

BIO SPECTRA

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

June 07, 2021

To Whom It May Concern,

The Uracil manufactured by BioSpectra and supplied to Merck & Co., Inc. is produced utilizing an alkaline solution. Crude Uracil is charged to a supersaturated Uracil Mother Liquor (ML) solution comprised of Sodium Hydroxide, Uracil, and purified water. The charged solution is heated in the designated hot tank to dissolve all Uracil before filtration. The solution is then filtered utilizing a three stage purification system into the designated cold tank where the temperature is reduced. The temperature is monitored until the specified temperature is reached. Once the slurry has reached the specified temperature, the purified Uracil is separated from the supersaturated solution via Centrifugation or Funnel Filter. The Uracil wet crystal is washed with purified water to remove residual Sodium Hydroxide. The wet crystal is then loaded onto product dedicated trays and stacked in a hot air drying room. The Uracil is dried until the in-process moisture specification is achieved.

Sincerely,
BioSpectra


Crystal Hamelburg

Associate Director, Compliance

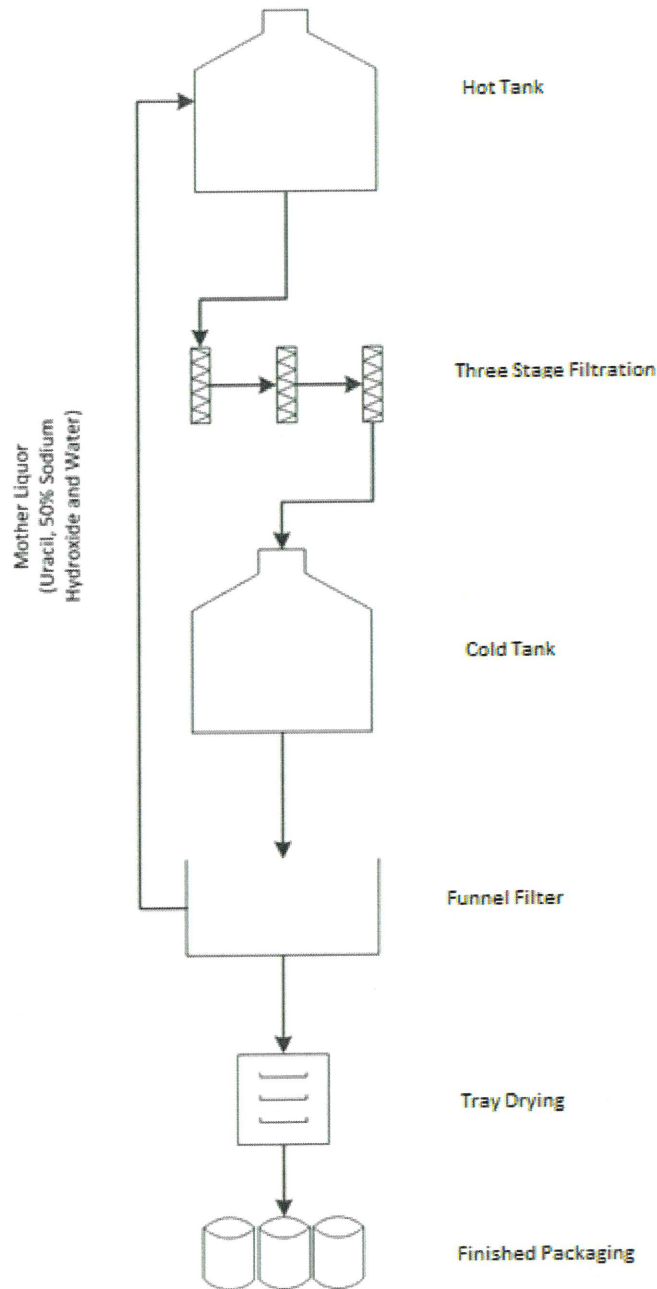
BioSpectra

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Printed On:	07-Jun-2021 04:17:37 PM	Meissner, Dora	: Printed By
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Approval:	McCollian, Carissa K	07-Jun-2021 03:46:17 PM	
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Uracil Process Flow Diagram – Funnel Filter



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