

Stability of J.T.Baker® Endonuclease

OBJECTIVE

J.T.Baker® Endonuclease is a bioengineered enzyme that effectively degrades both single stranded and double stranded DNA and RNA in various applications. The optimal temperature condition for degradation of nucleic acids is 37°C, however, data confirms partial activity at lower temperatures. Refer to Avantor Technical data sheet for J.T.Baker® Endonuclease, 400-100-1001. The recommended storage condition for J.T.Baker® Endonuclease is -20°C to prevent loss of activity and maintain a 24-month expiry, however, evaluating the stability of J.T.Baker® Endonuclease at ambient and 2-8 °C provides data that can help optimize operational efficiencies and evidence of the reliability of the enzyme in various manufacturing processes. The objective of this study is to determine the stability of J.T.Baker® Endonuclease at ambient and 2-8 °C to support customers who may store it temporarily under these conditions to facilitate easier handling and high-quality outcomes in end-user applications.

METHOD

Activity of Endonuclease was determined using a validated analytical method based on sonicated salmon sperm DNA as a substrate where one unit of endonuclease is defined as the amount of enzyme that will produce acid-soluble oligonucleotides equivalent to ΔA_{260} of 1.0 in 30 minutes 37°C. Testing was conducted per cGMP stability protocols (SB-23-038.Amb and SB-23-037.2-8) which evaluated samples stored in primary container at ambient and 2-8°C. Analyses were performed at initial timepoints and after approximately 30 days, 90 days, and 168 days for samples stored at ambient and initially and after approximately 30 days, 60 days, 90 days, and 168 days for samples stored at 2-8°C.

RESULTS

The results of each analysis per time point are displayed below in Figure 1. The activity remained within 14% of initial timepoint and met a specification of ≥ 250 Units/ μ L for both storage temperatures evaluated for the duration of the study.

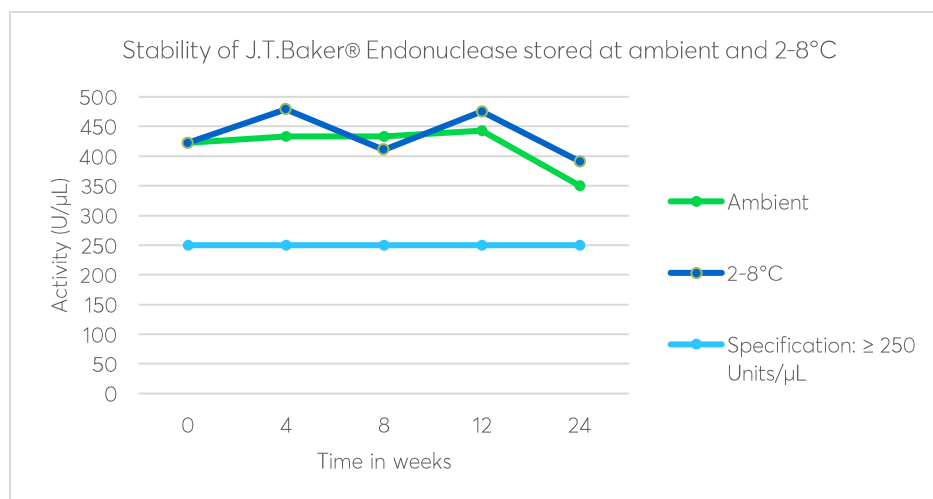


Figure 1: Stability of J.T.Baker® Endonuclease, lot MB23H18034, stored at ambient and 2-8°C. Activity was measured every 30 days (4 weeks) up to 168 days (24 weeks). Eight-week timepoint for ambient storage was not tested per protocol.

CONCLUSION

Manufacturing of Cell & Gene therapies involves a wide range of production challenges that can vary significantly in each facility, requiring flexible approaches to meet different operational requirements. Having the option to store the product in alternate temperature conditions provides flexibility and easier handling, ensuring it can be seamlessly integrated into a wide range of facilities' existing environments.

Data is representative of enzyme stability under controlled conditions to demonstrate feasibility of storing J.T.Baker® Endonuclease as high as ambient (25°C) temperature up to 24 weeks. This information is intended to provide evidence the product is stable under multiple temperature conditions and is not a guarantee of product performance. Further testing is recommended under your own internal conditions, if not intended for immediate use after removal from -20°C, to confirm these findings prior to revision of established operating procedures. J.T.Baker® Endonuclease is formulated using 50% Glycerin to prevent freezing, storage at -80°C is not advised. In AAV vector bioprocessing, J.T. Baker® Endonuclease has been shown to retain enzymatic activity in the presence of J.T. Baker® Cell Lysis Solution, part number BAKRG193, enabling robust and efficient cell lysis and DNA/RNA degradation in a single step.

PRODUCT INFORMATION



Part Number	Unit of measure	Storage	Quality
BAKR7108-10	100 KU		Ultrapure Bioreagent
BAKR7108-40	1,250 KU		
BAKR7108-50	5,000 KU		
BAKRGT20-05	25 KU		Biotech Reagent cGMP
BAKRGT20-10	100 KU		
BAKRGT20-25	500 KU		
BAKRGT20-40	1,250 KU		
BAKRGT20-50	5,000 KU		
BAKRGT20-62	12,500 KU		
BAKRGT20-80	25,000 KU		