



Yeast Cell Line Testing

Yeast Cell Bank Testing ensures the quality and consistency of yeast used in biopharmaceutical production. These methods are critical for both integrated and non-integrated yeast cell banks. Compliance with these standards is essential for the approval and ongoing quality assurance of biopharmaceutical products.

Yeast Cell Bank Development Testing

Critical Quality Attributes	Assay	Description
Characterization	Southern Blot- Clone Screening	Screen clones for number of unique genomic integrations
Identity	Sequencing – Sanger	Confirm full or partial yeast sequence by Sanger sequencing
	Sequencing – NGS	Confirm full or partial yeast sequence by NGS

Yeast Cell Bank Release Testing

Critical Quality Attributes	Assay	Description
Identity	Sequencing – Sanger	Confirm full or partial yeast sequence by Sanger sequencing
	Sequencing – NGS	Confirm full or partial yeast sequence by NGS
Content	Southern Blot- Integration Site analysis	Determine number of integration sites within cell bank and stability over time
	Integrated Gene Copy Number Analysis	Determine number of integrated copies of transgene per cell by QPCR or ddPCR
	Plasmid Copy Number Analysis	Determine number of episomal copies of transgene per cell by QPCR or ddPCR
	Marker Retention	Determine percentage of cells capable of maintaining selectable marker/plasmid
	Inserted Gene Sequence Confirmation	Confirm full or partial yeast sequence by Sanger sequencing
Purity	Sterility Testing	Confirm sterility of cell bank

Yeast Cell Bank Release Testing

Critical Quality Attributes	Assay	Description
Identity	Northern Blot	Confirm full or partial yeast sequence by Sanger sequencing
	Copy Number Analysis- QPCR	Confirm full or partial yeast sequence by NGS
Content	Copy Number Analysis- ddPCR	Determine number of integration sites within cell bank and stability over time
	mRNA Sequencing	Determine number of integrated copies of transgene per cell by QPCR or ddPCR
	Viability Assay	Determine number of episomal copies of transgene per cell by QPCR or ddPCR
	Sterility Testing	Determine percentage of cells capable of maintaining selectable marker/plasmid
	Mycoplasma Testing	Confirm full or partial yeast sequence by Sanger sequencing
Purity	Mycoplasma Testing	Confirm sterility of cell bank

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