



Food and Drug Administration
CBER/OCBQ/DBSQC

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Subject: Testing Memo for (b) (4) of Immune Globulin
Subcutaneous (Human), 20% Solution, STN: 125596/0, from Baxalta

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Summary

Three lots of Immune Globulin Subcutaneous (Human), 20% Solution drug product (DP) were tested for (b) (4) by (b) (4) following the manufacturer's SOP. DBSQC results are in compliance with the DP specifications for lot release as proposed by Baxalta, which include that IgG (b) (4)

Method

(b) (4)

Results

(b) (4)

1 page has been determined to be not releasable: (b)(4)