

# 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	✓	✓	✓		✓	✓	✓

## Process liquids stability data (continued)

Product description (concentration)	Storage conditions	Duration	Stability tests						
			Appearance	Conductivity	Endotoxin	Molarity	Osmolality	pH	Sterility
<b>Hank's Balanced Salt (1×) w/ Ca, Mg, phenol red</b>	Ambient	36 mo	✓		✓		✓	✓	✓
<b>MES (50 mM)</b>	15°C to 30°C	13 mo	✓	✓	✓	✓		✓	✓
<b>MES (50 mM), NaCl (200 mM)</b>	2°C to 8°C	13 mo	✓	✓	✓	✓		✓	✓
<b>Phosphate Buffered Saline (10×)</b>	Ambient	36 mo	✓		✓		✓	✓	✓
	40°C	24 wk	✓		✓		✓	✓	✓
<b>Dulbecco's Phosphate Buffered Saline (1×) w/ or w/o Ca, Mg, phenol red</b>	Ambient	36 mo	✓		✓		✓	✓	✓
<b>Sodium Chloride (100 mM)</b>	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Sodium Chloride (5 M)</b>	2°C to 8°C	24 mo	✓		✓	✓			✓
	Ambient	24 mo	✓		✓	✓			✓
	40°C	48 wk	✓		✓	✓			✓
<b>Sodium Chloride (100 mM), Phosphate (25 mM), and Caprylic Acid (25 mM)</b>	2°C to 8°C	5 mo	✓		✓		✓	✓	✓
	Ambient	5 mo	✓		✓		✓	✓	✓
	30°C to 35°C	3 mo	✓		✓		✓	✓	✓
<b>Sodium Citrate (100 mM)</b>	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Sodium Hydroxide (10 mM)</b>	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Sodium Hydroxide (3 M)</b>	2°C to 8°C	24 mo	✓		✓	✓		✓	✓
	Ambient	24 mo	✓		✓	✓		✓	✓
	40°C	48 wk	✓		✓	✓		✓	✓
<b>Sodium Phosphate (100 mM)</b>	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Sodium Phosphate Dibasic (100 mM)</b>	2°C to 8°C	9 mo	✓		✓		✓	✓	✓
	Ambient	9 mo	✓		✓		✓	✓	✓
	30°C to 35°C	9 mo	✓		✓		✓	✓	✓
<b>Sodium Phosphate Dibasic (10 mM), and Sodium Chloride (1 M)</b>	2°C to 8°C	9 mo	✓	✓	✓		✓	✓	✓
	Ambient	9 mo	✓	✓	✓		✓	✓	✓
	30°C to 35°C	9 mo	✓	✓	✓		✓	✓	✓
<b>Sodium Phosphate (10 mM), and Sodium Chloride (1 M)</b>	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Tris (20 mM)</b>	2°C to 8°C	12 mo	✓	✓	✓		✓	✓	✓
	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Tris (20 mM), NaCl (1.5 M)</b>	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>Tween™ 80 (1%)</b>	Ambient	12 mo	✓		✓			✓	✓
<b>Urea (5 M)</b>	Ambient	12 mo	✓	✓	✓		✓	✓	✓
<b>WFI Quality Water</b>	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-quadrupole 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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CY12720-28May20-FL



# HyClone classical media

## FORMULATION

### Balanced salt solutions

Component description	Product code SH30014		Product code SH30015		Product code SH30016	
	mg/L	mmol/L	mg/L	mmol/L	mg/L	mmol/L
Calcium chloride (anhydrous)	200	1.8021	140	1.2615	0	0
Potassium chloride	400	5.3655	400	5.3655	400	5.3655
Potassium phosphate monobasic (anhydrous)	0	0	60	0.4409	60	0.4409
Magnesium sulfate (anhydrous)	97.67	0.8112	97.67	0.8112	0	0
Sodium chloride	6800	116.3587	8000	136.8925	8000	136.8925
Sodium phosphate dibasic (anhydrous)	0	0	47.68	0.3359	47.68	0.3359
Sodium phosphate monobasic H <sub>2</sub> O	140	1.0146	0	0	0	0
D-Glucose (anhydrous)	1000	5.5506	1000	5.5506	1000	5.5506
Phenol red-Na	11	0.0292	11	0.0292	11	0.0292
Sodium bicarbonate	0	0	0	0	0	0

Component description	Product code SH30029		Product code SH30030		Product code SH30031	
	mg/L	mmol/L	mg/L	mmol/L	mg/L	mmol/L
Calcium chloride (anhydrous)	200	1.8021	140	1.2615	0	0
Potassium chloride	400	5.3655	400	5.3655	400	5.3655
Potassium phosphate monobasic (anhydrous)	0	0	60	0.4409	60	0.4409
Magnesium sulfate (anhydrous)	97.67	0.8112	97.67	0.8112	0	0
Sodium chloride	6800	116.3587	8000	136.8925	8000	136.8925
Sodium phosphate dibasic (anhydrous)	0	0	47.68	0.3359	47.68	0.3359
Sodium phosphate monobasic H <sub>2</sub> O	140	1.0146	0	0	0	0
D-Glucose (anhydrous)	1000	5.5506	1000	5.5506	1000	5.5506
Phenol red-Na	11	0.0292	11	0.0292	11	0.0292
Sodium bicarbonate	2200	26.1874	350	4.1662	350	4.1662

Component description	Product code SH30107		Product code SH30268		Product code SH30588	
	mg/L	mmol/L	mg/L	mmol/L	mg/L	mmol/L
Calcium chloride (anhydrous)	0	0	140	1.2615	0	0
Potassium chloride	400	5.3655	400	5.3655	400	5.3655
Potassium phosphate monobasic (anhydrous)	60	0.4409	60	0.4409	60	0.4409
Magnesium sulfate (anhydrous)	0	0	97.67	0.8112	0	0
Sodium chloride	8000	136.8925	8000	136.8925	8000	136.8925
Sodium phosphate dibasic (anhydrous)	47.68	0.3359	47.68	0.3359	47.68	0.3359
Sodium phosphate monobasic H <sub>2</sub> O	0	0	0	0	0	0
D-Glucose (anhydrous)	1000	5.5506	1000	5.5506	1000	5.5506
Phenol red-Na	0	0	0	0	0	0
Sodium bicarbonate	0	0	350	4.1662	350	4.1662

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CY12682-25Jun20-DF

