

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**TM
/ MEDIA / REAGENTS / SERUM / BUFFER



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 S1 - S5: Products for every step – cell bank to harvest.

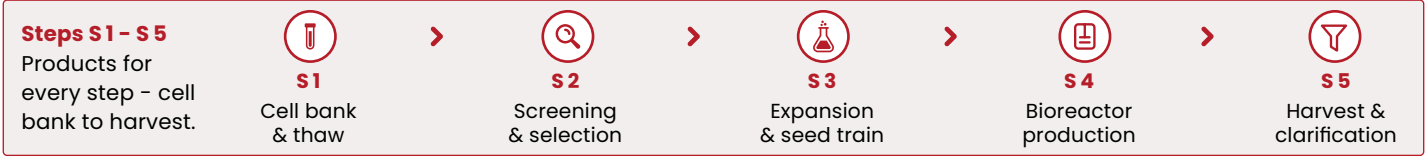


Scan for the full
cell culture range



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.



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

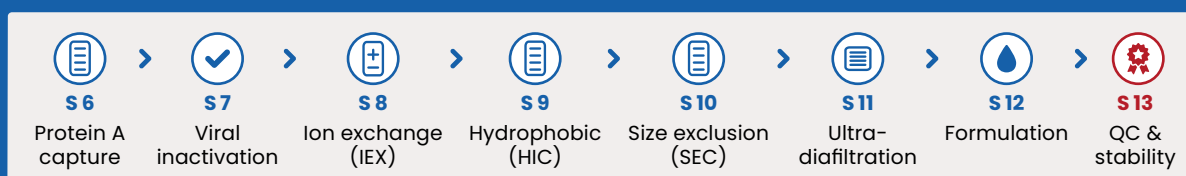
GMP TOMORROW

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.



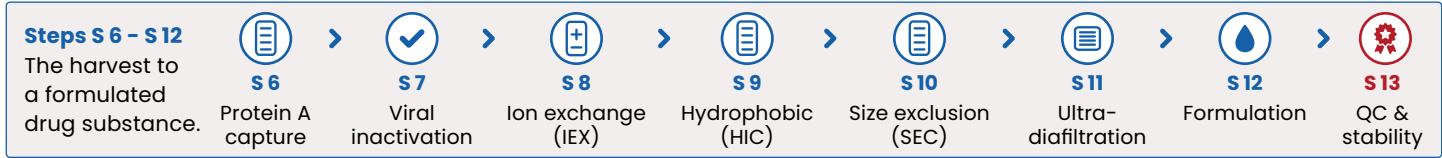
Steps S 6 – S 12: The harvest to a formulated drug substance.
Step 13 (QC & stability) is quality control, not a DSP step.



Scan for the full
downstream range

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.



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)

5 Products

Mandatory low-pH hold (ICH Q5A) to inactivate enveloped viruses. Citrate to acidify, Tris to re-neutralise; PANclear Octoxynol 10% Solution or PANclear APG 10% Solution for solvent/detergent viral inactivation.

COMPONENTS	ARTICLE NO.	COMPONENTS	ARTICLE NO.
Citrate 100 mM, pH 3.0	CT-62500	PANclear Octoxynol 10 % Solution*	CT-01001
Tris 1 M, pH 8.4	CT-05500	PANclear APG 10 % Solution*	CT-01101
WFI Quality Water	CT-991500		

*PANclear Octoxynol 10% Solution is made with genuine Triton™ X-100.

*PANclear APG 10% Solution is made with genuine Triton™ CG-110.

Triton is a trademark of The Dow Chemical Company; PAN is not affiliated with or endorsed by Dow.

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
> 50 x below monograph limit

TOC < 0.05 mg/L
> 10 x below monograph limit

Conductivity < 0.2 µS/cm
> 5 x below monograph limit

Nuclease-free
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.

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
PANclear Octoxynol 10 % Solution	CT-01001							●						1
PANclear APG 10 % Solution	CT-01101							●						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 Sulfate 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	5	6	6	6	9	13	