Stability of HyClone™ process liquids

HyClone process liquids span a complete range of buffers, acids, bases, alcohols, salts, detergents, and water for injection (WFI) quality water commonly used in bioprocess production. Various tests are employed to determine a validated shelf life for each process liquid.

Overview

Stability data for buffers and other process liquids used in the production of biopharmaceuticals and vaccines is a critical factor in maintaining regulatory compliance. Process liquids are relatively standardized with respect to component composition, but might vary with regard to component concentration. HyClone process liquids are tested against a variety of parameters to establish a validated shelf life for standard and nonstandard formulations. The stability testing data provided below provides a summary of formulations and test results as of the date of this publication. Additional stability testing data pertaining to existing or new formulations is added on a periodic basis.

Process liquids stability data

Product description (concentration)	Storage conditions	Duration	Stability tests						
			Appearance	Conductivity	Endotoxin	Molarity	Osmolality	pH	Sterility
Acetic Acid (4 M)	2°C to 8°C	24 mo	✓		✓			✓	✓
Citrate (100 mM)	2°C to 8°C	9 mo	✓		✓		✓	✓	✓
	Ambient	9 mo	✓		✓		✓	✓	✓
	30°C to 35°C	9 mo	✓		✓		✓	✓	✓
EDTA (0.5 M)	2°C to 8°C	24 mo	✓		✓			✓	✓
	Ambient	24 mo	✓		✓			✓	✓
	40°C	48 wk	✓		✓			✓	✓
Ethanol (20%)	2°C to 8°C	9 mo	✓		✓		✓	✓	✓
	Ambient	9 mo	✓		✓		✓	✓	✓
	30°C to 35°C	9 mo	✓		✓		✓	✓	✓
Glucose (50%)	15°C to 30°C	22 mo	✓		✓			✓	✓
Glycine (20 mM)	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Glycine (100 mM)	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Hank's Balanced Salt (1×) w/ Ca, Mg, phenol red	Ambient	36 mo	✓		✓		✓	✓	✓

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Process liquids stability data (continued)

Product description (concentration)	Storage conditions	Duration	Stability tests						
			Appearance	Conductivity	Endotoxin	Molarity	Osmolality	pH	Sterility
MES (50 mM)	15°C to 30°C	13 mo	✓	✓	✓	✓		✓	✓
MES (50 mM), NaCl (200 mM)	2°C to 8°C	13 mo	✓	✓	✓	✓		✓	✓
Phosphate Buffered Saline (10×)	Ambient	36 mo	✓		✓		✓	✓	✓
	40°C	24 wk	✓		✓		✓	✓	✓
Dulbecco's Phosphate Buffered Saline (1×) w/ or w/o Ca, Mg, phenol red	Ambient	36 mo	✓		✓		✓	✓	✓
Sodium Chloride (100 mM)	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Sodium Chloride (5 M)	2°C to 8°C	24 mo	✓		✓	✓			✓
	Ambient	24 mo	✓		✓	✓			✓
	40°C	48 wk	✓		✓	✓			✓
Sodium Chloride (100 mM), Phosphate (25 mM), and Caprylic Acid (25 mM)	2°C to 8°C	5 mo	✓		✓		✓	✓	✓
	Ambient	5 mo	✓		✓		✓	✓	✓
	30°C to 35°C	3 mo	✓		✓		✓	✓	✓
Sodium Citrate (100 mM)	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Sodium Hydroxide (10 mM)	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Sodium Hydroxide (3 M)	2°C to 8°C	24 mo	✓		✓	✓		✓	✓
	Ambient	24 mo	✓		✓	✓		✓	✓
	40°C	48 wk	✓		✓	✓		✓	✓
Sodium Phosphate (100 mM)	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Sodium Phosphate Dibasic (100 mM)	2°C to 8°C	9 mo	✓		✓		✓	✓	✓
	Ambient	9 mo	✓		✓		✓	✓	✓
	30°C to 35°C	9 mo	✓		✓		✓	✓	✓
Sodium Phosphate Dibasic (10 mM), and Sodium Chloride (1 M)	2°C to 8°C	9 mo	✓	✓	✓		✓	✓	✓
	Ambient	9 mo	✓	✓	✓		✓	✓	✓
	30°C to 35°C	9 mo	✓	✓	✓		✓	✓	✓
Sodium Phosphate (10 mM), and Sodium Chloride (1 M)	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Tris (20 mM)	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Tris (20 mM), NaCl (1.5 M)	Ambient	12 mo	✓	✓	✓		✓	✓	✓
Tween™ 80 (1%)	Ambient	12 mo	✓		✓			✓	✓
Urea (5 M)	Ambient	12 mo	✓	✓	✓		✓	✓	✓
WFI Quality Water	2°C to 30°C	36 mo	✓		✓			✓	✓
	20°C to 25°C	48 mo	✓		✓			✓	✓

Additional tests including cytotoxicity, Fourier transform infrared spectroscopy (FTIR) identification, and inductively coupled plasma-quadruple mass spectrometry (ICP-MS) are also available for some formulations.

Buffers and process liquids listed in this document were stored in single-use containers.

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