

Meeting Minutes

Applicant: PaxVax Bermuda Ltd.

Product: Cholera Vaccine Live Oral

STN: 125597

Meeting Date/Place: 8 Dec 2015/WO 71 Rm 4244

Attendees:

Manuel Osorio, Roger D Plaut, Scott Stibitz, Noel Baichoo, Al Del Grosso, Simleen Kaur, William McCormick, Karen Campbell, Marie Anderson, Scott E Norris, and Muhammad Shahabuddin

Summary of Product and Proposed Indication

Active immunization against disease caused by *V. cholerae* serogroup O1 in adults 18 years of age and older.

Purpose/Goals:

- Clarification of DBSQC's review responsibilities
- In-Support Testing requirements

General understanding

DBSQC should review the lot release tests and method validations only for lot release tests of drug substances and drug product to be agreed upon with the product reviewer(s)

1. Review the test methods to ensure that they are detailed enough to carry out the same tests in our lab following the sponsor's method.
2. Appropriate system suitability criteria and/or assay validity criteria are included in the procedure.
3. Review assay validation reports to ensure that the methods are appropriately validated for its intended use.

NOTE: We will not review anything regarding manufacturing, product characterization, stability studies, labeling etc.

DBSQC Review Assignments

DBSQC Reviewers assigned to 125597 are: Noel Baichoo, Al Del Grosso, Simleen Kaur, and Marie Anderson

DBSQC and DBPAP review assignments and in-support testing for (b) (4) drug product:

Test	(b) (4) /DP/Buffer	Reviewer	In Support Testing
Appearance	(b) (4) /DP/BUFFER	DBSQC	
Visual Control	DP/BUFFER	DBSQC	
(b) (4)	(b) (4) /DP	DBPAP	
(b) (4) Assay	(b) (4) /DP	DBPAP	
Moisture Content	(b) (4) /DP	DBSQC	X
Sachet Integrity Test	(b) (4) DP	DMPQ	
Viable Cell Count	(b) (4) /DP	DBPAP	
General Safety Test	DP/BUFFER	DBSQC	
(b) (4)	(b) (4) /DP/BUFFER	DBSQC	
Absence of Specified Organisms: (b) (4)	DP/BUFFER	DBSQC	
Identity of Carbonates and Bicarbonates	BUFFER	DBSQC	
Identity of Lactose	BUFFER	DBSQC	
(b) (4)	BUFFER	DBSQC	X
Sachet Integrity Test	BUFFER	DMPQ	
Reconstitution Time	BUFFER	DBSQC	X
Average (b) (4)	BUFFER	DBSQC	
Uniformity (b) (4)	BUFFER	DBSQC	
Assay for Ascorbic Acid	BUFFER	DBSQC	
(b) (4)	BUFFER	DBSQC	

Discussion:

1. Responsibility for review of tests
As documented above
2. In support testing and lot release of product
As documented above
3. Buffer
 - a. Criticality
 - b. A lot release protocol (LRP) template for the buffer was not submitted in the application
 - i. DBSQC (MJA) will submit IR for buffer LRP
4. Sachet Integrity test
 - a. Consider the sachet a container subject to Container Closure Integrity Testing
 - i. Under the review responsibility of DMPQ
 1. DBSQC (MJA) will contact DMPQ regarding need for a review.