

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: The file STN 125812

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Applicant: Humacyte Global, Inc.

Subject: Review of Analytical Methods used for Human Acellular Vessel (HAV) Drug Product (DP)

Recommendation: Approval

Executive Summary:

The following analytical methods used for lot release of Human Acellular Vessel (HAV) and the associated analytic method validations or qualifications, were reviewed:

1. Residual (b) (4) in DP by (b) (4)
2. Residual (b) (4) in DP by (b) (4)
3. Residual (b) (4) in DP by (b) (4)

Conclusion:

The analytical methods for residual (b) (4) by (b) (4), (b) (4) by (b) (4), and residual (b) (4) by (b) (4), and their validations reviewed for the Human Acellular Vessel drug product were found to be adequate for their intended use.

Documents Reviewed:

Information in sections of the original submission that describe control of DP (3.2.P.5), including descriptions of DP specifications, analytical procedures and validation of these analytical procedures were reviewed. Additional information in amendment 24, and amendment 32, were also reviewed.

Background:

On Dec 11, 2023, Humacyte Global Inc., submitted a Biologics License Application (STN 125812) for Human Acellular Vessel (HAV), a sterile, tissue-engineered, acellular conduit composed of human extracellular matrix (ECM) protein typically found in human blood vessels, for urgent atrial repair following extremity vascular trauma (b) (4) when autologous vein is not feasible. The HAV is engineered to create a biological matrix similar in protein composition and three-dimensional structure to native blood vessels, allowing it to be remodeled by the patient's cells after implantation. The DP is manufactured using human smooth muscle cells derived from an allogenic donor's aortic tissue, which are seeded into a tubular mesh scaffold and cultured in a biomimetic bioreactor system to generate a bioengineered human artery containing smooth muscle cells and the extracellular matrix the cells deposited. After culture, the HAV is decellularized through (b) (4)

The (b) (4) decellularization process removes the human cellular and genetic material while maintaining the extracellular matrix structure, mechanics, and biological activity. The HAV is manufactured within (b) (4) (b) (4). The manufacturing process introduces potential impurities such as (b) (4). For product quality, efficacy, and safety reasons, the residual impurities need to be reduced to the lowest level. The analytical methods to measure residual (b) (4) by (b) (4), (b) (4) by (b) (4) and residual (b) (4) by (b) (4) (b) (4) and their validations are used to monitor the DP impurities levels.

1. Residual (b) (4) by (b) (4)Introduction

(b) (4)

2 pages have been determined to be not releasable: (b)(4)

(b) (4)

Conclusion

The method to quantify residual (b) (4) in DP by (b) (4) was adequately validated and is suitable for its intended use as a lot release test with a specification of (b) (4)

2. Residual (b) (4) by (b) (4)

Introduction

(b) (4)

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

(b) (4)

Conclusion

The method to quantify residual (b) (4) in DP by (b) (4) was adequately validated and is suitable for its intended use with a specification of (b) (4)

3. Residual (b) (4) **by** (b) (4)

Introduction

(b) (4)

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

Conclusion

The method to detect the residual (b) (4) by (b) (4) was adequately validated and is suitable for its intended use at a specification of (b) (4) (b) (4)