California Facility Purified Water Specification Testing Results

For the month of: August 2017 (17213-17243)

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	18.37
pH**	Daily	N/A	5.5 – 7.5	7.23
Total Organic Carbon[1,3,5]	Monthly	ug/L	<500	112
Heavy Metals (Single)[1,3,4] (Cd, Cr, Cu, Ni, Pb and Zn)	Annually	mg/L	< 0.05	Cd – ND Cr – ND Cu – ND Pb – 0.00011 Ni –ND Zn – 0.00073
Heavy Metals (Total)[3,4]	Annually	mg/L	< 0.1	0.00084
Ammonia/OrganicNitrogen[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	<1.0
Water Quality[3,4] ratio	Annually	ratio	0.8 – 3.0	1.0
Use Test (Student *t*)[3]	Quarterly	N/A	≤ 2.78	< 2.78
Inhibitory Residue[4]	Annually	N/A	< 15%	4.6%
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 at the water source.
**Testing data is given as a monthly average.
***Testing data is given as an average.

References:

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

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

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

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

5. USP. *USP NF, Water for Pharmaceutical Purposes <1231>.* Rockville, MD: US Pharmacopeial Convention.

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