

Rapid GMP Lot Release Virology and Mycoplasma Testing

WuXi AppTec's dedicated GMP lot release program features virology and mycoplasma testing with two levels of rapid turnaround times – both substantially faster than the industry norm – and testing quality that is assured by our experienced staff, which has performed thousands of tests accepted for commercial and Phase 3 production lot release.

The program also offers other routine lot release assays:

Unprocessed Bulk Product Testing (GLP/GMP)
<ul style="list-style-type: none">• In Vitro Virus Screen• In Vivo Virus Screen• Mycoplasma• Sterility• Quantitative EM• Analytical Assays• Potency Assays

Purified Bulk Product Testing (GLP/GMP)
<ul style="list-style-type: none">• Residual DNA• DNA Sizing• Host Cell Protein• Other Residuals [BSA, Protein A]• Potency• Analytical [Identity, Purity, Concentration]

Purified Bulk Product Testing (GLP/GMP)
<ul style="list-style-type: none">• Sterility• Pyrogenicity• Endotoxin• General Safety• Potency• Analytical [Identity, Purity, Concentration]

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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VIROLOGY TESTING

In Vitro Viral Contaminant Assays

Over 20 cell lines and a wide variety of viruses are available.

Hemadsorption and hemagglutination can be included in the protocol.

Turnaround Times to Release of C of A

14-Day Assay (INDUSTRY NORM: 28 days)

RAPID RELEASE: 21 days

ULTRA RAPID RELEASE: 16 days

28-Day Assay (INDUSTRY NORM: 49 days)

RAPID RELEASE: 35 days

ULTRA RAPID RELEASE: 30 days

MYCOPLASMA TESTING

PTC version or EU version

Turnaround Times to Release of C of A

(INDUSTRY NORM: 49 days)

RAPID RELEASE: 35 days

ULTRA RAPID RELEASE: 30 days

ADDITIONAL PROGRAM FEATURES:

- Assigned project managers to coordinate qualifications/validations, schedules, testing preliminaries and other project needs
- Technical specialists to provide logistical support
- Highly-trained QA staff
- Personalized services
- Custom protocols and reports
- A validated test system (individual product qualification required for GMP)
- The convenience of a single shipment to one location, avoiding possible shipping delays

For more information on WuXi AppTec's services please contact:

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