



Food & Drug Administration  
10903 New Hampshire Ave.  
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## **DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** The file STN 125812/0

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

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

Kenneth Phillips, Ph.D., Lab Chief, LAC/DBSQC/OCBQ/CBER

**Sponsor:** Humacyte Global, Inc

**Subject:** Review of Analytical Method used for Human Acellular Vessel (HAV) Drug Product (DP) Lot Release

**Recommendation:** Approval

### **Executive Summary:**

The following analytical method used for lot release of HAV and the associated analytical method validation was reviewed and found to be adequate for its use:

1. (b) (4) (DP)

### **Documents reviewed:**


This is an electronic submission. Information submitted and reviewed includes:

- 125812/0 – 1.2 Cover letter, dated 8 December 2023
- 125812/0 – 3.2.P.5 Control of Drug Product
  - 3.2.P.1 Description and Composition of Drug Product
  - 3.2.P.5.1 Specifications
  - 3.3.P.5.6 Justification of Specifications
  - 3.2.P.5.2. Analytical Procedures
    - 3.2.P.5.2.3 (b) (4) content
  - 3.2.P.5.3 Validation of Analytical Procedures
    - 3.2.P.5.3.3 (b) (4) content
- 125812/0 – 3.2.P.5.4 Batch Analysis
- 125812/0.15 – 1.2 Cover Letter dated 3/25/2024 – Information Request
  - 1.11.1 Quality Information Amendment

Additional information in amendments specified below was also reviewed.

### Background

Humacyte Global, Inc submitted a BLA, STN125812 for HAV on December 8, 2023. HAV is a tissue engineered, novel, acellular tubular implant composed of human extracellular matrix (ECM) proteins typically found in human blood vessels. The HAV DP has dimensions of approximately 6 mm in inner diameter and 42 cm in length and is implanted using standard surgical techniques as a vascular conduit used to replace a patient's damaged blood vessels after sustaining trauma. HAV is manufactured in a bioreactor by (b) (4)



### Review Narrative

1. (b) (4) content (DP)



STN#125812/0 Review Memo

DBSQC

1 page has been determined to be not releasable: (b)(4)

(b) (4)

Conclusion

The validation data for the (b) (4) method performed at Humacyte Global, Inc. Durham, North Carolina, USA for the quantitation of (b) (4) in DP show that it is suitable for lot release testing.