



Purified Water Specification Testing Results (California Facility)

For the month of: **September 2013 (13244-13273)**

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 | 18.11 |
| pH* | Each use | N/A | 5.5 – 7.5 | 7.11 |
| Total Organic Carbon ^{1,3,5} | Monthly | ug/L | <500 | 232 |
| Heavy Metals* (Single) ^{1,3,4} (Cd, Cr, Cu, Ni, Pb and Zn) | Annually | mg/L | < 0.05 | Cd – ND Cr – ND Cu – ND Ni – ND Pb – ND Zn – ND |
| Heavy Metals* (Total) ^{3,4} | Annually | mg/L | < 0.1 | ND |
| Ammonia/Organic Nitrogen ³ | Monthly | mg/L | < 0.1 | ND |
| 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 <i>t</i>) ³ | Quarterly | N/A | ≤ 2.78 | 2.0 |
| Inhibitory Residue ⁴ | Annually | N/A | < 15% | - 4% |
| Maximum Silicate, SiO ₂ ^{3,4} | Annually | mg/L | ≤ 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.

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