



Food & Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

**DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** Biologics License Application, STN 125810/0

**From:** Emnet Yitbarek, Ph.D., LAC/DBSQC/OCBQ

**Through:** Maryna Eichelberger, Ph.D.  
Division Director, DBSQC/OCBQ

**Sponsor:** Biotest AG

**Subject:** Suitability of lot-release test methods for YIMMUGO drug substance and drug product

**Recommendation:** Approval

**Executive Summary:**

Analytical methods used for lot release of YIMMUGO were reviewed by Emnet Yitbarek (LAC), Claire Wernly (LMIVTS), and Jing Lin (LBVI). Their review memoranda are attached to this cover letter.

**Conclusion:** The analytical methods and their qualifications reviewed for YIMMUGO were found to be adequate for their intended use.