

BIO SPECTRA

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

Dear Valued Customer,

This letter serves as a change notification for Zone L Process Room L09 in BioSpectra's Bangor, PA facility. This change involves the transition of specific equipment in Process Room L09, currently dedicated for the manufacture of Guanidine Hydrochloride 6M Solution to multi-purpose use for the manufacture of Urea 6M Solution GMP Bio Excipient Grade. Accordingly, the equipment to be used will be subjected to Cleaning Validation as required and in accordance with our Cleaning Validation Master Plan and will use approved cleaning procedures and cleaning detergents.

This change has been approved in accordance with BioSpectra's Change Control Program as a level 2 Moderate Change and may be referenced as BCC21-91. This change will include the requirements for cleaning of select equipment located in process room L09 for the product change over from GMP Guanidine Hydrochloride 6M Solution to GMP Urea 6M Solution and vice versa. The select equipment that will no longer be dedicated are as follows: Process Tank 1 and Standpipe, Centrifugal Pump, Diaphragm Pump, Heat Exchanger and the Packaging Line.

The changes described only include the specific equipment designated as multi-use with no other change to the manufacturing process for GMP Guanidine Hydrochloride 6M Solution. The manufacturing process and product will continue to meet all quality and compliance standards for your associated product code. This change does not impact the quality and physical characteristics of the product and therefore, there are no specification or packaging updates associated with this change.

The implementation date of this change is expected to be December of 2021. After the cleaning validation has been completed an External Report will be generated and sent.

Please direct any questions or concerns regarding this change to: pdimarco@biospectra.us

Sincerely,



Carissa McCollian
Quality Assurance Manager – Bangor
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100 Majestic Way
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