



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.