WFI & Purified Water — specification reference 2026

Every limit below is quoted from the governing text named against it. Pharmacopoeial monographs and Indian statutory instruments are revised frequently — verify against the current official edition before using this in a specification, protocol or filing.

1. Quality attributes

Attribute	Water for Injection	Purified Water	Governing text
Conductivity	1.3 µS/cm at 25 °C (Stage 1)	1.3 µS/cm at 25 °C (Stage 1)	USP <645>, three-stage procedure
Total organic carbon	NMT 500 µg C/L	NMT 500 µg C/L	USP <643>
Bacterial endotoxins	NMT 0.25 USP EU/mL	No requirement	USP <85> (LAL) or <86> (recombinant)
Microbial action level	10 cfu / 100 mL	100 cfu / mL	USP <1231> — **informational**, not a specification
Production route	Distillation, or a process equivalent or superior to distillation in removing chemicals and microorganisms	Any validated route from potable feed water	USP Water for Injection monograph
Feed water	Potable water, continuous positive pressure, meeting EPA Primary Drinking Water Regulations (40 CFR 141)	Same	21 CFR 211.48 Plumbing

The action levels are not pass/fail limits

FDA, *Guide to Inspections of High Purity Water Systems (7/93)*: “None of the limits for water are pass/fail limits. All limits are action limits.” Exceeding one obliges an investigation and an impact assessment on every batch made since the last conforming result. USP places the microbial figures in the *informational* chapter <1231> and expects you to set in-house levels from your own system history.

2. What changes by market

Market	Instruments that apply	Live change to plan for
United States	USP monographs (enforceable via FD&C Act); USP <645>, <643>, <85>/<86>; 21 CFR 211.48, 211.113, 211.180; FDA 7/93 inspection guide	USP <86> (recombinant reagents) official since May 2025 — an addition to <85>, not a replacement
EU and UK	Ph. Eur. monographs 0169 (WFI) and 0008 (Purified Water); EMA guideline EMA/CHMP/CVMP/QWP/496873/2018, effective 1 Feb 2021	**Ph. Eur. 12.3 in force 1 July 2026:** oxidisable substances replaced by TOC at 0.50 mg/L; conductivity text clarified; method 2.2.44 revised
India	Indian Pharmacopoeia monographs; revised Schedule M notified by G.S.R. 922(E), 28 Dec 2023	Extension under G.S.R. 127(E) of 11 Feb 2025 expired 31 Dec 2025. Revised Schedule M applies to **all** manufacturers from 1 Jan 2026
WHO-GMP export	WHO TRS 1033, Annex 3 (2021)	Supersedes TRS 970 Annex 2 (2011). Any SOP citing TRS 970 for water is out of date

3. Qualification — the three-phase approach

Durations are as stated in WHO TRS 1033, Annex 3, section 11.3. Phases 1 and 2 are measured in **weeks**, not quarters — a point many SOPs get wrong.

Phase	Duration	What you are proving	Water release
Phase 1	**At least 2 weeks**	Intensive sampling at every point of use each working day. Establish operating ranges, prove SOPs and sanitisation, set provisional alert levels.	Not for manufacturing use
Phase 2	**At least a further 2 weeks**	Same intensive sampling, now under the routine SOPs written from Phase 1. Confirm consistent operation.	May be used, on a documented risk basis
Phase 3	**Balance of at least 12 months total**	Reduced routine frequency across a full year so seasonal variation in feed water and ambient temperature is captured.	Routine production use

4. Figures that circulate widely and do not survive a source check

Commonly stated	What the source actually says
Minimum loop velocity 0.7 m/s	No pharmacopoeia or regulator states a velocity. WHO TRS 1033 §8.6 asks for turbulent flow, “evidenced by, for example, a Reynolds number of > 4000”. Hot loops clear that threshold far below 0.7 m/s.
FDA requires dead legs ≤ 6D	The 7/93 guide reports that the *proposed* LVP Regulations defined dead legs as not exceeding six diameters. Those regulations were never finalised. 6D was never an FDA requirement.
WHO TRS 970 sets 3D	TRS 970 Annex 2 was superseded in 2021. The current text, TRS 1033 Annex 3, sets **no L/D ratio** — it requires dead legs to be minimised, measured and calculated.
Records retained 10 years (21 CFR 211.180)	211.180(a) requires retention “at least 1 year after the expiration date of the batch”, or 3 years after distribution for OTC products exempt from expiry dating under 211.137. Ten years is an EU-derived figure.
Ozone sanitisation at 3–5 ppm	Storage-tank residual dissolved ozone in more than 95% of installed systems sits between **0.02 and 0.2 mg/L**. A 3–5 ppm setpoint is one to two orders of magnitude high.
PQ Phase 1 = months 1–3, Phase 2 = months 4–9	WHO §11.3: Phase 1 at least two weeks, Phase 2 at least a further two weeks, all three phases together covering at least 12 months.
USP <1231> is a mandatory reference	USP general chapters numbered above 1000 are informational. USP states the microbial guidance sits in the informational chapter and that the user establishes in-house fitness-for-use levels.
USP <2> is General Notices	USP <2> is *Oral Drug Products — Product Quality Tests*. The General Notices are not a numbered general chapter.
WFI must be free of Pseudomonas, coliforms, E. coli	The USP water monographs contain no absence-of-specified-organisms test. Objectionable organism control is a risk-based cGMP obligation under 21 CFR 211.113, judged against product and route of administration.
Polished piping means Ra ≤ 0.6 µm	ASME BPE designates finishes explicitly: SF1 at 0.51 µm mechanically polished, SF4 at 0.38 µm electropolished. Specify the SF designation on the drawing, not a loose Ra figure.

Sources
FDA *High Purity Water System (7/93)* inspection guide · USP–NF Water for Injection monograph and USP FAQ on water for pharmaceutical and analytical purposes · WHO TRS 1033 Annex 3 (2021) · 21 CFR 211.48, 211.113, 211.180 (eCFR) · EMA/CHMP/CVMP/QWP/496873/2018 · Ph. Eur. Supplement 12.3 · G.S.R. 922(E) 28.12.2023 and G.S.R. 127(E) 11.02.2025 · ASME BPE surface finish designations · ISPE Baseline Guide Vol 4, 3rd ed. 2019. Full reference list with links at laafon.com.