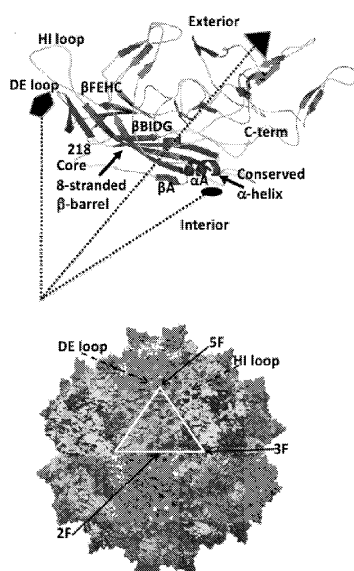




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(54) **Title:** CHARACTERIZATION OF IMPURITIES IN ADENO-ASSOCIATED VIRUS (AAV) SAMPLES AND FORMULATION COMPOSITIONS TO STABILIZE AAV

FIG. 1



(57) **Abstract:** Methods for characterizing DNA impurities in adeno-associated virus (AAV) samples or biopharmaceuticals are provided including the use of size exclusion chromatography and spectrophotometry. Methods and compositions are also provided to minimize leakage of packed DNA from AAV vector including the use of excipients, such as a sugar, an amino acid, a surfactant, or polyols.

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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