Topic: Colilert[®], Colilert[®]-18 and Colisure[®] are acceptable for use in

testing water for Pharmaceutical purposes

Source: *United States Pharmacopeia*, 32nd Edition

The National Formulary, 27th Edition

Non-US Monographs, v 1.0 March 1, 2009

Authors: The United States Pharmacopeial Convention, Rockville, MD

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Highlights:

- Colilert, Colilert-18 and Colisure are acceptable methods for testing source water in preparation for pharmaceutical purposes, including, but not limited to, use in preparing: Water for Special Pharmaceutical Purposes, Water for Hemodialysis, Purified Water and Water for Injection (pages 742-747)
- Section 1231, on page 741 of the <u>USP text</u>, states that "...water used in the production of drug substances or as source or feed water for the preparation of the various types of purified waters must meet the requirements of the National Primary Drinking Water Regulations (NPDWR) (40 CFR 141) issued by the U. S. Environmental Protection Agency (EPA) or the drinking water regulations of the European Union of Japan, or the WHO drinking water guidelines."

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