

GENERAL DESCRIPTION

J.T.Baker® Viral Inactivation Solution (JTB VIS) Biotech Reagent is a cGMP product supplied as ready-to-use, readily biodegradable, nonionic detergent solution for inactivation of viral contaminants in bioprocessing operations. JTB VIS is formulated with 10% active ingredient and purified using Avantor's purification technology to control critical impurities. JTB VIS is not listed on REACH SVHC (substances of very high concern) list, free of alkylphenol ethoxylates, and available in a variety of sizes to support processes from development to large scale commercial batches. J.T. Baker® Workflow Solutions offer consistent performance, high quality, and with local availability due to our global presence. Visit [Biopharma solutions](https://www.biopharma.solutions) | [Avantor \(avantorsciences.com\)](https://www.avantorsciences.com) for additional information on Avantor™ J.T. Baker® Workflow Solutions.

APPLICATION

J.T.Baker® Viral Inactivation Solution is effective for inactivation of virus during the production and purification of antibodies or large molecules. JTB VIS is compatible with proteins derived from mammalian cells and can be used in clarified harvest prior to the first capture column. JTB VIS is removed from the product stream through use of protein A resin to a level less than 1 ppm. Recommended use-dilution for viral clearance step is 1:100, equivalent to a maximum of 0.1% active ingredient in the harvest, which is shown to be effective to achieve >4 log viral clearance.

FEATURES

Readily biodegradable, free of alkylphenols
High purity, tested for bioburden and impurities
Effective inactivation of virus
Specifically formulated for bioprocess operations
Ease of use
0.1 µm filtered solution

BENEFITS

Addresses environmental concerns with current industry standard
Quality based product specifications for consistent performance
Ability to meet regulatory requirements for viral removal
Able to be cleared with typical downstream processing steps, detectable by routine analytical methods to 1 ppm
Reduced foaming and viscosity to minimize processing challenges
Elimination of aseptic manipulation to reduce chances of contamination

Global cGMP manufacturing and distribution facilities | Reliable supply and availability in most countries worldwide

SPECIFICATIONS

Appearance	Passes test
Identification	Conforms
Purity by HPLC	≥ 95%
Assay	Passes test
Acid value	≤ 10
Viscosity at 25°C	FIO* (Target 2-4cP)
Density (g/ml)	0.9 – 1.1
Limit of free ethylene oxide (ppm)	FIO* (Target < 1ppm)
Total Aerobic Microbial Count	1000 CFU/g
Total Yeast and Mold Count	10 CFU/g
Endotoxin (EU/mL)	FIO*
Elemental impurities (ppb)	FIO*
Protein reactive impurities (100X diluted) (ppm)	FIO*

*For information only

PROPERTIES

J.T.Baker® Viral Inactivation Solution exhibits comparable results to Triton™ X-100, while minimizing environmental concerns stemming from use of alkylphenols. JTB VIS has lower viscosity (2-4 cPs at 25°C) and foam generation (~20% lower foam height assessed by Ross Miles foam height analysis) compared to Triton™ X-100. Typical detergent concentrations are compared below (Table 1) to achieve >4 log reduction value (LRV) for viral inactivation. A maximum of 0.1% detergent, 1:100 dilution of JTB VIS, is recommended in monoclonal antibody process.

JTB VIS was evaluated for compatibility with protein therapeutics during the viral inactivation step. Four types of proteins, IgG₁, Fab, Fc-fusion, and bispecific antibodies concentrations of 1 – 10 mg/mL were incubated for 120 minutes at room temperature using 1% JTB VIS. The results demonstrate no impact to product yield or quality after proteins were exposed to detergent solution. (Figures 1 and 2). For more information on protein stability study with this product, refer to technical note, *Stability of protein therapeutics with J.T.Baker® Viral Inactivation Solution*. Presence of JTB VIS does not impact the binding capacity of protein A resins as demonstrated below (Figure 3). Further, JTB VIS is removed from product stream using protein A column to <1 ppm, the limit of detection from a starting concentration of 1,000 ppm. J.T.Baker® Viral Inactivation Solution Analytical method for detection of active ingredient, method 100-300-1001, is available under an active Confidentiality/Non-disclosure Agreement.

