



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125812/0

From: Salil K Ghosh, Ph.D., LAC/DBSQC/OCBQ/CBER

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

Sponsor: Humacyte Global, Inc.

Subject: Review of Analytical Methods used for SYMVESS drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of SYMVESS were reviewed by Hyesuk Kong (LMIVTS), Wei Tu (LBVI), and Salil K Ghosh (LAC). Their review memoranda are attached to this cover letter.

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