

From: Ritu Agarwal, Ph.D. LACBRP, DBSQC/OCBQ

Alfred Del Grosso, Ph.D. LACBRP, DBSQC/OCBQ

Subject: Test Results for Purity by (b) (4) Antihemophilic Factor (Recombinant)
PEGylated, Damoctocog Alfa Pegol lyophilisate Drug Product
Sponsor: Bayer HealthCare LLC
STN:125661

Lots (b) (4)
(b) (4)
(b) (4) (1000 IU/vial)
(b) (4) (1000 IU/vial)
(b) (4) (3000 IU/vial)
(b) (4) (3000 IU/vial)

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

Maryna Eichelberger, Ph.D. Director DBSQC/OCBQ

Summary:

Test results by DBSQC for Purity and (b) (4) comply with the drug product specifications for commercial lot release as proposed by Bayer in Section 3.2.P.5.1 of this BLA submission.

Purity (b) (4)




(b) (4)

Procedure

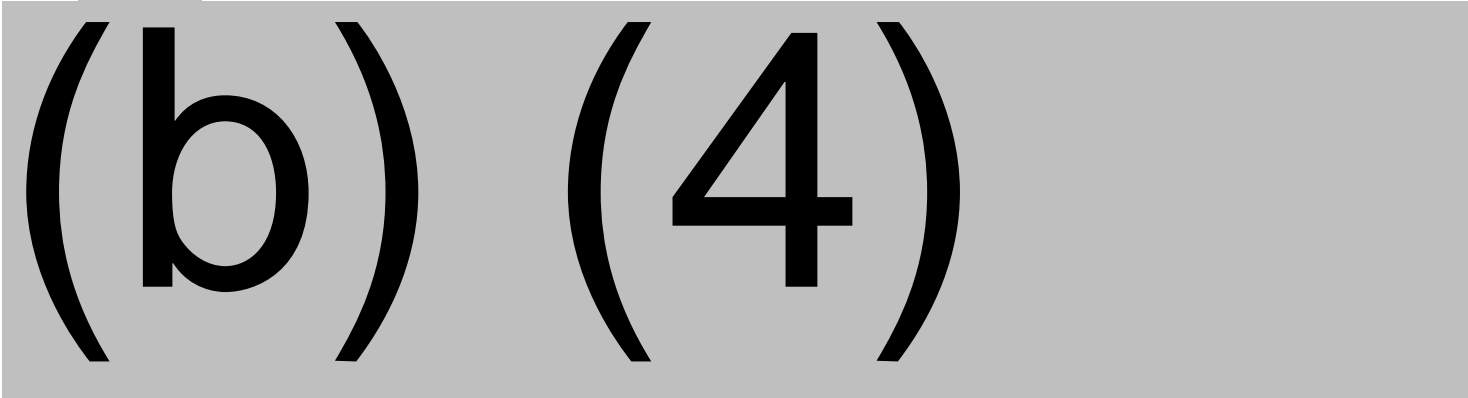
The procedure is described in Bayer's SOP 012700672. (b) (4)

Results






(b) (4)



(b) (4)



(b) (4)



Conclusion

The results obtained by CBER and the sponsor are comparable. The Drug Product



STN 125661/0

DBSQC - Chemical Test Memo

release specification for % Purity by (b) (4) procedure has been proposed as (b) (4)

Test results by CBER and Bayer both meet these criteria.