AVANCE BIOSCIENCES

CGMP Plasmid DNA Release Testing

Plasmid DNA testing is essential for verifying the identity, purity, concentration, and safety of plasmid preparations. These tests are crucial for ensuring that plasmid-based products perform as intended and comply with regulatory requirements. By choosing **Avance Biosciences**, you can be confident that your plasmid DNA products are thoroughly tested, minimizing risks, and enhancing product reliability.

Our plasmid testing services include:

Critical Quality Attributes	Assay	Description
Identity	Plasmid Sequence Confirmation	Sanger sequencing of plasmid insert or part of plasmid for identity
	Restriction map	Fragment analysis of digested plasmid by agarose gelelectrophoresis
Concentration	Plasmid concentration (A260)	Plasmid concentration measured by ultraviolet spectroscopy (UV) at 260 nm
Purity	Plasmid purity (A260/280)	Evaluate purity of plasmid by A260/A280 ratio using ultraviolet spectroscopy (UV)
	Plasmid topology % Supercoiled	Plasmid Topology analysis by Capillary electrophoresis (CE)
	Residual host RNA	Residual host RNA analysis using Agarose gel electrophoresis
	Residual host DNA	Quantitation of residual host cell DNA in test sample by QPCR
	Residual protein	Testing amount of total protein using Bicinchoninic acid assay (BCA)
	Host cell protein	Testing residual amount of E coli protein by ELISA
	Residual kanamycin	Testing residual Kanamycin antibiotics in plasmid product using colorimetric method
Safety	Endotoxin	USP <85>
	Bioburden	USP <61>
	Sterility	USP <71>
Other	Appearance	USP <790>
	pH	USP <791>

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