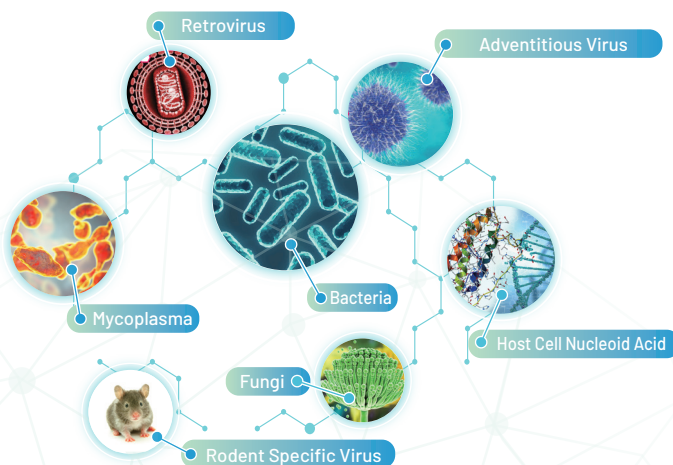


Unprocessed Bulk and Lot Release Testing for Recombinant Antibody Products

Following the requirement in medicine registration regulatory, a series biosafety testing activities constitutes recombinant antibody product lot release testing which is ensure the purify and safety of antibody medicine in clinical application.



To ensure the biosafety and quality of antibody products for the patients who using the medicine, BRC Biotech provides the full-validated lot release testing services for your products, including microbial contamination detection, adventitious virus detection, purity analysis, product impurity detection, etc.



- ✓ GMP-compliant testing system
- ✓ Meet the quality requirements of biopharmaceuticals

- ✓ Full-validated methodology
- ✓ Comply with the international regulations and guidance

- ✓ Completed project management
- ✓ Professional regulatory technical support

4 BRC Biotechnology provides antibody drug batch release testing that strictly follows GMP procedures and quality management systems, in line with domestic and international regulations for antibody drug biosafety control. To ensure the timely market launch of drugs, we also offer molecular detection techniques for rapid product release, as well as comparative validation with traditional methods.

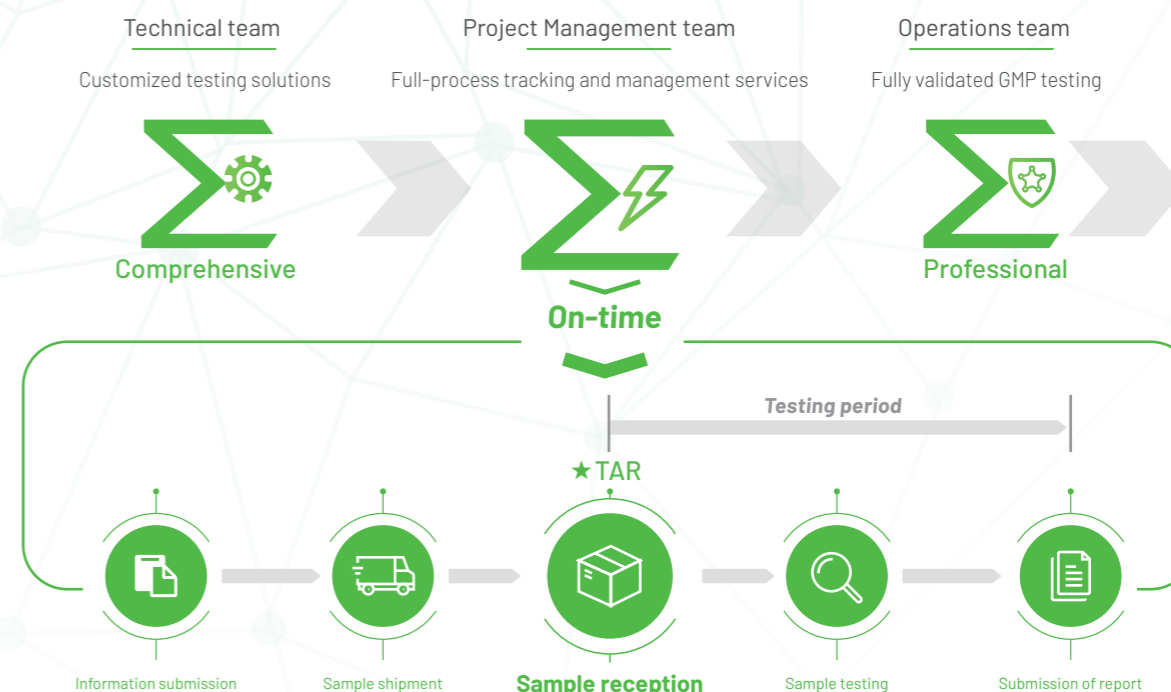
Category	Testing Items	Raw Materials	Unpurified Bulk Harvest	Purified Bulk
Bioburden	Bioburden Testing(USP, EP, CHP)	Y	Y	Y
Sterility	Sterility Testing by Membrane Filtration(USP, EP, CHP)	Y	Y	Y
Mycoplasma	Mycoplasma Culture-based Detection(USP, EP, CHP)	Y	Y	
	Mycoplasma Detection by Quantitative Polymerase Chain Reaction	Y	Y	
Safety	<i>in-vitro</i> Screening of Adventitious Viral Contaminants using Three/ Four Indicator Cell Lines		Y	Y
	Retrovirus-like Particle Quantitation		Y	
	Determination of Retroviruses by Transmission Electron Microscope		Y	
	Virus Determination by Quantitative Polymerase Chain Reaction	Y	Y	
Purity	Endotoxin Detection	Y		Y
	Determination of CHO Host Cell Residual DNA by Quantitative Polymerase Chain Reaction			Y
	Determination of CHO Host Cell Residual DNA Size Distribution			Y
	Determination of CHO Host Cell Residual Protein			Y
	Determination of Residual Protein A			Y
Physiochemical	Total Protein Determination			Y
	Determination of Osmolality			Y
	Determination of pH			Y
	Appearance			Y

