

# Final Review Memo (12/17/2008) - RiaSTAP

## MEMORANDUM

**From:** Alfred Del Grosso HFM-406, PQLS, DPQ, OVRR  
Hsiaoling Wang HFM-406, PQLS, DPQ, OVRR

**Subject:** Test Results for Residual Moisture, pH, Solubility  
and Appearance for Three (3) Lots of Human  
Fibrinogen Concentrate, Pasteurized, CSL Behring  
GmbH, (license #1765)

**STN: 125317/0**

Lots 00168111, 00268111, 00368111

**To:** Laura Wood HFM-340 LH, DH, OBRR and Pending  
License File STN 125317/0

**Through:** William McCormick HFM-407, DPQ, OVRR  
Rajesh Gupta HFM-407 PQLS, DPQ, OVRR

Determination of residual moisture content was performed by CBER using Karl Fischer coulometric titration with methanol extraction of the lyophilized sample. The reported results are the average of measurements performed on methanol extractions of the contents of two separate vials of each lot. Test results are as follows:

Lot #	Mfr Result % Moisture	CBER Result % Moisture	CBER Test Date
00168111 1		0.76	12/04/08
00268111 1		0.83	12/04/08
00368111 1		0.85	12/04/08

CSL Behring GmbH has specified a limit for residual moisture of -(b)(4)- for this product. Both CBER's and the manufacturer's test results for these lots meet this specification. Testing for pH, solubility and appearance were requested by Laura Wood, DH, OBRR. pH was performed as described in DPQ test method Doc. ID 000482, "pH Determination". Solubility and appearance were evaluated after reconstitution with 50 ml of Type 1 reagent grade water. pH, solubility and appearance evaluations were performed on single vials of reconstituted product for each lot submitted.

Lot #	Mfr Result pH	CBER Result pH	CBER Test Date
00168111 7.3		7.1	12/15/08
00268111 7.4		7.1	12/15/08
00368111 7.2		7.1	12/15/08

The allowable range for pH in the license application submitted for this product is -(b)(4)-. Results obtained by both CBER and the manufacturer meet this specification. Acceptance criterion for solubility is that dissolution time with slight swirling be not more than ---(b)(4)---. Appearance is described as "should be almost colorless, clear to

slightly opalescent” and “----- (b)(4) ----- minutes after dissolution at --(b)(4)-- degrees C”. The submitted samples of these lots were evaluated as meeting these criteria.

cc: Karen Campbell