Zirconium Oxide	Off White Ceramic	Tank Agitator	Filtration	Pre-Process Inspection, Preventative Maintenance	
Viton	Black or Brown Elastomer	Centrifugal Pump, Hose Connection for Liquid Fillers	Filtration	Pre-Process Inspection, Preventative Maintenance	
Buna N	Black Elastomer	Filter Housing O-ring	Filtration	Pre-Process Inspection, Preventative Maintenance	
Ceramic	Off White Ceramic	Centrifugal Pump	Filtration	Pre-Process Inspection, Preventative Maintenance	
Kalrez	Black or Brown Elastomer	Centrifugal Pump	Filtration	Pre-Process Inspection, Preventative Maintenance	

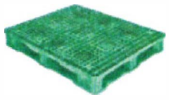
7.4. TUPPs originating from product contacting surfaces of the packaging components:

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

Originating from the Packaging Process				
Identity	**Characterization**	**Origin**	**How Prevented**	**Picture**
HDPE	White/opaque plastic	Finished Good Drums, Totes and Bottles	Inspection	 

7.5. TUPPs originating from non-product contacting surfaces of the packaging components.

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

Originating from the Packaging Process				
Identity	**Characterization**	**Origin**	**How Prevented**	**Picture**
HDPE	Green plastic	Pallet	Inspection	
Cardboard	Brown	Cardboard Box	Inspection