PAN BIOTECH

PAN CELLTECH

FACTSHEET
PROCESS GUIDE

MONOCLONAL ANTIBODY

ONE FOUNDATION FOR THE WHOLE ANTIBODY PROCESS

One partner, from research to GMP
Cell bank to drug substance, under one roof.

RESEARCH TODAY - GMP TOMORROW

BIOSOLUTIONS BY PAN

/ MEDIA / REAGENTS / SERUM / BUFFER

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info@pan-biotech.de

PAN BIOTECH™

RUO TODAY

UPSTREAM · USP

LIQUID CELL CULTURE SOLUTIONS FOR RESEARCH & INDUSTRY

Serum-free media for every antibody platform
Hybridoma, CHO and HEK293.

RUO TO GMP – NO REFORMULATION.

Steps S 1 – S 5: Products for every step – cell bank to harvest.

Scan for the full cell culture range

CERTIFIED ISO 9001:2015 COMPANY

MEDICAL DEVICES QUALITY MANAGEMENT ISO ISO 13485:2016

GOOD MANUFACTURING PRACTICE GMP

GATEWAY TO EUROPE

TOP CONTRACT MANUFACTURING ORGANIZATIONS IN EUROPE PAN-Biotech GmbH

UPSTREAM · USP

FROM CELL BANK TO SEED TRAIN

Serum-free media, feeds and supplements for every antibody platform - the same product from bench to clinic, RUO to GMP, with no reformulation.

Steps S 1 - S 5
Products for every step - cell bank to harvest.

S 1
Cell bank & thaw

S 2
Screening & selection

S 3
Expansion & seed train

S 4
Bioreactor production

S 5
Harvest & clarification

S 1 Cell Bank Management & Thaw / Cryorecovery — 7 Products

Thaw the master/working cell bank and recover viable cells. Cryomedia (Cryopan II with DMSO or DMSO-free III), DPBS & WFI for DMSO removal and washing, plus antibiotics for a clean, high-viability start.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
WFI Quality Water	CT-991500	Penicillin-Streptomycin	P06-07100 / CT-07110
DPBS w/o Ca & Mg	P04-36500 / CT-36500	L-Glutamine 200 mM	P04-80100 / CT-80100
Cryopan II (with DMSO)	P07-93100 / CT-94100	RNase/DNase Neutralizer	P10-61500
Cryopan III (DMSO-free)	P07-96100 / CT-96100		

S 2 Screening & Selection — 8 Products

Expand and select the high-producing clones. Classic base media (DMEM, RPMI), HAT/HT selection supplements for hybridomas and Accutase for gentle passaging.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
DMEM, stable Gln	P04-04500 / CT-04500	Penicillin-Streptomycin	P06-07100 / CT-07110
RPMI 1640, stable Gln	P04-18500 / CT-18500	Accutase	P10-21500
HAT Supplement 50×	P07-02100 / CT-02100	DPBS w/o Ca & Mg	P04-36500 / CT-36500
HT Supplement 50×	P07-01100 / CT-03100	WFI Quality Water	CT-991500

S 3 Cell Expansion & Seed Train - choose your platform

HYBRIDOMA

HybridBoost

SERUM-FREE
P04-995910 / CT-995905

Stable Gln + insulin + surfactant built in; 3x titre vs. FBS.

CHO

PANcell CHO Feed Kit

SERUM-FREE
P04-71102K

Chemically defined fed-batch; feed + boost.

HEK293

Panserin 293S / 293A

SERUM-FREE
P04-710609 / P04-710608

Suspension & adherent; DMEM/F12 base.

S 3 Seed-train supplements, feeds & utilities — 7 Products

Whatever platform you picked, the seed train runs on the same qualified supplements. Glutamine, ITS, Pluronic and pH/osmo utilities build biomass from shake flask to bioreactor inoculum - fewer SKUs to qualify.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
L-Glutamine 200 mM	P04-80100 / CT-80100	Sodium Bicarbonate 7.5 %	P04-44100
Stable Glutamine 200 mM (100×)	P04-82100 / CT-82100	DPBS w/o Ca & Mg	P04-36500 / CT-36500
ITS solution I (100×)	P07-03100 / CT-03110	WFI Quality Water	CT-991500
Pluronic F-68 10 %	P08-02100 / CT-02110		

PRODUCTION & HARVEST

Fed-batch or perfusion production, then separation of the mAb-containing supernatant from cells and debris.

S 4 Bioreactor Production (fed-batch / perfusion) — 13 Products

Fed-batch or perfusion production of the antibody. Production media (PANcell CHO / HybridBoost) plus glucose and glutamine feeds, ITS, Pluronic and pH/osmolality supplements to drive titre and viability up to 1,000 L.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
PANcell CHO Feed Kit	P04-71102K	MEM NEAA (100×)	P08-32100 / CT-32100
HybridBoost	P04-995910 / CT-995905	Insulin human recomb.	P07-04300
L-Glutamine 200 mM	P04-80100 / CT-80100	Sodium pyruvate 100 mM	P04-43100 / CT-43100
Glucose 20 %	CT-00331	WFI Quality Water	CT-991500
Pluronic F-68 10 %	P08-02100 / CT-02110	Stable Glutamine 200 mM (100×)	P04-82100 / CT-82100
Sodium Bicarbonate 7.5 %	P04-44100	ITS solution I (100x)	P07-03100 / CT-03110
HEPES 1 M	P05-01100 / CT-01100		

S 5 Harvest & Clarification — 6 Products

Separate the mAb-containing supernatant from cells and debris. Isotonic DPBS / saline and WFI for membrane pre-wetting, flushing and equilibration; RNase/DNase neutralizer for decontamination.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
DPBS w/o Ca & Mg	P04-36500 / CT-36500	Sodium Chloride 0.9 %	P05-39500 / CT-39500
WFI Quality Water	CT-991500	Accutase	P10-21500
DPBS 10x w/o Ca & Mg	P04-53500 / CT-53500	RNase/DNase Neutralizer	P10-61500

PAN CELLTECH™

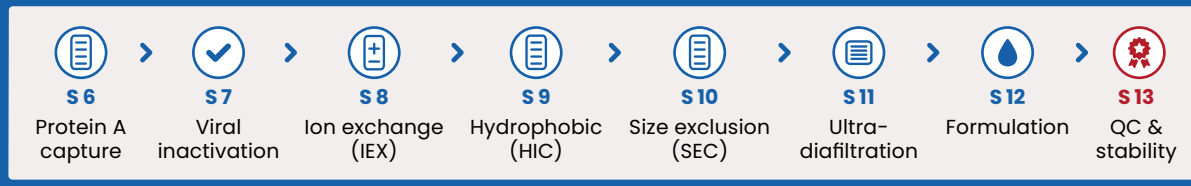
GMP TOMORROW

DOWNSTREAM · DSP

LIQUID PROCESS SOLUTIONS FOR BIOTECH & PHARMA

Buffers, Water for Injection & ready-to-use bundles.
From purification to formulation.

ONE QUALIFIED SUPPLIER - FROM BENCH TO CLINIC.



Steps S 6 - S 12: The harvest to a formulated drug substance.
Step 13 (QC & stability) is quality control, not a DSP step.

FDA REGISTERED · DMF BACKED · GMP GRADE · MADE IN GERMANY · Save our PLANET future-ready: solutions by PAN

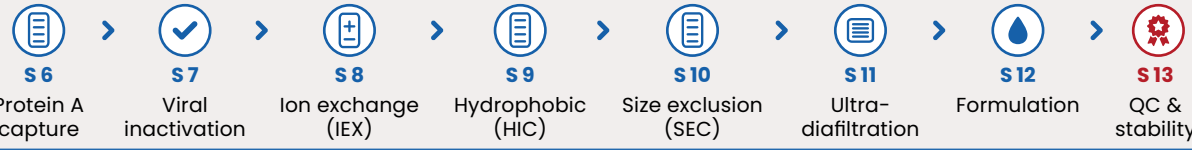
Scan for the full downstream range

DOWNSTREAM · DSP

FROM CAPTURE TO DRUG SUBSTANCE

Process buffers, universal stock solutions and Water for Injection - complete, documented and ready-to-use. Custom GMP at any step, no reformulation.

Steps S 6 - S 12
The harvest to a formulated drug substance.



S 6 Protein A Capture (affinity) — 7 Products

First purification step - Protein A affinity captures the antibody from the clarified harvest. Equilibration, low-pH elution (citrate or glycine) and Tris neutralisation, all built from universal stocks with WFI.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
NaCl 5 M	CT-77055	WFI Quality Water	CT-991500
Tris 1 M, pH 8.4	CT-05500	Sodium Chloride 0.9 %, GMP grade	CT-39500
Citrate 100 mM, pH 3.0	CT-62500	Ethanol 20 %	CT-89500
Glycine 100 mM, pH 3.0	CT-69500		

S 7 Viral Inactivation (low-pH hold) — 4 Products

Mandatory low-pH hold (ICH Q5A) to inactivate enveloped viruses. Citrate to acidify, Tris to re-neutralise; Triton X-100 as a solvent/detergent alternative.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
Citrate 100 mM, pH 3.0	CT-62500	WFI Quality Water	CT-991500
Tris 1 M, pH 8.4	CT-05500	Triton X-100 10 %	CT-01001

S 8 Ion Exchange (IEX: CEX + AEX) — 6 Products

Polishing by charge (CEX + AEX) to remove host-cell proteins, DNA and aggregates. Acetate, Tris and phosphate buffer bases with NaCl gradients; NaOH for column cleaning (CIP).

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
Sodium acetate 100 mM	CT-76451	Phosphate 100 mM	CT-18810 / CT-18850
NaCl 5 M	CT-77055	NaOH 1 M	CT-55105
Tris 1 M, pH 8.4	CT-05500	WFI Quality Water	CT-991500

S 9 Hydrophobic Interaction (HIC) - optional — 6 Products

Optional hydrophobic-interaction polishing for aggregate removal and bispecific mispair separation. Ammonium sulfate for high-salt binding, phosphate / Tris running buffers.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
Ammonium Sulfate 1 M	CT-67500	Tris 1 M, pH 8.4	CT-05500
Ammonium Sulfate 3 M	CT-68500	NaCl 5 M	CT-77055
Phosphate 100 mM	CT-18810 / CT-18850	WFI Quality Water	CT-991500

WFI Beyond - the water underneath

WFI Beyond (Article No. CT-981500) is Water for Injection engineered beyond Ph. Eur. monograph 0169 and backed by its **own filed FDA Drug Master File (MF044505).**

Endotoxin < 0.005 EU/mL	TOC < 0.05 mg/L	Conductivity < 0.2 µS/cm	Nuclease-free
> 50 x below monograph limit	> 10 x below monograph limit	> 5 x below monograph limit	RNase & DNase not detected

On request, every buffer on this page is available in a beyond-compendial version produced with WFI Beyond instead of standard WFI.

S 10 Size Exclusion (SEC) - polishing — 6 Products

Size-based polishing to separate monomer from aggregates and fragments.
Ready-to-use PBS or histidine/phosphate running buffers, ionic strength set with NaCl.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
DPBS w/o Ca & Mg	CT-36500	NaCl 5 M	CT-77055
Histidine 100 mM	CT-69510	DPBS 10x w/o Ca & Mg	CT-53500
Phosphate 100 mM	CT-18810 / CT-18850	WFI Quality Water	CT-991500

S 11 Ultrafiltration / Diafiltration (UF/DF) — 9 Products

Concentrate to the target dose and exchange into the formulation buffer. Histidine, acetate or phosphate diafiltration buffers plus stabilisers (sucrose, trehalose) and surfactants (PS20 / PS80).

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
Histidine 100 mM	CT-69510	Polysorbate 20 (PS20) 1 %	CT-00211
Sodium acetate 100 mM	CT-76451	Polysorbate 80 (PS80) 1 %	CT-00311
Phosphate 100 mM	CT-18810 / CT-18850	DPBS w/o Ca & Mg, GMP grade	CT-36500
Sucrose 30 %	CT-00131	WFI Quality Water	CT-991500
Trehalose 30 %	CT-00231		

S 12 Drug Substance Formulation & Final Bulk/DF — 13 Products

Set the final concentration and composition of the drug substance. Formulation buffer, tonicity (NaCl), cryoprotectants, surfactants and excipients (EDTA, L-arginine, mannitol).

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
Histidine 100 mM	CT-69510	Sodium acetate 100 mM	CT-76451
Sucrose 30 %	CT-00131	DPBS w/o Ca & Mg, GMP grade	CT-36500
Trehalose 30 %	CT-00231	WFI Quality Water	CT-991500
Polysorbate 20 (PS20) 1 %	CT-00211	EDTA 0.5 M, pH 8.0	CT-10500
Polysorbate 80 (PS80) 1 %	CT-00311	L-Arginine 1 M, pH 7.0	CT-69520
NaCl 5 M	CT-77055	Mannitol 10 % (w/v)	CT-00401
Phosphate 100 mM	CT-18810 / CT-18850		

S 13 Quality Control & Stability — SERVICES

Release testing and ICH-compliant stability: not a supply step, but we support it: CoA per lot, validated stability studies and DMF-backed regulatory support.

QC analytics: endotoxin (LAL), bioburden & sterility, pH, osmolality, conductivity, appearance, Raman identity, RNase/DNase analysis.

Stability studies: ICH Q1A, on request.

Regulatory support: FDA Type IV DMF, Letter of Authorization.

PROCESS-STEP MATRIX

EVERY MAB PRODUCT – MAPPED TO EVERY PROCESS STEP

A small set of universal stock solutions recurs across step after step. ● = **product** used in this process step.
Red = upstream (S1 - S5), blue = downstream (S6 - S12). QC/stability (S13) is release testing, not a supply step.

PRODUCT	ARTICLE NO.	S1 Thaw	S2 Screen	S3 Seed train	S4 Reac-tor	S5 Har-vest	S6 Pro-tein A	S7 Viral inact.	S8 IEX	S9 HIC	S10 SEC	S11 UF/DF	S12 For-mul.	STEPS
WFI Quality Water	CT-991500	●	●	●	●	●	●	●	●	●	●	●	●	12
WFI Beyond	CT-981500	●	●	●	●	●	●	●	●	●	●	●	●	12
DPBS w/o Ca & Mg	P04-36500 / CT-36500	●	●	●		●					●	●	●	7
DPBS 10× w/o Ca & Mg	P04-53500 / CT-53500					●					●			2
Sodium Chloride 0.9 %	P05-39500 / CT-39500					●	●							2
Cryopan II, with DMSO	P07-93100 / CT-94100	●												1
Cryopan III, DMSO-free	P07-96100 / CT-96100	●												1
Penicillin-Streptomycin	P06-07100 / CT-07110	●	●											2
L-Glutamine 200 mM	P04-80100 / CT-80100	●		●	●									3
Stable Glutamine 200 mM	P04-82100 / CT-82100			●	●									2
RNase/DNase Neutralizer	P10-61500	●				●								2
DMEM, stable Gln	P04-04500 / CT-04500		●											1
RPMI 1640, stable Gln	P04-18500 / CT-18500		●											1
HAT Supplement 50×	P07-02100 / CT-02100		●											1
HT Supplement 50×	P07-01100 / CT-03100		●											1
Accutase	P10-21500		●			●								2
PANcell CHO Feed Kit	P04-71102K			●	●									2
HybridBoost	P04-995910 / CT-995905			●	●									2
Panserin 293S / 293A	P04-710609 / P04-710608			●										1
Pluronic F-68 10 %	P08-02100 / CT-02110			●	●									2
Sodium Bicarbonate 7.5 %	P04-44100			●	●									2
ITS Solution I 100×	P07-03100 / CT-03110			●	●									2
Glucose 20 % Stock	CT-00331				●									1
HEPES Buffer 1 M	P05-01100 / CT-01100				●									1
MEM NEAA 100×	P08-32100 / CT-32100				●									1
Insulin human recombinant	P07-04300				●									1
Sodium Pyruvate 100 mM	P04-43100 / CT-43100				●									1
Ethanol 20 %	CT-89500						●							1
Triton X-100 10 %	CT-01001							●						1
NaCl 5 M Stock	CT-77055						●		●	●	●		●	5
Tris-HCl 1 M Stock, pH 8.4	CT-05500						●	●	●	●				4
Citrate Buffer 100 mM, pH 3.0	CT-62500						●	●						2
Glycine 100 mM, pH 3.0	CT-69500						●							1
Sodium Acetate 100 mM, pH 4.5	CT-76451								●			●	●	3
Phosphate Buffer 100 mM	CT-18810 / CT-18850								●	●	●	●	●	5
NaOH 1 M Stock	CT-55105								●					1
Ammonium Sulfate 1 M	CT-67500									●				1
Ammonium Sulphate 3 M Stock	CT-68500									●				1
Histidine 100 mM, pH 6.0	CT-69510										●	●	●	3
Sucrose 30 % Stock	CT-00131											●	●	2
Trehalose 30 % Stock	CT-00231											●	●	2
Polysorbate 20 (PS20) 1 %	CT-00211											●	●	2
Polysorbate 80 (PS80) 1 %	CT-00311											●	●	2
EDTA 0,5 M, pH 8,0	CT-10500												●	1
L-Arginine 1 M, pH 7,0	CT-69520												●	1
Mannitol 10 % (w/v)	CT-00401												●	1
Custom GMP Buffer	PAN Celltech · to your recipe						●	●	●					
PRODUCTS PER STEP		7	8	10	13	6	7	4	6	6	6	9	13	

Every buffer beyond-compendial with WFI Beyond, on request · custom GMP to your recipe · **info@pan-celltech.com**