



## STROUDSBURG 2024 ANNUAL MELAMINE AND RESIDUAL SOLVENTS RESULTS

BioSpectra's commitment is to send one manufactured lot per year for Residual Solvents testing. Similarly, BioSpectra is required by the Pharmaceutical Components at Risk for Melamine Contamination, Guidance for Industry to send one manufactured lot per year for Melamine testing. The results of the Stroudsburg 2024 requirements are detailed in the tables below. All materials met the requirements detailed in BSI-SOP-0355 (Annual Melamine and Residual Solvents Analysis Required).

TABLE 1: RESIDUAL SOLVENTS				
Product	Lot Number	Analysis	Specifications	Conforms (Yes/No/Not Applicable)
Guanidine Hydrochloride	GHCL-S05-1024-0072	Isopropanol	NMT 5000 ppm	<2620ppm
MOPS	MOPS-S02-1124-0247	Ethanol	NMT 5000 ppm	332 ppm
Tris Hydrochloride	THCL-0224-00048-PV Middle	Methanol Nitromethane	NMT 3000 ppm NMT 50 ppm	<48 ppm <48 ppm
Tris	TRIS-0224-00094-PV Drum 30	Methanol Nitromethane	NMT 3000 ppm NMT 50 ppm	<153 ppm <10 ppm
Urea	UREA-0224-00001-PV	Methanol Ethanol	NMT 3000 ppm NMT 5000 ppm	<30 ppm <50 ppm

**TABLE 2: MELAMINE**

<b>Product</b>	<b>Lot Number</b>	<b>Analysis</b>	<b>Specifications</b>	<b>Results</b>
Guanidine Hydrochloride	GHCL-S05-1024-0072	Ammelide Ammeline LC-MS/MS Cyanuric acid Melamine	Monitor Monitor Monitor 2.5 mg/kg max	< 0.9 mg/kg < 0.45 mg/kg < 0.45 mg/kg <0.15 mg/kg
MOPS	MOPS-S02-1124-0247	Ammelide Ammeline LC-MS/MS Cyanuric acid Melamine	Monitor Monitor Monitor 2.5 mg/kg max	< 0.9 mg/kg < 0.45 mg/kg <0.45 mg/kg < 0.15 mg/kg
Tris	TRIS-0224-00094-PV	Ammelide Ammeline LC-MS/MS Cyanuric acid Melamine	Monitor Monitor Monitor 2.5 mg/kg max	< 0.9 mg/kg < 0.45 mg/kg < 0.45 mg/kg < 0.15 mg/kg
Tris Hydrochloride	THCL-0224-00048-PV	Ammelide Ammeline LC-MS/MS Cyanuric acid Melamine	Monitor Monitor Monitor 2.5 mg/kg max	< 0.9 mg/kg < 0.45 mg/kg < 0.45 mg/kg < 0.15 mg/kg
Urea	UREA-0224-00001-PV	Ammelide Ammeline LC-MS/MS Cyanuric acid Melamine	Monitor Monitor Monitor 2.5 mg/kg max	< 0.9 mg/kg < 0.45 mg/kg 9.6 mg/kg < 0.15mg/kg