



## DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

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**Applicant** GlaxoSmithKline Biologicals SA (GSK)

**Subject** Review of Sterility, Endotoxin, and the (b) (4) [REDACTED]  
Analytical Methods used for the combined Men A,B,C,W, and Y Vaccine  
(PENMENVY).

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**Recommendation:** Approval

### Executive Summary:

The sterility, endotoxin and (b) (4) analytical methods used for testing and release of PENMENVY and the associated analytic method qualifications and (b) (4) validation, were reviewed. The assays were adequately described and shown to be suitable for their intended purpose.

**Conclusion:** The analytical methods and their qualifications/validation reviewed for PENMENVY drug product were found to be adequate for their intended use.

### Documents Reviewed

Information in sections of the original submission that describe control of Drug Product (DP) (3.2.P.5), including descriptions of DP specifications, analytical procedures of DP, and the qualifications and validation of these analytical procedures were reviewed. In addition, the responses to CBER's Information Requests (IRs) received on May 10, 2024 (Amendment #6) and June 12, 2024 (emailed communication from GSK) were also reviewed as mentioned below.

### Background

PENMENVY is presented as a vial of lyophilized MenACWY component (MenACWY Lyo), co-packaged with a pre-filled syringe containing the MenB liquid component

used to reconstitute the MenACWY component for intramuscular administration of approximately 0.5 mL of the reconstituted product by a whole content/whole content administration procedure. The MenACWY Lyo drug product component and the MenB liquid drug product component were approved due to PENMENVY being a combination of them both.

GSK's MenABCWY vaccine is indicated for active immunization to prevent invasive, meningococcal disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10 through 25 years of age.

When the original application was submitted, (b) (4) was the only general chapter available for (b) (4). However, during the review process, a new general chapter, (b) (4) was published to address (b) (4) for vaccines containing (b) (4), which is applicable to Men B and MenABCWY vaccines.

## **Review**



### **1. Sterility (b) (4) Final Container MenB DP**

#### **Introduction**

Sterility testing is performed on the MenB DP at GlaxoSmithKline Vaccines S.r.l. Bellaria-Rosia (GSK, Rosia) in Sovicille, Italy. Acceptance criteria of 'No Growth Detected' must be met for MenB DP.

#### **Method**

(b) (4)



(b) (4) GSK Rosia site. Note: GSK clarified that MenB (b) (4) used in these (b) (4) tests have the same (b) (4) as the final container DP and CBER finds this acceptable.

(b) (4)

### Conclusion

The method suitability test was performed and compliant with (b) (4) and the test results indicate there is no (b) (4), thus indicating the (b) (4) sterility test method is appropriate under the actual conditions of use.

## **2. Endotoxin (MenB DP)**




### Introduction

Endotoxin testing for MenB DP is performed at GSK, Rosia in Sovicille, Italy. Specification of (b) (4) for the DP must be met for MenB DP.

### Method

(b) (4)

(b) (4)



### Conclusion

The method suitability test was performed and compliant with (b) (4) and the test results indicate the (b) (4) test method is appropriate under the actual conditions of use.



### **3. (b) (4) (MenB DP)**

#### Introduction



(b) (4) is performed on the MenB at GSK Vaccines S.r.l. in Rosia Italy. Specification of (b) (4) for the DP must be met for MenB DP.

#### Method

(b) (4)



(b) (4)



#### **4. Sterility (MenACWY DP)**




##### Introduction

Sterility testing is performed on the MenACWY DP at GlaxoSmithKline Biologicals


(b) (4) Acceptance criteria of 'No Growth Detected' must be met for MenACWY DP.

##### Method

(b) (4)



(b) (4)



#### Conclusion

The method suitability tests were performed and compliant with (b) (4) and the test results indicate there is no product inhibition of microorganism growth, thus indicating the (b) (4) sterility test method is appropriate under the actual conditions of use.



### **5. Endotoxin (MenACWY DP)**

#### Introduction


Endotoxin testing for MenACWY DP is performed at GlaxoSmithKline Biologicals (b) (4) Specification of (b) (4) for the DP must be met for MenACWY DP.

#### Method

(b) (4)

(b) (4)



#### Conclusion

The method suitability test was performed and compliant with (b) (4) and the test results indicate the (b) (4) test method is appropriate under the actual conditions of use.


#### **6. (b) (4) (MenABCWY DP)**

##### Introduction

(b) (4) is performed on the MenABCWY reconstituted vaccine (RV) DP at GSK, Rosia in Sovicille, Italy. Specification of (b) (4) for the DP must be met for MenABCWY RV DP.

##### Method


(b) (4)







(b) (4)



Conclusion

The method validation tests were performed and compliant with (b) (4) and (b) (4) thus indicating the (b) (4) is appropriate under the actual conditions of use.