

From: Khurana, Taruna
Sent: Tuesday, December 13, 2016 7:23 AM
To: 'Margaretten, Nadine'
Cc: Steele, Matthew; Sweeney, Colleen
Subject: RE: STN 125592 IR 12132016

Hi Nadine,

We have the following request for information;

Please provide the following information for the control tablet in Enclosure 5 “Control limits for current control tablet (b) (4)” submitted on July 1, 2016 in amendment 11

1. Please specify the upper and lower limits for the total allergenic activity of the control tablet and how did you define these limits
2. Please indicate the validated range for the control tablet if different from upper and lower limit as indicated in enclosure 5
3. Please indicate the unitage in enclosure 5
4. Please specify the values used for calculation of standard deviation 5.85

Please address the following in reference to (b) (4) assay indicated in Lot Release Protocol;

5. Please specify the validated range for the sample. Please clarify if this is different from range (b) (4) as indicated in release protocol
6. Please justify the reliability of suitability criteria of CV (b) (4) of a sample calculated only from (b) (4)
7. Attachment 1, (b) (4) table has HDM DP Tablet control, 12 DU HDM tablet indicated as (b) (4). The same lot for control tablet is indicated as 6 DU in Enclosure 3 “Validation Protocol” in amendment 11 submitted on July 1, 2016. Please clarify this discrepancy

You can contact me if you have any question.

Thank you

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