

# Conformance Lots and Friday Meeting Information - GLASSIA, November 4, 2009

From: Ward- Peralta, Cherie

Sent: Wednesday, November 04, 2009 1:10 PM

To: '----(b)(4)----'

Subject: STN 125325/0 Kamada Conformance Lots and Friday Meeting Information.

Attachments: Concurrent testing template letter.doc

Hello -(b)(4)-

Attached is information on how and where to submit Kamada conformance lots to FDA. As mentioned last night, the FDA reviewer will be out of the office on Monday, therefore, we request to hold the meeting on Friday at 9:30 am EST . Below are some of the questions that will be discussed in Friday's Meeting:

1. The half-life of Kamada-API based on 168 hours blood sampling scheme is too long. Generally, the blood samples should be taken long enough so that at least 4 to 5 half-lives are covered. This long half-life will have impact on the extrapolation of AUC from 0 to infinity (acceptable extrapolation is 20% of the total) which in turn will have impact on the clearance. In your study, the extrapolation of AUC is more than 20%. Please comment to resolve this issue.
  2. Is the analysis of PK data based on baseline correction? Please comment on differences between PK estimates obtained from baseline and without baseline corrected concentrations.
  3. Besides compartmental analysis have you tried non-compartmental analysis?
  4. Factor for conversion from uM to mg/mL
  5. Also, could you please provide a call in number for Friday's meeting with Kamada.
- If you have any questions, please contact me.

Thanks

Cherie Ward-Peralta

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HFM-380 FDA/CBER

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Hello,

The address and additional information is listed below. The address could also be found in the 21 CFR Subpart A 600.2 (c) (1).

All other biological products (including those for release action, in support of licensing actions or a complaint sample) should be addressed as follows:

Shipped by Courier Service:

Sample Custodian (ATTN: HFM-672)

Center for Biologics Evaluation and Research

Bldg: NLRC-B, Room: 113

5516 Nicholson Lane

Kensington, Maryland 20895

The reason for the sample submission should appear on the external shipping label and also on the packing slip if one is used. Examples of this include: product release sample(s); inspection sample(s); in support of license action (include CBER assigned STN/Supplement Number); complaint sample(s); or research sample(s).

If commercial carriers are used, manufacturers should arrange for prepaid delivery from Washington area airports directly to the CBER. Commercial carriers must be instructed to deliver between the hours of 8:00 a.m. and 3:30 p.m., weekdays only (excluding federal holidays). Packages should include holding instructions to carrier if delivery cannot be made during these hours.

All product samples submitted to the CBER for release or for license actions must have an identifying label affixed to each individual sample container. The container label should include, at a minimum, the proper name for the product, the lot number and the manufacturer's name, address, and license number. Final containers of products which cannot be labeled individually such as capillary tubes, multiple puncture devices, etc. need not bear an individual identifying label provided the container(s) is (are) placed in a package to which a label is affixed. Because of the risk of not being able to identify correctly the samples, the practice of shipping multiple unlabeled samples in plastic bags or other temporary package forms with only a single unaffixed label is not acceptable.

If the samples and protocols will not be sent at the same time for this BLA, the firm needs to have the attached form completed and submitted with the samples in the same packaging. If the protocol will be submitted with the sample then template letter is not needed.

If you have any questions let me know.

Thank you,

Joseph Quander III

Chief, Product Release Branch

CBER/OCBQ/DMPQ

(301) 594-6517; (301) 594-6924(Fax)

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