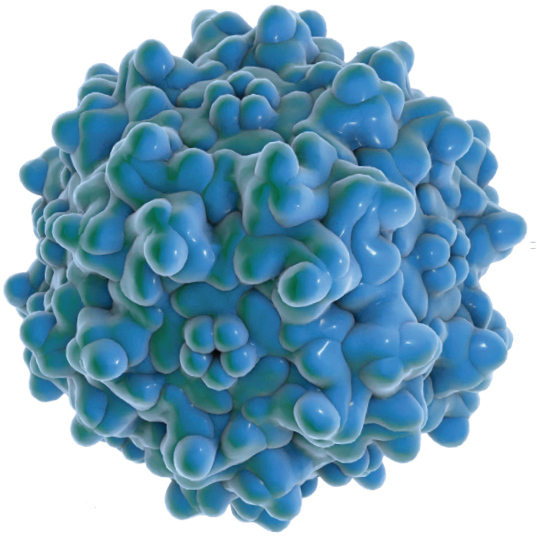
replication-competent AAV testing

WuXi AppTec offers a comprehensive GLP/GMP testing platform for gene-mediated cell therapy and viral vector-based gene therapy programs. With more than 25 years of experience in providing fully integrated biosafety testing for these programs, we have supported a vast number of successful regulatory submissions.



Justification

While AAV (adeno-associated virus) vectors are engineered to be replication defective, generation of replication-competent AAV (rcAAV) can still occur during vector manufacturing by means of recombination events within the producer cells. Even though vector production systems have been specifically developed to reduce the risk of rcAAV generation, there is still a significant safety concern driving the recommendations for testing for rcAAV in cell banks, vector and final product release for AAV-based gene therapy products.

Regulations

Guidelines on testing for rcAAV are quite vague. CBER recommends testing be performed to determine the amount of replication-competent AAV present in the final vector product, but no further specifics are provided. Based on input from our virologists and regulatory specialists, our rcAAV tests 3 flasks of the test article at 10^{10} vg/flask. Our team of virology and regulatory experts can help develop a successful testing strategy for your unique program.

Sources

Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)

Allen et al. 1997. Identification and Elimination of Replication-Competent Adeno-Associated Virus (AAV) That Can Arise by Nonhomologous Recombination during AAV Vector Production. Journal of Virology. 6816-6822

Testing Services

WuXi AppTec utilizes a two-part system employing a cell-based assay to amplify rcAAV, which is followed by a Taqman qPCR to amplify and detect AAV2 Rep DNA sequence. Our assay was developed to have a LOD of just 1 IU. We can also develop custom or semi-custom assays to meet your specific rcAAV vector testing needs.

Replication-Competent AAV Detection (rcAAV)

Replication-Competent AAV (rcAAV) Detection (GLP)
Test Code 21428.1 *TAT 42 days*

Replication-Competent AAV (rcAAV) Detection (R&D)
Test Code 24128.2 *TAT 35 days*

In addition to rcAAV testing, WuXi AppTec offers manufacturing services and integrated testing programs for all stages of clinical product development. With a full suite of standard and custom assays, we can design a customized testing program to assess the potency, purity, and safety of your viral vaccine or gene therapy product at phase-appropriate levels (R&D, GLP, and GMP) to support your regulatory filing.

Talk to us and find out how our rcAAV testing services can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

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