



Advancion Quality Program Overview

Delivering Transparency and Trust for Essential Life Sciences Ingredients and Consumables

Essential inputs. Extraordinary outcomes.™

Let advancion help guide the selection process for your essential raw materials

Navigating through the complex regulatory environment

With the ever-evolving Life Sciences regulatory environment, it can be difficult to determine if a raw material is suitable for a particular process and final use. That is why Advancion offers a simple and transparent platform to help you find the right level of quality and process control to manage risk and ensure a reliable supply chain.

Product selection

Advancion has safely produced and delivered biological buffers and other critical ingredients to market-leading companies across the globe for more than 70 years. Our manufacturing processes are purposefully designed to produce product grades with the specifications and quality support to ensure we provide the right product for every application. From general purpose reagents and basic raw materials to IPEC GMP-compliant multicompendial buffers, we have you covered.

Quality level guidance

Advancion products are categorized into 4 quality levels which vary based on the quality systems employed, documentation, process controls, and customer support. Use the table to identify the product quality level that meets your regulatory requirements, risk tolerance, and development/commercialization strategy.

Advancion Product Quality Levels for Life Sciences Ingredients and Consumables

Quality Level 1	Raw materials with basic testing and documentation. Typically used for research or industrial applications.
Quality Level 2	Raw materials manufactured under ISO 9001 with verified process controls and monitoring in a non-cGMP environment.
Quality Level 3	Raw materials manufactured under ISO 9001 with verified process controls and monitoring in a non-cGMP environment and with additional testing and documentation.
Quality Level 4	Raw materials manufactured in compliance with IPEC GMP guidelines and with the most comprehensive testing, documentation, and quality support. Typically required for many Life Sciences applications.

Our 4 distinct quality levels provide a clear framework for defining specific product attributes, ensuring they align with your manufacturing and control requirements. Selecting the most suitable quality profile depends on your unique need for processes that are controlled, verified, or validated as necessary.

	Quality Level 1	Quality Level 2	Quality Level 3	Quality Level 4
Quality System and Change Notification				
Quality System	ISO 9001	ISO 9001	ISO 9001	ISO 9001 IPEC GMP
GMP Trained Personnel	●	●	●	●
Documentation Management System	●	●	●	●
Customer Change Notification, Limited List	●	●	●	
Customer Change Notification in Accordance with IPEC Level 2				●
Quality and Regulatory Documentation				
Certificate of Analysis	●	●	●	●
Packaging Configuration	●	●	●	●
Safety Data Sheet	●	●	●	●
Regulatory Data Sheet (BSE/TSE Statements, etc.)		●	●	●
Nitrosamine Impurities Monitoring			●	●
Residual Solvents			●	●
Elemental Impurities Monitoring, Limited List		●	●	
Elemental Impurities Monitoring, in Accordance with USP <232>				●
Qualification and Validation				
Verified Manufacturing/Cleaning Process		●	●	●
Validated Manufacturing/Cleaning Process				●
Verified Analytical Methods	●	●	●	●
Validated Analytical Methods				●
Potential for Shelf Life Extension, if Data Available			● ¹	● ¹
Access to Analytical Methods				●
Formal Stability Program				●
Shelf Life Based on Historical Data	●	●	●	N/A
On-Site Audit	● ¹	● ¹	●	●
Virtual Audit	● ¹	●	●	●
Paper-Based Audit		●	●	●
Site Quality Self-Assessment Document	●	●	●	●
Quality Agreement				●

¹ Service can be provided for an additional fee

Advancion product and quality level matrix

	Quality Level 1	Quality Level 2	Quality Level 3	Quality Level 4
TRIS AMINO™ (Tromethamine)				
TRIS AMINO™ Crystal	●			
TRIS AMINO™ Buffer		●		
TRIS AMINO™ AC Buffer		●		
TRIS AMINO™ ULTRA PC			●	
TRIS AMINO™ AC ULTRA PURE				●
TRIS AMINO™ ULTRA PURE				●
TRIS AMINO™ Hydrochloride (HCl)				
TRIS AMINO™ HCl Standard			●	
TRIS AMINO™ HCl Biologics Plus				●
AMP (Aminomethyl Propanol)				
AMP-95™	●			
AMP-90™	●			
AMP-ULTRA™ PC		●		
HEPES				
HEPES Buffer			●	
HEPES ULTRA PC™			●	
HEPES Biologics				●
HEPES Biologics Plus				●
HEPES Sodium Salt Biologics Plus				●

Product Stewardship

Through our investments in application and new product development, we have a deep understanding of where our chemistries are (and can potentially be) used to actively address global trends in Life Sciences, Beauty and Personal Care, and other essential industries to help make our lives healthier, and more sustainable and comfortable. To help ensure that Advancion products are not used in ways for which they are not intended, Advancion personnel will assist customers in dealing with environmental and product safety considerations. Before handling any of the products, obtain available product safety information including the Safety Data Sheet(s) and take the necessary steps to ensure safety of use. For assistance, product Safety Data Sheets, or other information, please visit advancionsciences.com or contact us at info@advancionsciences.com

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