* The detection scheme strictly adheres to the requirements of the Chinese Pharmacopoeia, the United States Pharmacopoeia, and the European Pharmacopoeia for the biosafety control of antibody products.

Regulatory for Lot Release Testing

Administration	Guideline	Year
NMPA	General principles of virus safety evaluation of biological tissue extraction and eukaryotic cell expression biological products	2005
	General principles of evaluation of mammalian cell substrate quality control technology for the production of recombinant biological products	2008
	Chinese Pharmacopoeia. Manufacture and quality control of animal cell substrate for biological products	2015
FDA	Points to consider in the characterization of cell lines used to product biologicals	1993
	Points to consider in the manufacture and testing of monoclonal antibody products for human use	1997
EMA	Guideline on virus safety evaluation of biotechnological investigational products	2008

Project Management Ensure the On-time Delivery



Product Specific Qualification

In both ICH Q2 and the Chinese Pharmacopoeia 2020, product-related specificity of testing methods are required to be fully qualified. At least three batches of antibody products should be used for the product specific qualification before go to market, to evaluated the validated methods is appliable for the dedicated products under commercial process.

Reference

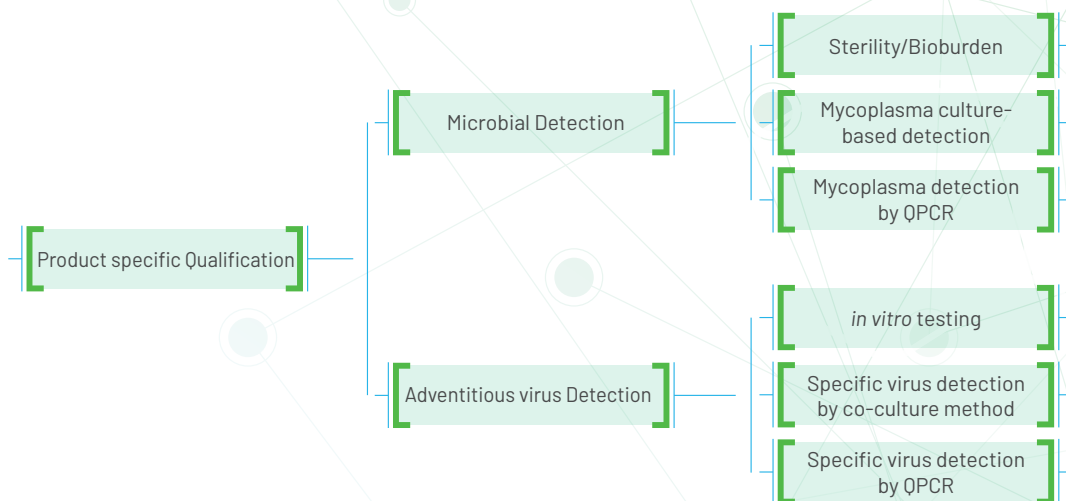
ICH Q2 (R1): Regulatory guidance for the validation of GMP analytical methods in presence of active substance.

ICH Q2 (R2): Validation of Analytical Procedures.

ICH Q14: Analytical Procedure Development.

ChP 2020.

BRC Biotech Providing the PSQ as:



Product Specific Qualification, PSQ

- ✓ Good Manufacturing Practices (GMP)
- ✓ Comprehensive quality management system
- ✓ Automated testing process
- ✓ Compliant product-specific validation services



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