



Food and Drug Administration
CBER/OCBQ/DBSQC

From: Alfred Del Grosso, Ph.D. Team Leader Chemistry, LACBRP, DBSQC

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Subject: Test Results for Residual Moisture for CSL Behring Antihemophilic Factor (Recombinant) Single Chain (rVIII-Single Chain) Drug Product Samples **STN: 125591/0**

To: File STN 125591/0

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

William McCormick, Ph.D. Director DBSQC

Summary of Testing:

Test results for residual moisture by DBSQC and CSL Behring comply with the proposed drug product specification.

1) Residual Moisture (CBER TMID 000476)

Determination of residual moisture content was performed by CBER using Karl Fischer coulometric titration with methanol extraction of the lyophilized sample (DBSQC Test Method Doc. ID 000476). Each lot result represents the average of three titrations, each from the extracted contents of two vials that were assayed individually. As described in the BLA, the sponsor determines moisture in this product by (b) (4)

CBER Analyst was Ritu Agarwal.

Table 2 – Residual Moisture

Lot#	Potency	CBER		CSL Behring
		% w/w Moisture	Test Date	(b) (4) Moisture
(b) (4)	250 IU	0.2	02/05/16	(b) (4)
(b) (4)	3000 IU	< 0.1	02/05/16	(b) (4)
(b) (4)	1000 IU	0.1	02/05/16	(b) (4)
(b) (4)	1000 IU	0.3	02/05/16	(b) (4)
(b) (4)	250 IU	0.4	02/08/16	(b) (4)
(b) (4)	500 IU	0.5	02/08/16	(b) (4)

CSL Behring has specified a release limit for residual moisture of (b) (4) for this product. CBER test results for these lots meet this criterion along with test results submitted by the sponsor.