

## DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

**To:** The file

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**Applicant:** Precigen, Inc.

**Subject:** Review of analytical methods used for lot release PRGN-2012 (*zopapogene imadenovec*) [REDACTED]

### Recommendation:

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#### Executive Summary:

The following analytical methods used for lot release of *zopapogene imadenovec* (b) (4) and the associated analytical method validations, were reviewed:

(b) (4)  
[REDACTED]

**Conclusion:** The analytical methods and their validations and/or qualifications reviewed for the PRGN-2012 (b) (4) were found to be adequate for their intended use.

#### Documents Reviewed

Information in the original submission describing analytical procedures for PRGN-2012 adenoviral vector release testing (3.2.S.4), and the validation reports for these analytical procedures (Module 3.2.R) were reviewed. Information submitted in Amendments 0.33 and 0.43 was also reviewed.

#### Background:

Precigen, Inc. submitted BLA 125832 for PRGN-2012, a gorilla adenovirus-based gene therapy. The PRGN-2012 is a vector containing the human papillomavirus (HPV) antigen under control of a

constitutive cytomegalovirus (CMV) promoter. The DS is manufactured by (b) (4)

(b) (4) The DP is a [REDACTED] with the target PRGN-2012 concentration of  $5.0 \times 10^{11}$  PU/mL. This PRGN-2012 DP is a suspension for subcutaneous injection with a proposed indication for treatment of adults with recurrent respiratory papillomatosis (RRP) which is caused by chronic infection with HPV type 6 or type 11.

(b) (4)

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