# HARDY DIAGNOSTICS

## Purified Water Specification Testing Results (California Facility)

## For the month of:  October 2013 (13274-13304)

Listed below are the testing results for the purified water used in the manufacture of products at Hardy Diagnostics.

| Test | Testing Frequency | Units | In-House Specification (method detection limit) | Testing Data |
|---|---|---|---|---|
| Minimum Resistivity*[1,3,4,5] | Continuous Monitoring | Megohm* cm | > 18.0 | 18.18 |
| pH* | Each use | N/A | 5.5 – 7.5 | 7.19 |
| Total Organic Carbon[1,3,5] | Monthly | ug/L | <500 | ND |
| Heavy Metals* (Single)[1,3,4] (Cd, Cr, Cu, Ni, Pb and Zn) | Annually | mg/L | < 0.05 | Cd – ND<br>Cr – ND<br>Cu – ND<br>Ni – ND<br>Pb – ND<br>Zn – ND |
| Heavy Metals*  (Total)[3,4] | Annually | mg/L | < 0.1 | ND |
| Ammonia/OrganicNitrogen[3] | Monthly | mg/L | < 0.1 | 0.070 |
| Total Chlorine Residual[3,4] | Monthly | mg/L | <0.1 | ND |
| Maximum  Bacterial Content[1,3,4,,5] | Weekly | colony forming units (CFU) per milliliter | <10 | <1 |
| Water Quality[3,4] ratio | Annually | ratio | 0.8 – 3.0 | 1.12 |
| Use Test (Student $t$)[3] | Quarterly | N/A | $\leq$ 2.78 | 2.0 |
| Inhibitory Residue[4] | Annually | N/A | < 15% | - 4% |
| Maximum Silicate, $SiO_2$ [3,4] | Annually | mg/L | $\leq$ 0.05 | ND |

ND = Not Detected at or above the method detection limit.
*Testing data is given as a monthly average.

**References:**

1. *Preparation and Testing of Reagent Water in the Clinical Laboratory*, C3-A4. Clinical Laboratory Standards  (CLSI), Villanova, PA, 2006.

2. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22-A3. Clinical Laboratory Standards Institute (CLSI – formerly NCCLS), Villanova, PA, 2004.

3. *Standard Methods for the Examination of Water and Wastewater*, 21st ed., editors Andrew D. Eaton, Lenore S. Clesceri, et al. American Public Health Association, Washington, D.C. 2005.

4. *Manual for the Certification of Laboratories Analyzing Drinking Water*, Criteria and Procedures Quality Assurance 5th ed., Environmental Protection Agency (EPA).

5.  USP. *USP 35-NF 30, Water for Pharmaceutical Purposes <1231>.* Rockville, MD: US Pharmacopeial Convention; 2012:886-907.

*Wendy Hadley*

Wendy Hadley
Manager of Quality Control

**Hardy Diagnostics**
1430 W. McCoy Lane
Santa Maria, CA 93455
(800) 266-2222   FAX (805) 346-2760 www.hardydiagnostics.com