

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125510/0.0
Review Office	OVRR
Applicant	Novartis Vaccines and Diagnostics, Inc. / Lic. # 1751
Product	Influenza Vaccine, Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	03-NOV-2015 05:20 PM
Author	AMIN, PANKAJ
Outside Phone Number	N/A – Request sent by email
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Request for clarification regarding equipment at the (b) (4) facility
FDA Participants	Pankaj Amin, Qiao Bobo, Kirk Purtzman
Applicant Participants	Mayuresh Gadre

Telecon Body:

From: Amin, Pankaj (Pete) [<mailto:Pete.Amin@fda.hhs.gov>]

Sent: Tuesday, November 03, 2015 5:20 PM

To: GADRE, MAYURESH

Cc: Bobo, Qiao; Prutzman, Kirk C

Subject: Novartis 125510/0 request for clarification

Dear Mayuresh,

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I need following clarification by end of this week.

Regarding (b) (4) facility:

Equipment sterilization- autoclave loads (section 3.2.A.1.7.1.9):

- Section 3.2.A.1.7.1.9 states that formulation tanks and filling components of syringe filling machine (b) (4). Table 3.2.A.1.7.1.9.-1 and 2 provides autoclave qualification reports and results summary. It is not clear that any of the autoclave loads changes due to the sterilization of dedicated equipment used for adjuvant manufacturing from list provided in these tables (Table #3.2.A.1.7.1.9.-1 and #3.2.A.1.7.1.9-2) ?

Equipment (section # 3.2.A.1.4.2)

Table 3.2.A.1.4.3-1 list product contact equipment for MF-59 for sterile filtration, also additional tables list equipment used for formulation process, syringe filling in module 1. Please clarify if any additional (adjuvant product contact equipment) that is not listed in these tables.

Equipment cleaning validation – (b) (4)

- For Squalene analysis (Table 3.2.A.1.7.1.8-4) limit is (b) (4). Please verify the detection limit for this method (ability to detect (b) (4)
- Table #3.2.A.1.7.1.8-17 provides filling machine cleaning validation results. What is rational for not testing (not applicable) (b) (4) for Squalene (limit (b) (4), only (b) (4) was tested during validation. Please justify your rational.

Regarding automated syringe inspection machine PQ (b) (4)

Acceptance criteria for “vary critical” defect is listed as 100%, however (b) (4)

and conclusion was that 100% acceptance criteria were met. please clarify your conclusion.

Thanks

Pete Amin

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recipient of the email, please disregard its contents, contact the sender at once by return email and then delete both messages. (b) (4) .