

# Residual Moisture Test - Wilate, December 10, 2007

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Subject: Residual Moisture Test for six (6) Lots of Coagulation Factor VIII/von Willebrand Factor Complex (Human) from Octapharma/1646

**STN 125251\_0**

Residual moisture was measured by CBER using a Karl Fischer coulometric titration with methanol extraction of the lyophilized samples. Octapharma's results are by a ----(b)(4)----- method described in this BLA submission that is standardized against a ----(b)(4)----- procedure. Test results are as follows:

| Mfr. -(b)(4)- Results |              | CBER's KF Results * |           |
|-----------------------|--------------|---------------------|-----------|
| Lot#                  | Moisture (%) | Moisture (%)        | Test Date |
| ----(b)(4)-----       | 1.1          | 0.93                | 05Dec07   |
| ----(b)(4)-----       | 1.1          | 0.83                | 05Dec07   |
| ----(b)(4)-----       | 0.9          | 0.72                | 05Dec07   |
| ----(b)(4)-----       | 0.9          | 1.0                 | 05Dec07   |
| ----(b)(4)-----       | 1.2          | 0.94                | 05Dec07   |
| ----(b)(4)-----       | 1.           | 0.97                | 05Dec07   |

Octapharma has proposed a limit for the residual moisture content of -(b)(4)- for this product. Test results obtained by both CBER and the manufacturer meet this specification.

\* Moisture values of Lots -----(b)(4)----- are average of 3 samples; moisture values of Lots -----(b)(4)----- are average of 2 samples.

cc: N. Baylor

R. Gupta