



Food & Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

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

**To:** Biologics License Application, STN 125817/0

**From:** Alicia Howard, Ph.D., DBSQC/OCBQ

**Through:** Maryna Eichelberger, Ph.D.  
Division Director, DBSQC/OCBQ

**Sponsor:** Novavax Inc.

**Subject:** Suitability of lot-release test methods for Novavax COVID-19 Vaccine, Adjuvanted (Nuvaxovid) (b) (4) Drug Product

**Recommendation:** Approval

### **Executive Summary:**

Analytical methods used for lot release of Nuvaxovid were reviewed by Alicia Howard (LBVI), Jing Lin (LBVI), Tao Pan (LAC), and Simleen Kaur (LMIVTS). Their review memoranda are attached to this cover letter.

### **Conclusion:**

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