



Vaccine Process Solutions -Tofflon Lifescience

Vikrant Hedau
Director
Tofflon India Pvt Ltd

Contents

Tofflon

01 Tofflon Life Science

02 Tofflon Vaccine Process Solutions

- Upstream Solution with real Case Show
- Downstream Solution with real Case Show
- Egg base Influenza vaccine solution
- Pneumococcal Vaccine purification Solutions

Introduction

30⁺

30 Yrs in the Pharmaceutical
Eqt. MFG

Years of Experience

50⁺

Products in more than 50
countries and regions around
the world

Countries & Regions

2000⁺

2000 Patents
200 Software copyright

Intellectual Property

3000⁺

Serving more than 3,000
pharmaceutical companies
worldwide

Pharmaceutical
Customers

16,000⁺

More than 16,000 sets of
equipment and systems around
the world

Equipments & Systmes
Installations Worldwide

Tofflon

Tofflon Enterprise Solution for Biopharma

Biopharma/CGT

Machine

+ **E**ngineering

+ **C**onsumables



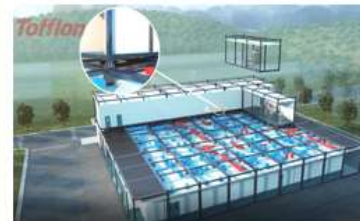
DS



DP



Modular Construction



Site Built Construction



DC

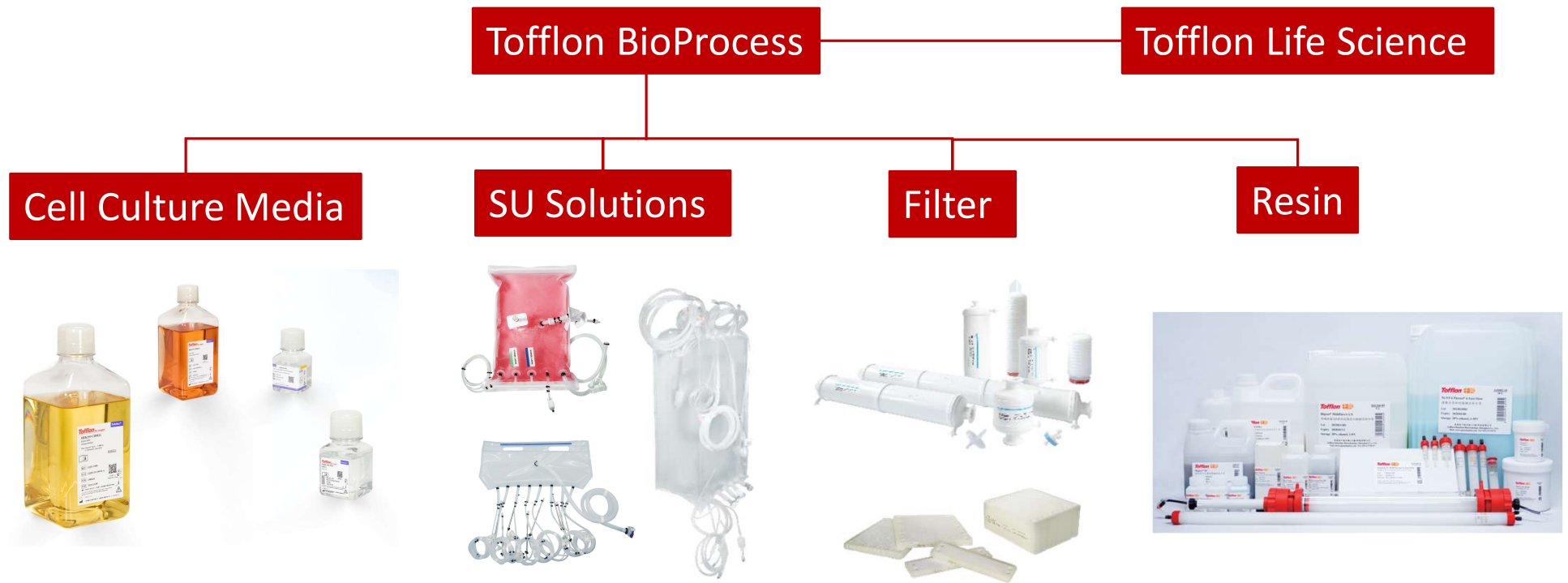


R&D/Pilot Scale

Large Scale

Tofflon

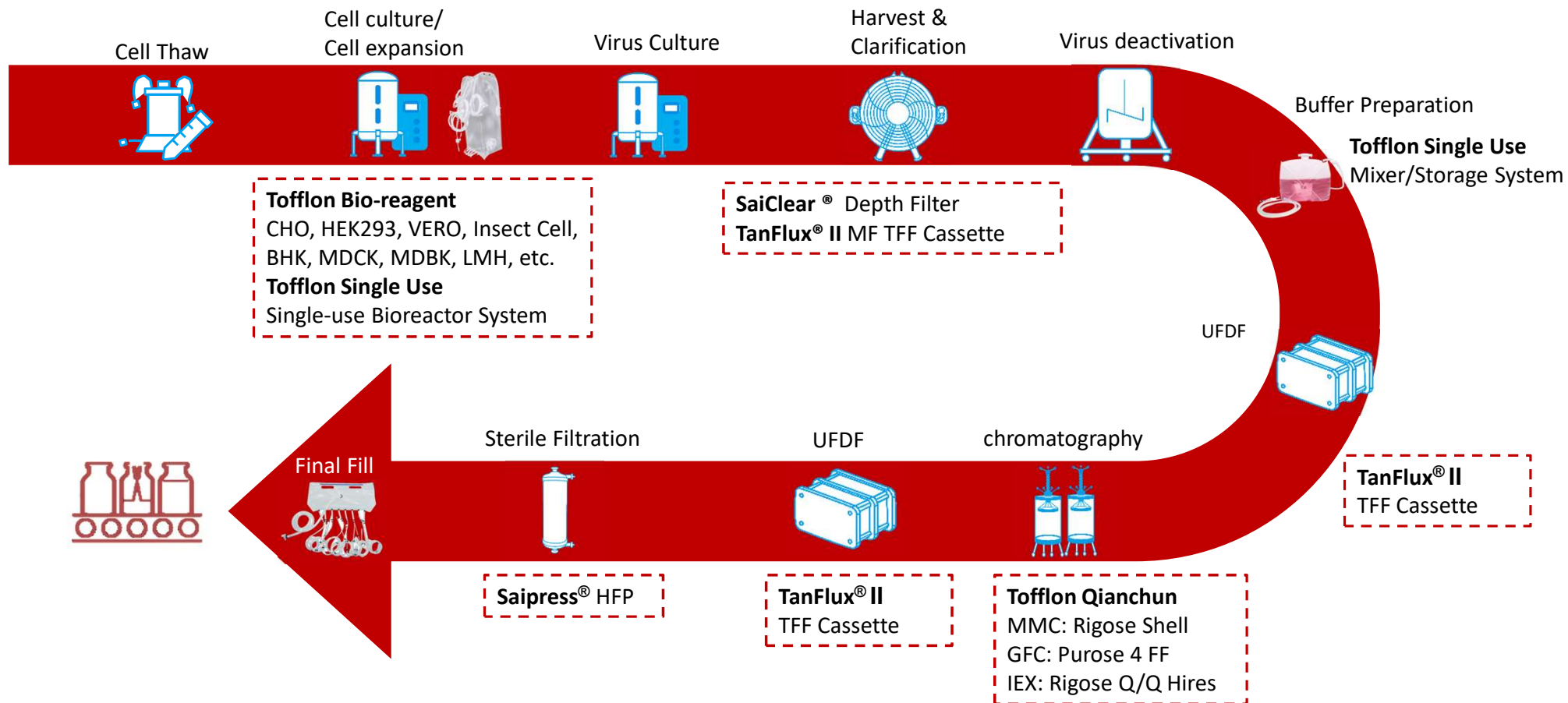
Product Line



Be committed to provide biopharma industry with reliable and comprehensive process solutions.

Tofflon

Tofflon Total Process Solution from upstream to down stream



Tofflon

Single-use Solutions

Single-use Solutions are designed for upstream applications in cell therapy, antibody drug seed expansion and vaccine production.

Features

- Availability of multiple options of product contact layer
- Complete validation package
- Easy handling and to avoid the risk of cross-contamination
- Multi-layer co-extruded film with high mechanical strength, excellent biocompatibility
- Unique design of mixing paddle and ventilating disc to achieve rapid mixing and dissolved oxygen effect.
- 100% integrity testing.
- Flexible customisation of product size, piping, fittings and filters



Applications

1. Cell Culture
2. Mixing and storage of intermediate products

Cell Culture Media

Media Type	Cell Line	Feature
Chemical Defined	HEK293	HEK293 and CHO series products are fully chemically defined media, suitable for a variety of vaccine production • no animal source • no human source • no protein and any hydrolysate
	CHO	
Serum Free	Insect	The Insect,MDCK,BHK and Vero series are serum-free media, suitable for a variety of vaccine production • no animal source • no human source • low protein content
	MDCK	
	BHK	
	Vero	

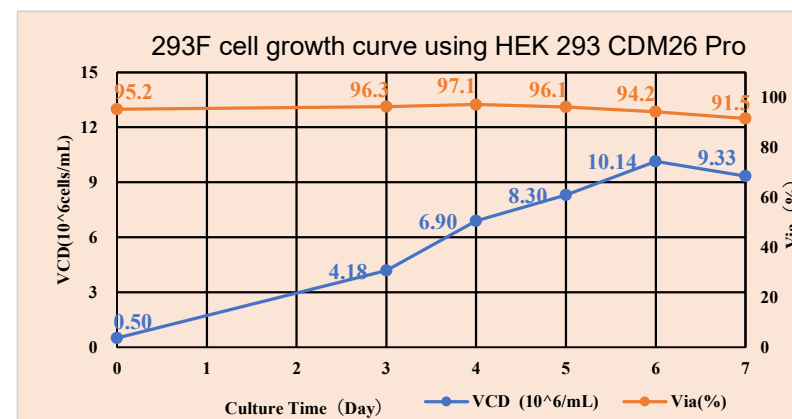
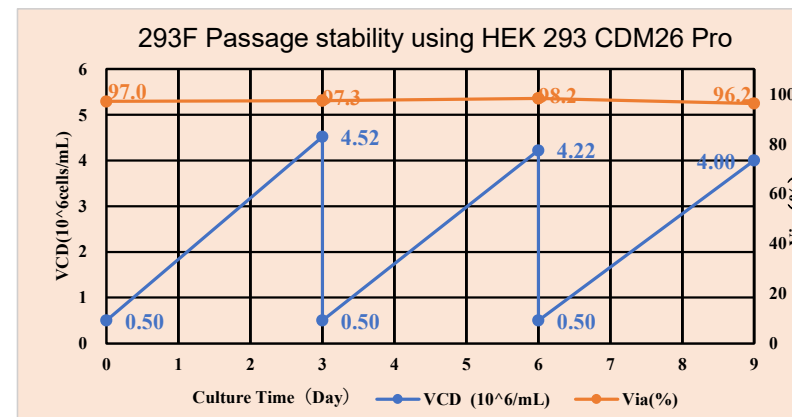
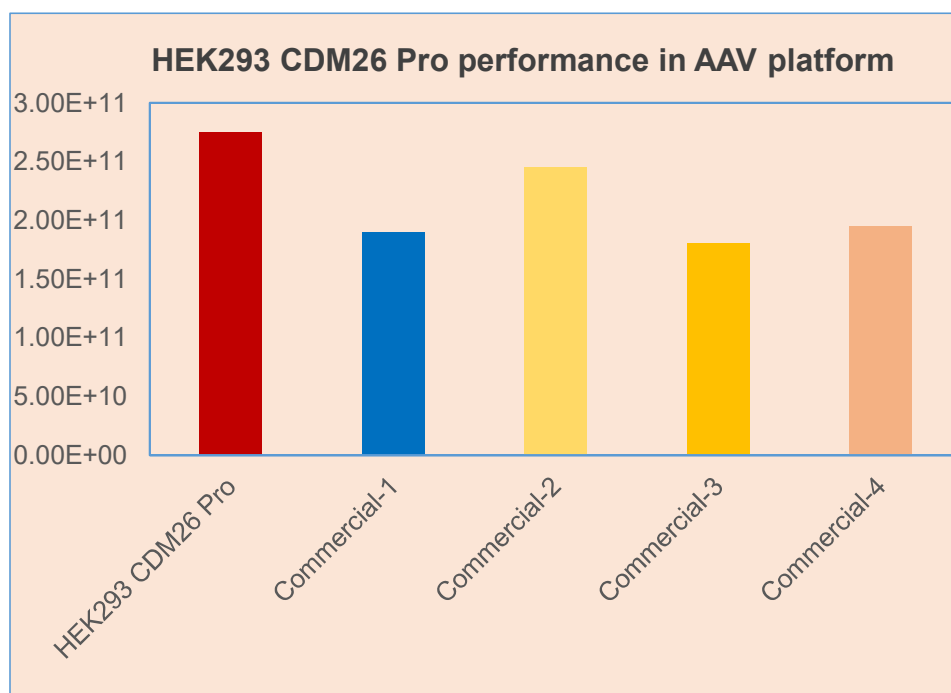
*Tofflon can provide standardized media test trials, and can also help customers with media development services.



