

7. Quality Control Testing Waive all QC testing Perform QC testing as indicated below*(Check desired tests and list specification; list information required on CoA)***Test**

- Appearance
- Target pH @ 17–20°C
- Final pH @ 17–20°C *(specify range)*
- Conductivity
- Sterility
- Endotoxin
- Other

Specification

Certificate of Analysis Requirements

8. Concurrent Use Policy

HyClone's products are designed to meet quality standards based on current Good Manufacturing Practices (cGMPs). Allowance of products to be delivered to the customer prior to release by Quality assurance, except under a concurrent use certificate signed by the customer and approved by HyClone QA, violates cGMP. HyClone is committed to compliance with cGMP.

Liability: The product shall be inspected by HyClone before shipping and by the customer upon receipt of shipment for any defects. HyClone's only liability to the customer for any product that HyClone determines was defective at the time of shipment from HyClone shall be (i) replace the product at no charge or (ii) refund or give credit for the amount paid. Customer hereby acknowledges that the product is being manufactured in compliance with specifications provided by customer and customer hereby agrees to indemnify and hold harmless HyClone against any action for infringement, such as patent, trademark or copyright infringement arising from the manufacture, use or sale of the product. HyClone will not be responsible for test results outside of the range specified by the customer, until a history has been established (minimum of one production batch). Customer shall be obligated to purchase the first production batch as per the above.

Intended Use: HyClone is regulated under the FDA as a Class 1 Medical Device Manufacturer. As such all custom products are manufactured under the intended use of "For Further Manufacturing." This statement will be shown on the product label.

9. Additional Comments**10. Customer Information**

Company:

Date:

Client:

Client Title:

Tel:

Fax:

E-mail:

Address:

City:

State/Province:

Country:

ZIP/Postal Code:

Approval Signature: X

HyClone Use Only

Sales Representative:

Can HyClone make this product? Yes No Pilot:Determined by: Product Management DCAT

Part No:

DCAT Signature: