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TECHNICAL PAPER

WFI BEYOND · MONOCLONAL ANTIBODIES

BEYOND COMPENDIAL: WFI BEYOND FOR MONOCLONAL ANTIBODIES

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4 Aug 2026
Why your Water for Injection sets the quality standard for antibody manufacturing.

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Why your Water for Injection sets the quality standard for antibody manufacturing.

Prepared by **PAN-Biotech** · Author: **Jens Hartmann, President & CEO, PAN-Biotech**
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Key takeaways

- Water for Injection touches almost every step of an antibody process – the base of nearly every buffer and the vehicle for the final formulation – so its quality is distributed across the whole workflow.
- For antibodies, trace / elemental impurities (iron, copper) are the specific stability risk: they catalyse oxidation and drive aggregation, and conductivity alone does not capture them.
- WFI Beyond goes beyond the monograph where it matters: endotoxin < 0.005 EU/mL (~50x below the limit), TOC < 0.15 mg/L (more than 3x below), nucleases not detected, and 24 elements controlled by ICP-MS to ICH Q3D.
- A filed FDA Type IV Drug Master File (MF044505) lets you reference PAN-CellTech's confidential data in your own submission through a letter of authorisation.
- Sterile, single-use, pre-sterilised (e.g. gamma-irradiated) formats from 500 mL and 1000 mL bottles to bags of 1 to 1000 litres; a two-year shelf life at +15 to +25 °C.

In brief

Water for Injection is the most underestimated raw material in antibody manufacturing – the base of nearly every buffer and the vehicle for the final formulation. Its quality cascades into the whole process: if the water is the weak point, so is the antibody. WFI Beyond is built to go beyond the compendial monograph on exactly the attributes that decide antibody stability – with the elemental impurities that drive aggregation certified on the Certificate of Analysis and a filed FDA Drug Master File behind it.

1. Founded on water

In 1988, in the village of Aidenbach in Lower Bavaria, PAN-Biotech was founded for one simple reason: the water. For the thirty-eight years since, that water has been the quiet foundation of PAN-Biotech's cell-culture media – the products that made the company's name with biologics developers worldwide. PAN-CellTech carries that same foundation forward into GMP: regulated, clinical-grade manufacturing for the companies building today's antibodies.

2. The input every antibody process takes for granted

Water for Injection is everywhere and noticed nowhere. It is the base of almost every buffer and the vehicle for the final formulation, so no other single input touches so many stages of an antibody process. That ubiquity is exactly why it is dangerous to underestimate: because the water flows into nearly every step, its quality is distributed across the entire process, and small deficiencies compound into aggregation, instability and lost yield.

3. What actually threatens your antibody

„Meets WFI" tells you a water cleared the compendial floor; it does not tell you whether it was made for your molecule. The monograph was written for injectable water in general – not for the specific vulnerabilities of a monoclonal antibody. Four attributes decide the outcome, and for antibodies the order matters:

- **Trace / elemental impurities – the antibody-specific lead.** Iron, copper and other ions catalyse oxidation and drive aggregation – a direct threat to antibody stability and shelf life that conductivity alone does not capture. It is the attribute most specific to antibodies, and the one most often overlooked.
- **Endotoxin.** Pyrogenic and a direct patient-safety concern. The compendial limit (0.25 EU/mL) is a ceiling not to be exceeded – but for a biologic the goal is to sit as far below it as possible, not merely to clear it.
- **Nucleases.** Residual RNase and DNase are a quiet source of variability for analytical work and downstream processing.
- **Organic carbon (TOC).** A general marker of purity: the lower the organic load, the fewer unknowns introduced into a sensitive process.

4. The WFI Beyond standard

WFI Beyond is built to go beyond the monograph on exactly these attributes. „Beyond compendial" is not a slogan; it is a measured fact, certified lot by lot on the Certificate of Analysis.

