



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration  
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**From:** Alfred V. Del Grosso, Ph.D., OCBQ/DBSQC

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**Subject:** DBSQC Chemistry Test results for Dynavax Technologies Corporation, Hepatitis B Vaccine (Recombinant), Adjuvanted, (Heplisav)

- 1) HBsAg protein concentration by (b) (4) Assay
- 2) 1018 ISS Adjuvant Content by (b) (4) Assay

Lots 1017099  
1017100  
1033385

**To:** File STN 125428

**Through:** Lokesh Bhattacharyya, Ph.D., Chief LACBRP, OCBQ/DBSQC

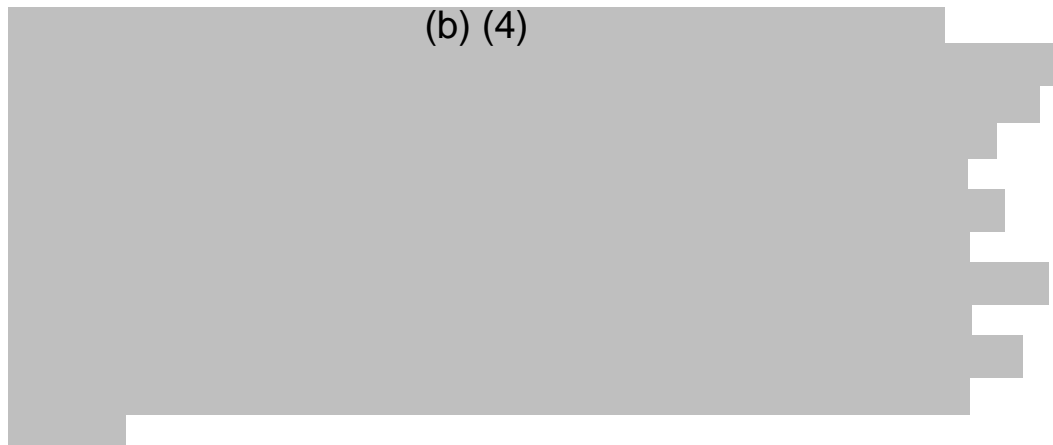
William M. McCormick, Ph.D., Director, OCBQ/DBSQC

**Summary of Testing**

Test results by DBSQC and the sponsor are in compliance with the proposed Drug Product specifications.

**1) HbsAg Protein – (b) (4) Assay**

(b) (4)



The reported results are the average of measurements performed on (b) (4) final container vials. CBER analyst was Tao Pan.

**Table 1. HbsAg Concentration by (b) (4) assay**

<u>Lot number</u>	<u>CBER</u>		<u>Dynavax</u>
	<u>Concentration (µg/mL)</u>	<u>Test Date</u>	<u>Concentration (µg/mL)</u>
1017099	44.0	10/24/2016	39
1017100	45.7	10/24/2016	39
1033385	44.2	10/24/2016	39

The proposed specification for HBsAg concentration in Heplisav Drug Product is (b) (4). CBER test results meet this criterion along with those of the manufacturer.

## 2) 1018 ISS Adjuvant in Heplisav drug product

The concentration of 1018 ISS Adjuvant in Heplisav drug product (DP) is determined by (b) (4)

(b) (4)

The reported results are the average of measurements performed on three separate final container vials. CBER analyst was Hsiaoling Wang.

**Table 2. 1018 ISS adjuvant content by (b) (4)**

<u>Lot number</u>	<u>CBER</u>		<u>Dynavax</u>
	<u>Concentration (µg/mL)</u>	<u>Test Date</u>	<u>Concentration (µg/mL)</u>
1017099	6442	9/22/2016	6371
1017100	5921	9/22/2016	5910
1033385	5801	9/22/2016	5770

The proposed specification for ISS 1018 adjuvant concentration in Heplisav Drug Product is (b) (4). CBER test results meet this criterion along with those of the manufacturer.