J.T.BAKER® CELL LYSIS SOLUTION TECHNICAL DATA

GENERAL DESCRIPTION

J.T.Baker® Cell Lysis Solution Ultrapure Bioreagent is a ready to use reagent containing a proprietary blend of biodegradable nonionic surfactants to solubilize the cell membrane lipid bilayer to release enclosed viral particles. The innovative formulation provides viral particle protection and higher recovery during the lysis step. J.T.Baker® Cell Lysis Solution is not listed on REACH SVHC (substances of very high concern) list, free of alkylphenol ethoxylates, and is available in a variety of sizes to support processes from development to large scale commercial batches. J.T.Baker® Cell Lysis Solution may be stored at ambient temperature. The product is a ready to use solution in 100X concentration that has a light yellow to dark amber color. J.T.Baker® Workflow Solutions offer consistent performance, high quality, and cost-effective products, with assured availability due to our global presence. Visit Biopharma solutions | Avantor (avantorsciences.com) for additional information on Avantor™ J.T.Baker® Workflow Solutions for CGT Workflows.

APPLICATION

J.T.Baker® Cell Lysis Solution is designed for the extraction of viral particles, such as Adeno-associated Virus (AAV) particles from HEK293 and SF9 cells and prevention of viral particle damage during the cell lysis step. J.T.Baker® Cell Lysis Solution has been shown to not impact enzymatic activity of endonuclease activity when used in combination with J.T.Baker® Endonuclease, enabling robust and efficient cell lysis and DNA/RNA degradation in a single step. J.T.Baker® Cell Lysis Solution does not contain Mg^{2+}. When used in combination with J.T.Baker® Endonuclease, or other enzymes for AAV vector bioprocessing, addition of Magnesium Chloride Hexahydrate, part number JT2449, to a target concentration ≥2 mM is recommended.

FEATURES	BENEFITS
Readily biodegradable, free of alkylphenols	Addresses environmental concerns with current industry standard
Comparable performance to Triton™ X-100	Robust and efficient, providing rapid lysis over a range of cell densities
Formulation protects viral particles	Improved process yield
Ease of use	Able to be cleared in typical downstream processing steps, detectable by routine analytical methods
Reduced foaming and viscosity	Minimize processing challenges
Quality based product specifications	Consistent performance for research use to large-scale commercial manufacturing
0.2 µm filtered solution	Elimination of aseptic manipulation to reduce chance of contamination
Global cGMP manufacturing and distribution facilities	Reliable supply and availability in most countries worldwide
Proven performance with J.T.Baker® Workflow solutions	End to end solutions to streamline workflows and supply

SPECIFICATIONS

Appearance	Tested in 3 – 5 mL volume in scintillation vial, clear and colorless or yellow solution*
Refractive Index	1.1 – 1.5
Viscosity at 25°C	For information only
Density	0.9 – 1.2 g/mL
Target pH	For information only
Total microbial count	No growth detected
UV-Vis Absorption maximum at 380-450nm	For Information Only

*Product may have a light yellow to dark amber color when observed in larger volume

Avantor Performance Materials, LLC | 100 Matsonford Road, Suite 200 | Radnor, PA 19087, United States

PROPERTIES

J.T.Baker® Cell Lysis Solution exhibits comparable cell lysis efficiency to Triton™ X-100 at typical usage concentration. Cell lysis efficiency is shown by measurement of cell viability in HEK293 cells, initial cell density approximately 5.0 x 10^6 vc/mL, following lysis using J.T.Baker® Cell Lysis Solution at 1:100 dilution for one-hour, ambient temperature. (Figure 1). J.T.Baker® Cell Lysis Solution is effective over a broad range of operating conditions supporting variable incubation times (Figure 1), a wide range of cell densities (Figure 2) and shows robustness across a wide range of temperatures (Figure 3). J.T.Baker® Cell Lysis Solution offers protection of viral vectors from sheer stress caused by agitation during cell lysis, enabling higher recovery compared to traditional cell lysis solution. In one study, both Triton™ X-100 and J.T.Baker® Cell Lysis Solution were added to viral vector solutions at typical use-dilutions of 0.1% and 1%, respectively, and agitated for one-hour at 250 RPMs. Recovery was determined using qPCR. Results indicate viral vector recoveries increased 15% using J.T.Baker® Cell Lysis Solution compared to use of Triton™ X-100. (Figure 4). J.T.Baker® Cell Lysis Solution is effective on HEK293 and SF9 cells, demonstrated by incubating initial densities of approximately 6.0 x 10^6 cells/mL with 1:100 Cell lysis solution, resulting in 4.5% and 1.5% cell viability, respectively, after a 5-minute incubation.

