Water, balanced salt solutions, and liquid media

HYCLONE MEDIA AND SUPPLEMENTS

HyClone™ standard liquid media and balanced salt solutions are manufactured using powdered media and salts as starting material (Fig 1). Standard liquid products are membranesterilized through final 0.1 µm pore-size filters. Filter integrity tests are performed both before and after filtration. All aseptic fills are performed in a class 100 clean room.

Key features of liquid media and balanced salts:

- · Traceable and documented origin of all formula ingredients
- Validated and consistent production processes for lot-to-lot consistency
- · Manufactured according to cGMP guidelines

Specifications

Refer to individual product labels for intended use statement on custom liquid products.

All liquid media should be stored refrigerated at 2°C to 8°C. It is not recommended to freeze liquid media, as some components precipitate irreversibly when exposed to temperatures below 0°C. All balanced salt solutions should be stored at room temperature (15°C to 30°C). Check individual product label for proper storage temperatures and expiration date.

To protect photo-sensitive components from harmful photo-oxidation, unused portions of liquid media should be stored away from light. Media containing HEPES buffer might exert cytotoxic effects on cells in culture when exposed to fluorescent light at 2 mW/cm² for as little as 30 min (1,2,3).

Deterioration of liquid media and salts may be observed by any or all of the following indicators:

- · Color change
- Precipitation
- Cloudiness



 $\textbf{Fig 1.} \ \text{Liquid media and balanced salt solutions are supplied ready for use.}$

If a liquid product exhibits any of these characteristics or other signs of deterioration, please contact your local sales representative for assistance.

Suggested preparation

The addition of supplements (serum, antibiotics, etc.) to a liquid medium should be carried out under aseptic conditions. The addition of supplements might affect the shelf-life of the product and invalidate the expiration date indicated on the product label. If you have questions concerning supplementation, please contact your local sales representative for technical assistance.



Quality control testing

Our liquid media and balanced salt solutions are subjected to stringent quality control testing to ensure product performance. Sterility testing is performed on each lot of liquid medium and salt solution using the membrane filtration method described in the current U.S. Pharmacopeia (USP). Should the customer desire to perform in-house sterility tests, we recommend using the current USP sterility test method. Sterility testing by incubating medium at 37°C might cause irreversible precipitation, affect product efficacy and shelf-life, and lead to false conclusions.

Table 1 provides a list of standard or optional testing performed on each lot of liquid medium and salt solution. The certificate of analysis provides release criteria and actual test data for each lot.

Table 1. Quality control testing Chart (S = standard, O = optional, N/A = not applicable)

	Standard liquid media	Custom liquid media	Liquid salts
Biological performance			
Growth promotion	S	N/A	N/A
Cytotoxicity	0	S	S
Microbiological testing		•	•••••
Sterility	S	S	S
Mycoplasma/virus*	0	0	0
Endotoxin	S	S	S
Physicochemical tests		•	••••
pH [†]	S	S	S
Osmolality	S	S	S
Key elements	0	0	0

^{*} Mycoplasma/virus screening is not routinely carried out on products. Refer to the certificate of analysis for actual test results.

Custom production

Formulations and delivery systems can be customized to your specific process requirements or optimized to maximize process yields. Custom media and process liquids can be manufactured in a cGMP environment to meet your needs.

Rapid Response Production (RRP)

Our RRP program (non-cGMP) manufactures up to 200 L of your custom prototype formulation within seven working days of your request. Use our RRP service to expedite the development and testing of custom media for your biopharmaceutical manufacturing process.

References

- Spierenburg, G.T., Oerlemans, F.T.J.J., Van Laarhoven, J.P.R.M., and De Bruyn, C.H.M.M. Cancer Res. 44, 2253 (1984)
- Zigler, Jr., J. S., Lepe-Zuniga, J. L., Vistica B. and Gery, I. *In Vitro Cell Dev. Biol.* 21, 282 (1985)
- 3. Lepe-Zuniga J.L., Zigler, Jr., J.S. and Gery, I. *Journal of Immunological Methods*, **103**, *145* (1987)

Ordering information

Product	Product code
HyClone Dulbecco's Phosphate Buffered Saline (DPBS), 1× Without calcium, magnesium, phenol red	SH30028
HyClone Dulbecco's Phosphate Buffered Saline (DPBS), 1× With calcium, magnesium, without phenol red	SH30264
HyClone Dulbecco's Phosphate Buffered Saline (DPBS), 10× Without calcium, magnesium, phenol red	SH30378
HyClone Dulbecco's Phosphate Buffered Saline (DPBS), 10× With calcium, magnesium	SH30597
HyClone Earle's Balanced Salt Solution (EBSS), 1× With calcium, magnesium, phenol red	SH30029
HyClone Hank's Balanced Salt Solution (HBSS), 1× With calcium, magnesium, phenol red	SH30030
HyClone Hank's Balanced Salt Solution (HBSS), 1× Without calcium, magnesium, with phenol red	SH30031
HyClone Hank's Balanced Salt Solution (HBSS), 1× With calcium, magnesium, without phenol red	SH30268
HyClone Hank's Balanced Salt Solution (HBSS), 1× Without calcium, magnesium, phenol red	SH30588
HyClone HEPES 1 M Solution	SH30237
HyClone HEPES 50 mM Solution With 0.15 M NaCl, 20 mM EDTA, pH 8.0	SH30291
Phosphate Buffered Saline (PBS), 1× (0.0067 M PO4) Without calcium, magnesium, phenol red	SH30256
Phosphate Buffered Saline (PBS) 10× (0.067 M PO4) Without calcium, magnesium, phenol red	SH30258
HyClone Water, cell culture-grade Endotoxin-free, (P 0.005 EU/mL), deionized, distilled, 0.1 µm sterile filtered	SH30529
HyClone Water, molecular biology-grade DNase-, RNase-, and protease-free (no activity within assay detectability limits), deionized, distilled, 0.1 μm sterile filtered.	SH30538
HyClone Water, water for injection (WFI)-quality Meets current USP monograph criteria for WFI packaged in bulk for commercial use elsewhere. Not for diagnostic or therapeutic Use.	SH30221

[†] pH is as tested at time of manufacture. pH might change over time, but may be adjusted using standard techniques.

Product	Product code	
HyClone Basal Medium Eagle (BME) with Earle's Balanced Salt Solution (EBSS)	SH30157	
HyClone Dulbecco's Modified Eagle's (DME) medium F12 1:1	SH30023	
HyClone Dulbecco's Modified Eagle's (DME) medium, high glucose	SH30022	
HyClone Dulbecco's Modified Eagle's (DME) medium, low glucose	SH30021	
HyClone Ham's F12 medium	SH30026	
HyClone Iscove's Modified Dulbecco's medium (IMDM)	SH30228	
HyClone Leibovitz L-15 medium	SH30525	
HyClone McCoy's medium	SH30200	
HyClone HyClone Medium 199	SH30253	
HyClone Minimum Essential Medium (MEM)	SH30024	
HyClone RPMI 1640 medium	SH30027	

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