



From: Hsiaoling Wang, Ph.D., OCBQ/DBSQC
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Subject: DBSQC Chemistry Test Results for (b) (4) of
Immunoglobulin by (b) (4), Human Rabies Immune Globulin
(Kamada-HRIG) Solution for Injection from Kamada Ltd.

Lots RA5131115 (150 IU/mL, 2 mL)
RA5141115 (150 IU/mL, 2 mL)
RA3151115 (150 IU/mL, 10 mL)
RA3161215 (150 IU/mL, 10 mL)
RA3020216 (150 IU/mL, 10 mL)
RA3050513 (150 IU/mL, 10 mL)

To: File STN 125613

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 (DP) specifications for (b) (4), which are (b) (4) and (b) (4), respectively.

A (b) (4) method is used for the determination of (b) (4) in the Kamada-HRIG DP. The separation is achieved using a (b) (4) with a (b) (4). The (b) (4) is obtained from a (b) (4). The DP samples containing (b) (4) protein are (b) (4) protein concentration with (b) (4) solution before (b) (4). An assay reference sample, which is a (b) (4), and a DBSQC control sample are included in (b) (4) for (b) (4) and system suitability check. Combined percentages of (b) (4) are calculated as (b) (4) in the sample. Acceptance criteria of system suitability check from the DBSQC control are: the resolutions between (b) (4) are (b) (4) and (b) (4), respectively and the (b) (4) and (b) (4) of the (b) (4) are (b) (4) and (b) (4), respectively.

A different (b) (4) condition is used by the sponsors for the analysis of the DP samples. The methods used by DBSQC and the sponsor are summarized in the Table 1.

(b) (4)

One assay reference sample and six lots of DP samples were analyzed in the DBSQC laboratory on February 2, 2017 by Hsiaoling Wang.

The results from DBSQC lab and those from the sponsor are presented in the Table 2. DBSQC results are the averages of duplicate injections. In all cases, the results of obtained at the DBSQC laboratory for (b) (4) are higher than those obtained by the sponsor, while those for (b) (4) are lower. However, in all cases, the results are within the proposed specification of (b) (4) for (b) (4) and (b) (4) for (b) (4). The sponsor did not report the percent of (b) (4). But, DBSQC found 0.7% - 0.8% of (b) (4) in all samples.

(b) (4)