

## **DBSQ/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** The file BLA 125820/0

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**Applicant:** Bavarian Nordic A/S

**Subject:** Review of biological methods and associated validations used for Chikungunya Vaccine, Recombinant

**Recommendation:** Approval

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### **Executive Summary:**

This review covers the following critical quality attributes and their analytical methods:

1. (b) (4)
2. (b) (4)
3. (b) (4)
4. Identity (b) (4)

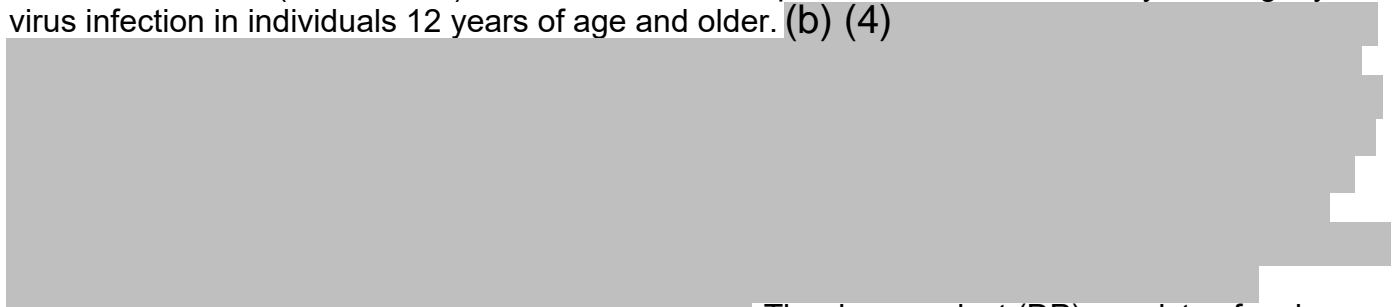
**Conclusion:** The analytical methods and their validations and/or qualifications reviewed for the VIMKUNYA (b) (4) drug product were found to be adequate for their intended use.

### **Documents Reviewed:**

Information submitted in 125820/0.2 that describes control of (b) (4) Drug Product (DP) (3.2.S.4 and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures, and validation of analytical procedures were reviewed. Additional information in Amendment 125820/0.36, submitted in response to Information Request #31 was also reviewed.

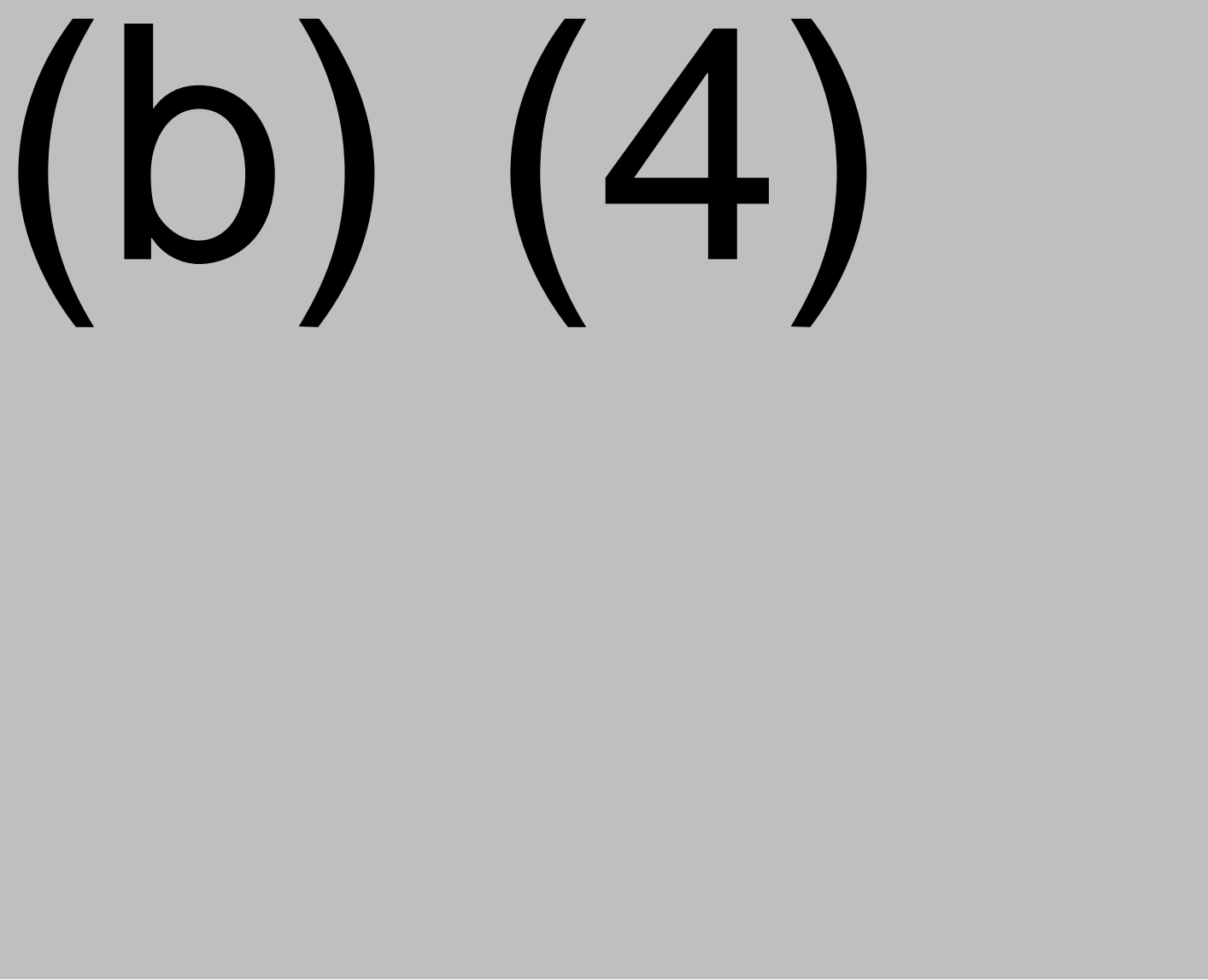
**Background:**

Bavarian Nordic A/S submitted an original BLA 125820 for VIMKUNYA, a Chikungunya Virus Virus-Like Particle (CHIKV VLP) Vaccine, indicated to prevent disease caused by chikungunya virus infection in individuals 12 years of age and older. (b) (4)



The drug product (DP) consists of a glass syringe, filled with 0.8 mL (40 µg) BDP, and sealed with rubber stopper. Finished drug product (FDP) is produced by addition of a polypropylene finger flange and plunger rod.

(b) (4)



8 pages have been determined to be not releasable: (b)(4)

(b) (4)

(b) (4)

#### 4. Identity (b) (4) (b) (4)

##### Introduction

The (b) (4) is used to confirm identity (b) (4) of CHIKV VLP DP for lot release. Potency of the DP is determined as a (b) (4) It is also used to determine stability. The release criteria for DP are (b) (4)

##### Method

(b) (4)

4 pages have been determined to be not releasable: (b)(4)