

Table 8: Viral Delivery Therapeutics

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Scope:

The complexities of Viral Delivery Therapeutics had limited the application of traditional analytical methods. The limitation of chromatographic techniques in the characterization of the capsid species needs to be addressed. Currently, the gold standard in capsid characterization is Analytical Ultracentrifugation. The information-rich and multi-faceted methods of AUC can not only address capsids but also HOC (Higher Order Capsids) and other impurities in a single analysis.

Questions for Discussion:

1. What are the limitations of chromatographic methods in evaluating capsids and HOCs?
2. What information from the methods evaluating the capsids species are you most interested in, sans Empty/Full?
3. How can one use AUC as a release test? If not, why?
4. What are orthogonal techniques to evaluate the capsid species, besides chromatographic, CDMS, and AUC? Are they viable options?