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DEGRADATION AND IMPURITY PROFILE REPORT: GUANIDINE HYDROCHLORIDE BIO EXCIPIENT GRADE 2019

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1. PURPOSE AND SCOPE:

1.1. This report is intended to summarize, identify, and possibly quantify any impurities found in the Guanidine Hydrochloride product manufactured and purified at BioSpectra, Inc, at the Stroudsburg, Pa Facility.

1.1.1. In the case where an impurity was found, a limit was set to the maximum allowable for establishing as pure of a product as possible. In the case where a limit could not be set, a procedure was written and followed, to identify if the possible impurity was present or not (i.e. an identity test, which is qualitative.)

1.1.2. The profiling results and data will allow BioSpectra to further understand the purity and characteristics of Guanidine Hydrochloride.

1.1.3. The four stages of Guanidine Hydrochloride that were tested are Raw Material (RM), Mother Liquor (ML), Wet Crystal (WC), and Finished Good (FG). There was at least one sample from each stage used for analysis.

1.1.4. The analyses used to determine the presence of impurities and degradation products are as follows:

1.1.4.1. Cyanide

1.1.4.1.1. All four stages were analyzed.

1.1.4.2. Heavy Metals (as Pb)

1.1.4.2.1. All four stages were analyzed.

1.1.4.3. Identity (IR)

1.1.4.3.1. All four stages were analyzed.

1.1.4.4. Melamine

1.1.4.4.1. All four stages were analyzed.

1.1.4.5. Trace Metals (As, Cu, Pb, and Fe)

1.1.4.5.1. All four stages were analyzed.

1.2. All results were recorded in the current Validation Notebook.

2. RESPONSIBILITIES:

2.1. The Director of Quality Control was responsible for the control, training, implementation, and maintenance of the protocol utilized for analysis.

2.2. The QC Analysts were responsible for performing the testing stated in the Protocol and recording all results in the Validation Notebook.

2.3. The QC Document Specialist was responsible for outlining results and writing the report.

3. REFERENCES:

3.1. Degradation and Impurity Profile Protocol Guanidine Hydrochloride 2016 and 2017, DCN:16-000096

3.2. Endosafe PTS Endotoxin Reader SOP, DCN:16-000367

3.3. Guanidine Hydrochloride Testing Methods, DCN: 16-000493

3.4. Guanidine Hydrochloride Validation Protocol Addendum 2019, DCN:19-002740

3.5. NexION 350X ICP-MS SOP, DCN:16-001923

3.6. Spectrum Two UATR SOP, DCN: 16-001330

3.7. Lambda 25 UV/Vis Operation and Calibration, DCN 16-000359

4. PROCEDURE:

4.1. All testing was performed per the Degradation and Impurity Profile Protocol Guanidine Hydrochloride 2016 and 2017 and the Guanidine Hydrochloride testing methods, as referenced in section 3.

5. RESULTS:

Table 1: Identification, Melamine, Cyanide, and Heavy Metals

Lot Number	Source	Identification	Melamine	Cyanide	Heavy Metals
		Passes Test	Passes Test	<0.1 ppm	10 ppm max
20180920	RM	Passes Test	Passes Test	<0.1 ppm	<10 ppm
20180919	RM	Passes Test	Passes Test	<0.1 ppm	<10 ppm
GH3200-272-0119-PV WC FF2 MIDDLE	WC	Passes Test	Passes Test	<0.1 ppm	<10 ppm
GH0100-199-0119	ML	Passes Test	Passes Test	<0.1 ppm	<10 ppm
GH3200-272-0119-PV	FG Drum 20	Passes Test	Passes Test	<0.1 ppm	<10 ppm

Table 2: Trace Metal Results

Lot Number	Source	Trace Metals (ppm) Raw Material and Mother Liquor (Report) Finished Good and Wet Crystal (1 ppm max.)			
		Arsenic (As)	Copper (Cu)	Iron (Fe)	Lead (Pb)
20180920	RM	0.018	0.003	0.188	0.002
20180919	RM	0.016	0.007	0.158	0.008
GH3200-272-0119-PV WC FF2 MIDDLE	WC	<1	<1	<1	<1
GH0100-199-0119	ML	0.015	0.019	0.179	0.001
GH3200-272-0119-PV	FG Drum 20	0.013	0.00006	0.00	0.00

6. CONCLUSION:

6.1. All samples, from all stages of the process, met the required specifications as dictated in the Degradation and Impurity Profile Protocol.

6.2. In conclusion, there are no additional identifiable impurities in the Guanidine Hydrochloride Bio Excipient process at this time. No limit adjustments or specification changes will occur as a result of the analysis.