Dear Sir/Madam,

B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product

f) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products

Comments: We would expect that the above mentioned change code should also cover the terminally sterilized products with some additional documentation support.

B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product

a) Replacement or addition of a site where batch control/testing takes place

Comments: We would expect that the above mentioned change code should also cover the addition of control site where some specific tests where we do in third party laboratories in which the batch control site was not having such type of equipments like osmalarity and etc.

B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.

Comments: We would expect that the above mentioned change code should also cover the terminally sterilized products under Type 1B.

B.III.1 Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability:

Comments: We would expect that the above mentioned change code should also cover the addition of New Ph.Eur Certificate of Suitability from different polymorphic forms under category Type 1B with some additional documentation support and conditions.

Regards

Suresh Kadaru

Regulatory Affairs

Astron Research Limited

Premier House, Bodakdev, S-G Highway

Ahmedabad-308 054

Gujarat, INDIA