Figure 1: J.T.Baker® Cell Lysis Solution efficacy comparing various cell lysis solutions and incubation times at 37°C

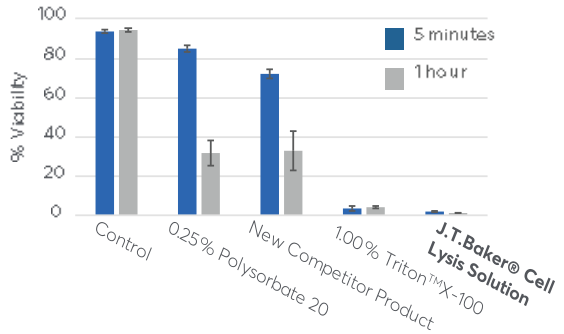


Figure 2: .J.T.Baker® Cell Lysis Solution effect on various HEK293 cell concentrations after 60 minutes at 16 - 24°C

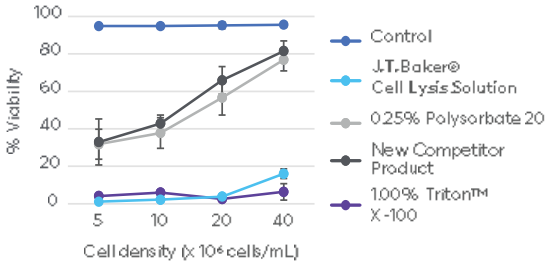


Figure 3: J.T.Baker® Cell Lysis Solution effectiveness on HEK293 cells at an initial density of 5 x10^6 cells/mL after a one-hour incubation across various temperatures.

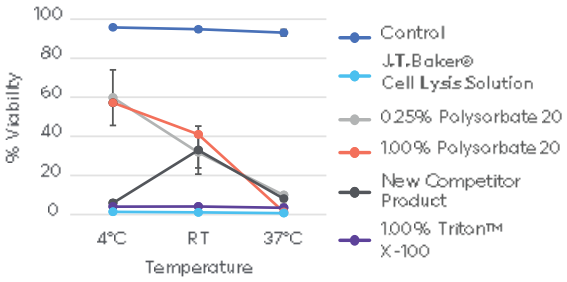
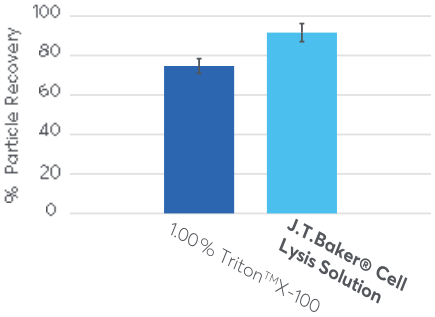


Figure 4: J.T.Baker® Cell Lysis Solution viral vector recovery versus traditional cell lysis solution demonstrating a 15% increase in recovery over Triton™ X-100



INSTRUCTIONS FOR USE

Following transfection and production of AAV, harvest adherent cells and pool into a suitable container. It may be possible to add directly to culture vessel used for adherent cell line. For suspension cells, J.T.Baker® Cell Lysis Solution may be added directly to culture. J.T.Baker® Cell Lysis Solution is typically used at a concentration of 1:100 (v/v). Incubate under agitation or on a shaker at 4 – 37°C for 60 – 120 minutes. Specific process conditions should be confirmed by end-user with in-house testing. Post-incubation, transfer cell lysate to an appropriate container for centrifugation and further processing. Store J.T.Baker® Cell Lysis Solution at 16 – 24°C (ambient temperature).