Table 1: JTB VIS comparison to achieve >4 LRV versus other commonly used detergents.

Detergent	Final detergent concentration in harvest to achieve >4 LRV
J.T.Baker® Viral Inactivation Solution	≤ 0.1%
Triton™ X-100 ¹	0.1-1%
Polysorbate 20 ¹	> 1%
Polysorbate 80 ¹	> 1% (commonly used with TnBP)

1. Viral Inactivation: Low pH and Detergent, Laura Durno, Omar Tounekti, Conference Proceeding, vol. 69, No.1, Jan-Feb 2015

Figure 2: Bispecific antibody stability after exposure to 1% (v/v) J.T.Baker® Viral Inactivation Solution

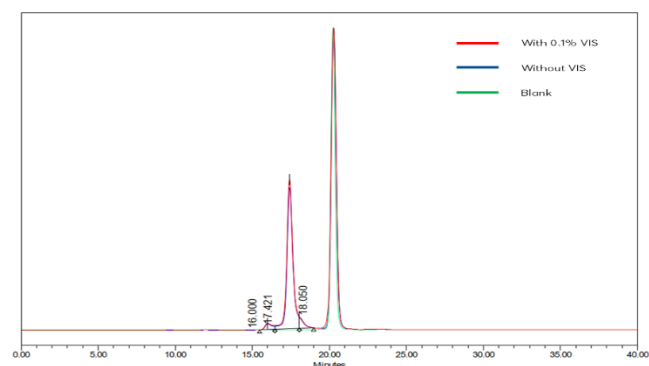


Figure 1: Fc-fusion protein stability after exposure to 1% (v/v) J.T.Baker® Viral Inactivation Solution

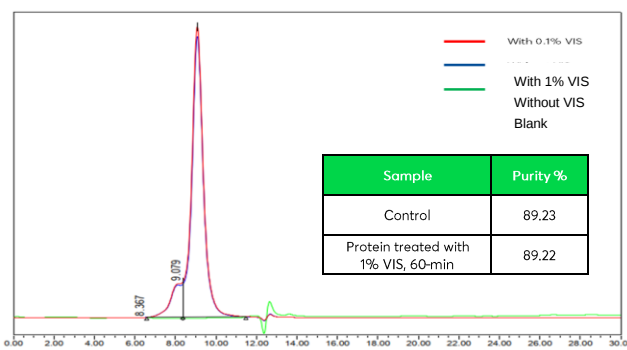
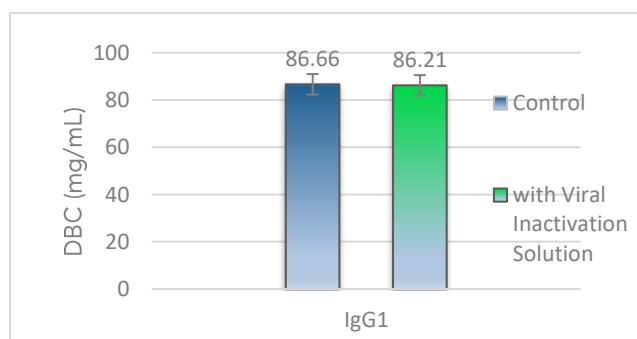


Figure 3: Dynamic binding capacity of protein A resin (J.T.Baker® PROchievA™) for IgG₁ after exposure to 1% J.T.Baker® Viral Inactivation Solution



INSTRUCTIONS FOR USE

J.T. Baker® Viral Inactivation Solution can be added directly to clarified harvest without further dilution. The recommended use-dilution for viral clearance step is 1:100 (v/v) by adding 1mL of JTB VIS to 99 mLs of clarified harvest material. Typical viral inactivation time is 60 – 120 minutes. Specific process conditions should be confirmed by user with in-house testing. Store JTB VIS at 15 – 25°C (ambient temperature). The shelf-life for the product is 24-months after the date of manufacture when stored at ambient temperature.