



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

**DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** Biologics License Application, STN 125722/0

**From:** Hsiaoling Wang, Ph.D., LAC/DBSQC/OCBQ

**Through:** James Kenney, D.Sc. for Maryna Eichelberger, Ph.D.  
Acting Division Director, DBSQC/OCBQ

**Sponsor:** PTC Therapeutics, Inc.

**Subject:** Review of lot-release test methods for Eladocagene exuparvec drug substance, drug product and in-process control

**Recommendation:** Approval

**Executive Summary:**

Analytical methods used for lot release of Eladocagene exuparvec were reviewed by Hsiaoling Wang (LAC), Yen Phan (LMIVTS), Noel Bachoo and Wei Tu (LBVI). Their review memoranda are attached to this cover letter.

**Conclusion:** The analytical methods and their validations and/or qualifications reviewed for the Eladocagene exuparvec drug substance, drug product and in-process control were found to be adequate for their intended use, except for the outstanding issues for (b) (4) drug product. PTC Therapeutics has provided written commitment to resolve the issues as Postmarketing Study Commitment (PMC) in amendment 50. An additional PMC is committed in amendment 55 to assess the suitability of the drug product sterility method to detect (b) (4), an environmental isolate, to provide additional sterility assurance.