

# Test results by DBSQC Memo - Eloctate

Department of Health & Human Services  
Public Health Service

Food and Drug Administration  
CBER/OCBQ/DBSQC

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**From:**

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**Subject:** Test Results for 1) Residual Moisture, 2) ----b(4)-----  
-----, 5) Reconstitution Time and 6)  
Appearance for Biogen Idec, Inc. Fc Fusion Protein rFVIIIFc  
**STN: 125487/0**  
Lots -b(4)--- (500 IU), --b(4)---- (1000 IU), --b(4)-----  
(2000 IU)

**To:** File STN 125487/0

**Through:** Lokesh Bhattacharyya, Ph.D. HFM-682 Lab Chief LACBRP, DBSQC

William McCormick, Ph.D. HFM-680, Director DBSQC

**Summary of Testing:** Test results by DBSQC are in compliance with proposed drug product specifications.

**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). CBER analyst was Tao Pan. Each lot result represents the average of three titrations from the extracted contents of three vials. Biogen Idec uses a ----b(4)-----  
----- for moisture determination in the final product. Data for these lots from Biogen are average results from Product Quality Summary information submitted as part of Amendment 0.37, received 02/28/14. Test results are as follows:

Lot#	CBER % w/w Moisture	Test Date	Biogen Idec % w/w Moisture
-b(4)---	0.1	04/16/14	-b(4)--

--b(4)--	0.2	04/16/14	-b(4)--
-b(4)----	0.2	04/16/14	-b(4)--

Biogen Idec. has specified a release limit for residual moisture of --b(4)-- (w/w) for this product. CBER test results for these lots meet this criterion along with those submitted by the manufacturer.

2) ---b(4)-----

--b(4)-----  
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	--b(4)---	--b(4)----
-b(4)--	--b(4)-----	--b(4)---
-b(4)---	----b(4)-----	-b(4)---
-b(4)----	----b(4)-----	-b(4)---
-b(4)---	----b(4)-----	-b(4)---

Biogen has proposed the specification for -----b(4)-----  
----- Test results for the above lots by CBER meet this criterion along with those of the sponsor.

3) ---b(4)-----

--b(4)-----  
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	--b(4)---	-b(4)---
-b(4)-	--b(4)-----	-b(4)---
--b(4)---	b(4)	-b(4)---
-b(4)----	b(4)	-b(4)---
-b(4)---	b(4)	-b(4)---

Biogen has not established release limits for –b(4)------. The result is reported as a component of drug product batch data. Manufacturer’s results were not submitted as part of the Product Quality Summary in Amendment 0.37. A stability specification is set as – b(4)----- of the release value.

**4) –b(4)-----**

--b(4)-----  
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	-b(4)--	
<b>b(4)</b>	<b>-b(4)---</b>	<b>-b(4)----</b>
-b(4)---	-b(4)---	-b(4)---
-b(4)---	-b(4)---	-b(4)---
-b(4)---	-b(4)---	-b(4)---

--b(4)-----  
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**5) Reconstitution time**

Reconstitution time was evaluated concurrently with reconstitution for the determination of b(4). CBER analyst was A. Del Grosso.

Lot#	CBER		Biogen Idec
	Reconstitution Time	Test Date	Reconstitution Time
-b(4)--	40 sec.	04/29/14	-b(4)--
-b(4)--	30 sec.	04/29/14	-b(4)-- .
-b(4)--	30 sec.	04/29/14	-b(4)-- .

---b(4)------. Results obtained by CBER meet this specification along with average times reported by the manufacturer in Amendment 0.37.

**6) Appearance, Lyophilized**

Specification for Appearance, Lyophilized is “White to Off white cake to Powder”. CBER analyst was A. Del Grosso. CBER observations were consistent with this requirement.

**Appearance of the Reconstituted Solution**

Specifications for Appearance of the Reconstituted Solution were described as: Color ---- b(4)-----, and “Essentially free of particles”. As standards for the observation of Color or Clarity were not available, CBER evaluation of the reconstituted

solutions was only done by subjective visual observation. Reconstituted solutions were visually clear without evidence of particles.