



Food and Drug Administration
CBER/OCBQ/DBSQC

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Subject: Testing Memo for (b) (4) Purity of Immune Globulin
Intravenous (Human) Drug Product, **STN: 125590/0**, from ADMA
Biologics, Inc. by (b) (4)

Through: Lokesh Bhattacharyya, Ph.D. Lab Chief LACBRP, DBSQC
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Summary

Three lots of Immune Globulin Intravenous (Human) Drug Product (DP) were tested for (b) (4) purity analysis following the manufacturer's SOP, QC2161, version: 11.

Test results by DBSQC are in compliance with the DP specifications for lot release as proposed by ADMA in Section 3.2.P.5 of this BLA submission.

Method

The (b) (4) assay serves as a quantitative method for relative percentages of API and impurities test for the Immune Globulin Intravenous (Human). The specifications for purity are (b) (4)

Purity of IgG DP sample is determined by a (b) (4) method using (b) (4)

Results

DBSQC - Chemical Test Memo

The test was performed by Hsiaoling Wang on Feb. 25, 2016. All system suitability checks for (b) (4) RSD of (b) (4) for first (b) (4) and (b) (4) for all (b) (4), resolution between (b) (4) and (b) (4) for SST, meet acceptance criteria. Results from DBQSC and the sponsor's results are listed in Table 1. A typical (b) (4) of sample is presented in Figure 1.

(b) (4)