



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

**DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** Biologics License Application, STN 125813/0

**From:** Alicia Howard, Ph.D., LBVI/DBSQC/OCBQ

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

**Sponsor:** Autolus Inc.

**Subject:** Suitability of lot-release test methods for Obecabtagene autoleucel critical component and drug product

**Recommendation:** Approval

**Executive Summary:**

Analytical methods used for lot release of Obecabtagene autoleucel were reviewed by Simleen Kaur (LMIVTS), Kouassi Ayikoe (LAC), and Alicia Howard (LBVI). Their review memoranda are attached to this cover letter.

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