BSE/TSE, ICHQ3 Declaration

WFI Beyond, Water for Injection, acc. to EP monograph 0169 and beyond compendial

Product	Article Number
WFI Beyond, Water for Injection, acc. to EP monograph 0169 and beyond compendial (bottles)	CT-981500 CT-981000

Aim of Statement:

This statement gives an overview of a potential influence during manufacture and filling of the following aspects on the respective buffer / product:

- Residual solvents according to ICH Q3
- Elemental impurities ICH Q3
- Nitrosamine EMA
- Impurities ICH Q3
- TSE/BSE

The following tables (Table 1and Table 2) contain all raw material, solutions and equipment contacting the product directly.

PAN Celltech GmbH – Am Gewerbepark 6 – 94501 Aidenbach – GERMANY
www.pan-biotech.com – phone +49-8543-601630 – fax +49-8543-601649

Table 1: List of used raw materials and solutions with direct contact to the product.

Raw materials	Material	Comment	Impurities[1)]	Residual solvent[2)]	Elemantal impurities[3)]	Nitrosamines[4)]
water for injection (WFI)	Produced on site	N/A	ok	ok	ok	ok
Solutions						
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 2: List of used manufacturing equipment with direct contact to the product.

Manufacturing equipment	Material	Comment	Impurities[1)]	Residual solvent[2)]	Elemantal impurities[3)]	Nitrosamines[4)]
Tubing weight	Stainless steel	dedicated equipment	ok	ok	ok	ok
Tank liner	Low density Polyethylene (LDPE)	single use	no information	no information	no information; parameter tested upon product release	no information
Braided platinum cured silicone tubing	Silicone, platinum	single use	ok	no information	no information; parameter tested upon product release	no information
Bottle PET	PET (bottle) HDPE (screw-cap)	single use	no information; bottles are tested against USP Class VI, USP 37 <661> and ISO 10993-3 demonstrating biological compatibility	no information; according to manufacturer if residual solvents are to be found the concentration is expected to be below the limits given in the ICH guidelines	no information; parameter tested upon product release	no information; according to manufacturer no nitrosamines are present in the raw materials.

PAN Celltech GmbH – Am Gewerbepark 6 – 94501 Aidenbach – GERMANY
www.pan-biotech.com – phone +49-8543-601630 – fax +49-8543-601649

Manufacturing equipment	Material	Comment	Impurities[1)]	Residual solvent[2)]	Elemantal impurities[3)]	Nitrosamines[4)]
Seal (Ti-clamp connection)	Platin cured silicon	single use	no information; seals are produced according to ASME-BPE and comply to USP level VI tested against USP Class VI	no information	no information; parameter tested upon product release;	no information
Bio Barb Sanitary (Adapter Tri-clamp)	Polypropylene (PP)	single use	no information	no information	parameter tested upon product release	ok
Glas faucet	Glas, Type III	single use	no information	no information	no information; parameter tested upon product release	no information
Filter (ZESGA-010TT-PN3)	Polyethersulfone (PES) Polyester (PET) Polypropylene (PP) Nylon Silicone Polycarbonate (PC)	single use	ok	ok	ok	ok

PAN Celltech GmbH – Am Gewerbepark 6 – 94501 Aidenbach – GERMANY
www.pan-biotech.com – phone +49-8543-601630 – fax +49-8543-601649

Manufacturing equipment	Material	Comment	Impurities[1)]	Residual solvent[2)]	Elemantal impurities[3)]	Nitrosamines[4)]
Prefilter (ZESGA-020TT-PN3)	Polyethersulfone (PES) Polyester (PET) Polypropylene (PP) Nylon Silicone Polycarbonate (PC)	single use	ok	ok	ok	ok

1) ok = no known impurities concerning the filled product

2) ok = no residual solvents or below ICH limit

3) ok = no elemental impurities or below ICH limit

4) ok= contains no nitrosamine /nitrite/amine

PAN Celltech GmbH – Am Gewerbepark 6 – 94501 Aidenbach – GERMANY
www.pan-biotech.com – phone +49-8543-601630 – fax +49-8543-601649

TSE/BSE:
The product is manufactured using exclusively raw materials of non-animal origin and does not come in contact with material of animal origin during manufacture and processing based on the supplier declaration that are available on file in our QC System. As a result, we can certify that these products are not in scope of the note for guidance EMA/410/01 Rev. 3 of the EC regarding TSE/BSE risk assessment.

ICH Q3D:
Elemental impurities of the Raw material and the manufacturing equipment are controlled on a risk-based approach in accordance with ICH Q3D. The final product is tested according to Ph. Eur. 2.4.20., procedure 2 (ICP-MS, validated method, 24 elements) against the limits given in ICHQ3D.

To the best of our knowledge, the information contained in this certificate is true and accurate as of the date published. The information contained in this statement is confidential and for informational purpose only. The content of this document contains general information and may not reflect current legal or regulatory developments or information. The information is not guaranteed to be correct, complete or current. PAN makes no warranty, expressed or implied, about the accuracy or reliability of the information.

PAN Celltech GmbH – Am Gewerbepark 6 – 94501 Aidenbach – GERMANY
www.pan-biotech.com – phone +49-8543-601630 – fax +49-8543-601649

	Function	Signature, Date
Created by	Quality Assurance	30. OKT. 2026
Reviewed by	Quality Assurance	30. OKT. 2026
Released by	Quality Assurance	30. OKT. 2026

Änderungshistorie / *Change history*:

Version	Date	Change Reason	Change content
00	21.07.2026	Ersterstellung / *First Version*	n.a.
01	30.10.2026	Update	Correction of prefilter number and material Editorial changes

PAN Celltech GmbH – Am Gewerbepark 6 – 94501 Aidenbach – GERMANY
www.pan-biotech.com – phone +49-8543-601630 – fax +49-8543-601649