ATTRIBUTE	WFI BEYOND	WHY IT MATTERS FOR ANTIBODIES
Elemental impurities	24 elements by ICP-MS, controlled to ICH Q3D	Limits metal-catalysed oxidation and aggregation – the antibody-specific stability risk
Endotoxin	< 0.005 EU/mL (~50x below the 0.25 limit)	Minimises pyrogenic risk far beyond the monograph floor
Total organic carbon	< 0.15 mg/L (more than 3x below the 0.5 limit)	Exceptional organic purity; fewer unknowns in a sensitive process
Nuclease activity	RNase & DNase not detected (fluorometric)	Protects analytics and downstream work

ATTRIBUTE	WFI BEYOND	WHY IT MATTERS FOR ANTIBODIES
Sterility	Sterile – single-use, pre-sterilised (e.g. gamma-irradiated)	Ready to use; removes a contamination entry point
Animal origin	Animal-component-free; TSE/BSE statement	Closes a regulatory and safety question across the chain
Regulatory support	Filed FDA Type IV DMF (MF044505)	Reference our confidential data in your submission via a letter of authorisation

> **Made and assured under GMP.** WFI Beyond is manufactured by PAN-CellTech under EU GMP Annex 1 within an ISO 9001 quality system, with aseptic filling validated by routine media fills performed twice a year. A dedicated ICH-format stability study supports a two-year shelf life at +15 to +25 °C – part of the assurance the product carries from delivery through use.

5. From source to single-use bag

A premium source is the beginning of the story, not the end of it. WFI quality is ultimately made by purification and control, then proven by testing and documentation. Every lot is characterised against the attribute panel above and supplied with a Certificate of Analysis. Under GMP, that documentation is not paperwork around the product – it is part of the product. WFI Beyond is available sterile-filtered and in single-use, pre-sterilised (e.g. gamma-irradiated) formats from 500 mL and 1000 mL bottles to bags from 1 to 1000 litres; the single-use film is qualified and screened for extractables – DEHP and other phthalates, Bisphenol A, dioxin and melamine were not identified – so a contamination and leachables entry point is removed at your end.

The regulatory keystone. Of everything in that package, the Drug Master File does the most work. WFI Beyond is backed by a Drug Master File filed with the US FDA (MF044505); PAN-CellTech also holds a filed DPBS DMF (MF044371). A DMF on file lets you reference our confidential manufacturing and quality data directly in your own regulatory submission – through a simple letter of authorisation – so the authority can rely on it in full without your team ever obtaining, holding or recreating it. A DMF on file is open for reference; the FDA reviews its contents only when a customer references it in an application.

6. Conclusion

Water is the input every antibody process takes for granted and the one whose quality reaches furthest. For a monoclonal antibody, the attributes that distinguish a premium WFI – low elemental impurities, ultra-low endotoxin, nuclease-free – are not a refinement; they protect stability, yield and the final product. WFI Beyond is water made for your molecule.

FAQ 1

What makes WFI Beyond different for a monoclonal antibody?

It goes beyond the compendial monograph on the attributes that decide antibody stability: the trace / elemental impurities that catalyse oxidation and aggregation are controlled by ICP-MS to ICH Q3D and certified on the Certificate of Analysis, endotoxin and TOC sit far below the monograph limits, and RNase / DNase are not detected.

FAQ 2

How far below the endotoxin limit is WFI Beyond?

Endotoxin is specified at less than 0.005 EU/mL – about 50x below the compendial limit of 0.25 EU/mL – so pyrogenic risk sits far beneath the monograph floor.

FAQ 3

Is WFI Beyond backed by a Drug Master File?

Yes. WFI Beyond is backed by a Type IV Drug Master File filed with the US FDA (MF044505); PAN-CellTech also holds a filed DPBS DMF (MF044371). A DMF on file lets you reference the confidential manufacturing and quality data in your own submission through a letter of authorisation.

FAQ 4

Which formats and pack sizes are available?

WFI Beyond is supplied sterile-filtered and in single-use, pre-sterilised (e.g. gamma-irradiated) formats – from 500 mL and 1000 mL bottles to bags from 1 to 1000 litres. The single-use film is qualified and screened for extractables (DEHP and other phthalates, Bisphenol A, dioxin and melamine were not identified).

FAQ 5

Is WFI Beyond animal-free, and what is the shelf life?

It is animal-component-free and supplied with a TSE/BSE statement. A dedicated ICH-format stability study supports a two-year shelf life at +15 to +25 °C. It is manufactured by PAN-CellTech under EU GMP Annex 1 within an ISO 9001 quality system.

Request the specification and Certificate of Analysis

To request the WFI Beyond specification and Certificate of Analysis, or to discuss a qualified water supply for your antibody programme, get in touch.

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