



## MEMORANDUM

**Date:** June 05, 2024

**From:** George Kastanis, MS  
Quality Assurance Branch (QAB)  
Division of Biological Standards and Quality Control (DBSQC)  
Office of Compliance and Biologics Quality (OCBQ)  
Center for Biologics Evaluation and Research (CBER)  
Food and Drug Administration (FDA)

**To:** The file: STN 125810/0

**Subject:** Review of Lot Release Protocol (LRP) Template for Immune globulin intravenous, human, included in STN 125810/0.

**Through:** Varsha Garnepudi, MS, Branch Chief QAB/DBSQC/OCBQ/FDA  
Maryna Eichelberger, PhD, Director, DBSQC/OCBQ/CBER/FDA

**Applicant:** Biotest AG

**Product:** Immune globulin intravenous, human  
Trade Name: YIMMUGO

**Summary:** The LRP template for Immune globulin intravenous, human, submitted in amendment 125810/0.101 on May 31, 2024, is acceptable for use.

## **1 General Information**

### **1.1 CMC Review Identifiers and Dates**

**1.1.1 Biologics License Application STN:** 125810/0

**1.1.2 Submission received by CBER:** June 30, 2023

**1.1.3 Review completed:** June 05, 2024

**1.1.4 Material Reviewed:** BLA 125810/0

**1.1.5 Related Master File, INDs and BLAs:** STN 125810/0

## **2 Review**

### **2.1 Documents Reviewed**

The LRP template for Immune globulin intravenous, human, submitted on August 01, 2023, in amendment 125810/0.1

The LRP template for Immune globulin intravenous, human, submitted on May 23, 2024, in amendment 125810/0.94

The LRP template for Immune globulin intravenous, human, submitted on May 29, 2024, in amendment 125810/0.100

The LRP template for Immune globulin intravenous, human, submitted on May 31, 2024, in amendment 125810/0.101

### **2.2 Review**

An LRP template was not provided with the initial BLA submission on June 30, 2023. An IR was sent on July 26, 2023, asking Biotest AG to submit the LRP template.

A response was submitted on August 01, 2023, in amendment 125810/0.1 with the LRP template. The LRP template was reviewed by OCBQ/DBSQC, OCBQ/DMPQ/PRB and OTP/OPPT with formatting, finished product specification, sterility and endotoxin related comments. These comments include adding the cc: line, lot number, licensed product name, reason for submission statement, pass statement and the responsible person's signature on the first page of the LRP template (formatting comments), to update the specifications in "Table IV. Tests on the finished product" to match line items also present in the most current Drug Product specifications (finished product specification

comments), to add more details to sterility test results, such as temperature and tested sample quantity for (b) (4) media types following the provided CBER templates (sterility comment) and to add more information to the (b) (4) (b) (4) test results according to the CBER provided template (endotoxin comment). An IR was sent to Biotest AG on May 16, 2024.

A response was submitted on May 23, 2024, in amendment 125810/0.94. This revised template was reviewed by OCBQ/DBSQC, OCBQ/DMPQ/PRB and OTP/OPPT with a comment to change the units of IgG, IgA and IgM in the "Results" column of "Table IV. Tests on the finished product" from µg/mL to mg/mL. An IR was sent to Biotest AG on May 28, 2024.

A response was submitted on May 29, 2024, in amendment 125810/0.100. This revised LRP template was reviewed by OCBQ/DBSQC and OCBQ/DMPQ/PRB with a comment to delete the word "sterile" from the "Result:" line in the Sterility section of the LRP template and replace it with either the word "blank" or "xxxxx". An IR was sent to Biotest AG on May 30, 2024.

A response was submitted on May 31, 2024, in amendment 125810/0.101. This revised LRP template was reviewed by OCBQ/DBSQC and OTP/OPPT with no comments.

### **3 Conclusions**

The lot release protocol template for Immune globulin intravenous, human, submitted in amendment 125810/0.101 on May 31, 2024, is acceptable for use. This template may be used for future lot release submissions.