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Quantitative Interpretations of USP & EP Limit Tests for Purified Water

USP Limit Tests

Species	Testing Methodology	Quantitative Interpretation	Justification
Calcium	no turbidity with Ammonium Oxalate	< 0.5 ppm	Osmonics <i>Pure Water Handbook</i> ; testing methodology unchanged from <i>USP XXII</i> to <i>USP 24</i>
Sulfate	no turbidity with Barium Chloride	< 0.5 ppm	Osmonics <i>Pure Water Handbook</i> ; testing methodology unchanged from <i>USP XXII</i> to <i>USP 24</i>

EP Limit Tests

Species	Testing Methodology	Quantitative Interpretation	Justification
Chloride	no turbidity with Silver Nitrate	< 0.5 ppm	Same basic chemistry as in <i>USP XXII</i> limit test; see <i>Osmonics Pure Water Handbook</i>
Sulfate	no turbidity with Barium Chloride	< 0.5 ppm	Essentially the same as USP limit test
Calcium and Magnesium	100 mL sample → pure blue with Ammonium Chloride buffer, Eriochrome Black T, and 0.5 mL of 0.01 M EDTA	< 0.62 ppm Ca; < 1.03 ppm Mg	Calculated based on 1:1 reaction with amount of EDTA added. Each limit calculated assuming the other species to be absent.

References

United States Pharmacopeia 24, 1999 (Official from January 1, 2000), pp. 1753-1754.

United States Pharmacopeia XXII, 1989 (Official from January 1, 1990), p. 1457.

Osmonics Pure Water Handbook, 1991, pp. 102-103.

European Pharmacopoeia, 3rd Edition, 1996 (Effective 1 January 1997), pp. 1723-1724.