
DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: BLA STN 125816/0

From: M. Nahid Parvin, Ph.D., LBVI/DBSQC/OCBQ/CBER

Through: Muhammad Shahabuddin, Ph.D., Lab Chief, LBVI/DBSQC/OCBQ/CBER
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Product: Avance Nerve Graft (processed nerve allograft)

Applicant: Axogen Corporation (Axogen)

Subject: Review of Analytical Method used for Avance Nerve Graft Drug Product (DP) Lot Release

Recommendation: Approval

Summary:

The active (b) (4) analytical method used for lot release of Avance Nerve Graft DP and its analytical method validation or method transfer qualification, were reviewed.

Conclusion: The analytical method and its validation/method transfer qualification for the Avance Nerve Graft DP were determined 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 procedure, and validation of the analytical procedure were reviewed. Additional information in amendments #125816/0.31 received on April 14, 2025, was also reviewed.

Background:

Axogen submitted rolling BLA STN 125816 for Avance Nerve Graft (processed nerve allograft) on May 14, 2024. This regenerative peripheral nerve scaffold is indicated for treating peripheral nerve functional deficits. The product consists of a decellularized and sterilized extracellular matrix (ECM) derived from human peripheral nerve tissue, supplied as one sterile processed nerve allograft

soaked in Lactated Ringer's solution, is available in 16 combinations of diameters between 1 to 5 mm and lengths between 15 to 70 mm.

The manufacturing process is continuous, beginning with peripheral nerve tissue obtained from cadaveric donors meeting applicable eligibility requirements. The Avance Method decellularizes human nerve tissue, removes axonal-growth inhibiting components, and clears cellular and non-cellular debris while preserving ECM structure and bioactive laminin. Following packaging in a sterile barrier system and terminal sterilization, the (b) (4) becomes the drug product.

Avance Nerve Graft maintains the ECM structure of human peripheral nerve, comprising epineurium, perineurium, fascicles, and laminin-lined endoneurial tubes. These endoneurial tubes serve as guidance channels for Schwann cells and regenerating axons. The product's potency is defined as neuroregenerative capacity, dependent on active basement membrane proteins lining the endoneurial tubes, with laminin being the most potent promoter of neurite growth.

The product contains laminin (b) (4)

The (b) (4) method measures the concentration of (b) (4) (b) (4) technique in Avance Nerve Grafts. In this review memo, (b) (4) method validation or method transfer qualifications for the following facilities were reviewed.

1. (b) (4)
2. Axogen Corporation, Axogen Processing Center (APC), (b) (4)

1. (b) (4)

(b) (4)

