U.S. FOOD & DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b) (6) ANALYTICAL METHOD REVIEW MEMO

To: The file 125817/0

From: (b) (6)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Through: (b) (6)
CBER/FDA

(b) (6)
/CBER/FDA

Applicant: Novavax Inc.

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

Recommendation: Approval

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

1. Relative Potency by (b) (4)
2. Purity by (b) (4)
3. Identity by (b) (4)
4. Residual Baculovirus by (b) (4)
5. Residual DNA by (b) (4)

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

Documents Reviewed: Information in sections of the original submission that describe control of (b) (4) DP (3.2.S.4 and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures of (b) (4) DP and validation of these analytical procedures were reviewed. Materials related to the current strain and manufacturing process were submitted to the BLA in

Amendment 0.42. Additional information in Amendments 0.37, 0.46, 0.81, 0.83, and 0.93 were also reviewed.
Method validation reports submitted to 3.2.S and 3.2.P for validations performed at the (b) (4) site, where release testing was discontinued in April 2023 (per Novavax's response to CBER IR for (b) (4) Records dated 03Apr2024), were also reviewed. During extensive review of materials in BLA 125817/0 section 3.2.R, the (b) (6) reviewer located SOPs for tests performed at the (b) (4) site, the location where Novavax (b) (4) using the methods reviewed in this memo. The SOPs referenced the relevant reports for (b) (4) . An information request was sent to Novavax requesting the (b) (4) reports, which were submitted in Amendment 0.93.

Background: Novavax Inc. submitted BLA 125817/0 for Nuvaxovid a COVID-19 Vaccine, Adjuvanted.

1. Relative Potency by (b) (4) DP)

Introduction

Relative potency (RP) by (b) (4) is a lot release test performed on the SARS-CoV-2rS (b) (4) DP. The test is performed at the (b) (4) . The release and stability specifications are strain dependent. For the JN.1 strain, the (b) (4) release and stability specifications are (b) (4) The JN.1 DP release specification is (b) (4) , and the stability acceptance criterion is (b) (4) .

Method

The SOPs used at the current testing site were not submitted to the appropriate section of the BLA. On August 30, 2024, an IR was sent to Novavax requesting the SOPs, which were subsequently provided in Amendment 0.37 submitted on September 17, 2024.

(b) (4)

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(b) (4)

Conclusion

The Relative Potency Assay by (b) (4) was appropriately validated for its intended purpose at (b) (4) site and is suitable for relative potency lot release testing of Nuvaxovid (b) (4) DP.

2. Determination of purity by (b) (4)

Introduction

(b) (4)

Method

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(b) (4)

3. Identity by (b) (4) DP)

Introduction

The assay was previously validated at (b) (4), and later qualified at (b) (4). The test is performed for (b) (4) DP lot release and has a specification of “identity confirmed”.

Method

This method is used to confirm the identity of the SARS-CoV-2 spike protein (rS) and variants in (b) (4) DP using (b) (4) followed by (b) (4). The procedure is outline in document 2025-0001-002.

(b) (4)

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Reviewer Comments

(b) (4)

Conclusion

Based on the comparable method validation results at (b) (4) sites, the procedure was appropriately validated for identification of SARS-CoV-2-rS (b) (4) DP nanoparticle vaccine. The method is suitable for routine testing at the (b) (4) site.

4. Residual Baculovirus by (b) (4)

Introduction

(b) (4)

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(b) (4)

5. Residual DNA by (b) (4)

Introduction

(b) (4)

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