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## Pure Steam

[NOTE—For microbiological guidance, see general information chapter [Water for Pharmaceutical Purposes \(1231\)](#).]

H<sub>2</sub>O            18.02

### DEFINITION

Pure Steam is water that has been heated above 100° and vaporized in a manner that prevents source water entrainment. It is prepared from water complying with the EPA National Primary Drinking Water Regulations, or with drinking water regulations of the European Union or of Japan, or with WHO drinking water guidelines. It contains no added substance. The level of steam saturation or dryness and the amount of noncondensable gases are to be determined by the Pure Steam application.

[NOTE—Pure Steam is intended for use where the steam or its condensate comes in contact with the article or the preparation. Pure Steam quality is difficult to assess in its vapor state; therefore, the attributes of its condensate are used to test its quality. The process used to create and collect the condensate for analysis must not adversely impact these quality attributes.]

### SPECIFIC TESTS

- [TOTAL ORGANIC CARBON \(643\)](#): The condensate meets the requirement.
- [WATER CONDUCTIVITY, Bulk Water \(645\)](#): The condensate meets the requirement.
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): The condensate contains less than 0.25 USP Endotoxin Unit/mL when used in the production of parenterals.

### ADDITIONAL REQUIREMENTS

*Delete the following:*

▲. [USP REFERENCE STANDARDS \(11\)](#)

[USP 1,4-Benzoinone RS](#)▲ (ERR 1-Nov-2018)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PURE STEAM	<a href="#">Antonio Hernandez-Cardoso</a> Senior Scientific Liaison	GCCA2020 General Chapters - Chemical Analysis 2020
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	GCCA2020 General Chapters - Chemical Analysis 2020

**Chromatographic Database Information:** [Chromatographic Database](#)

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