Tofflon

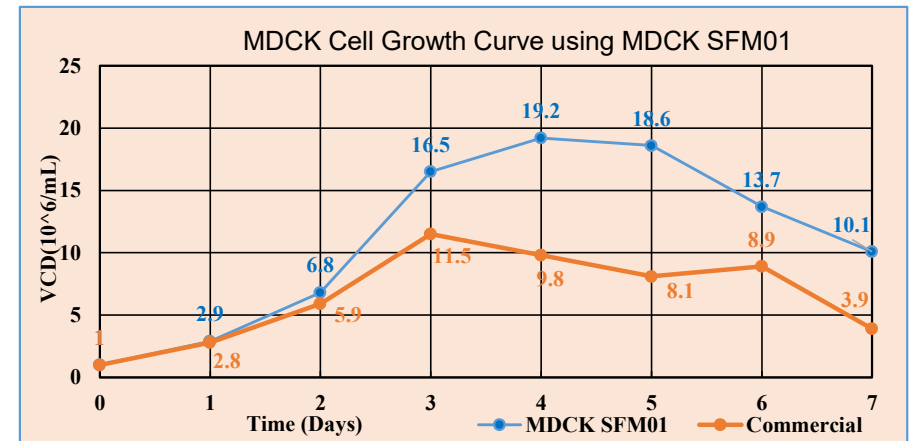
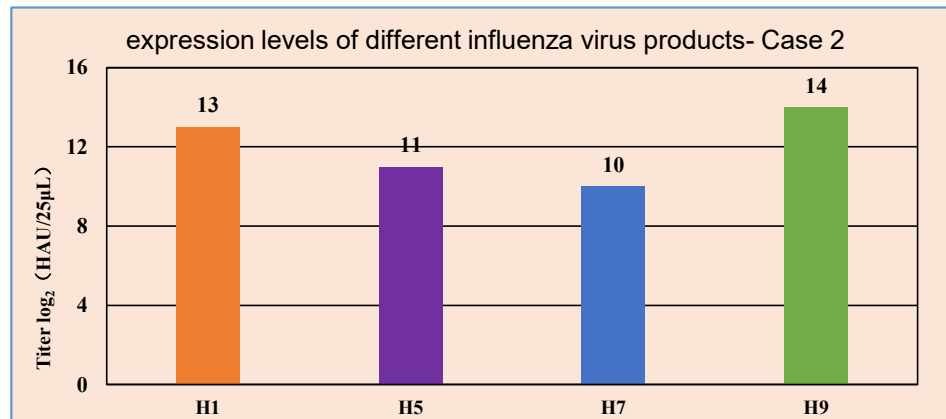
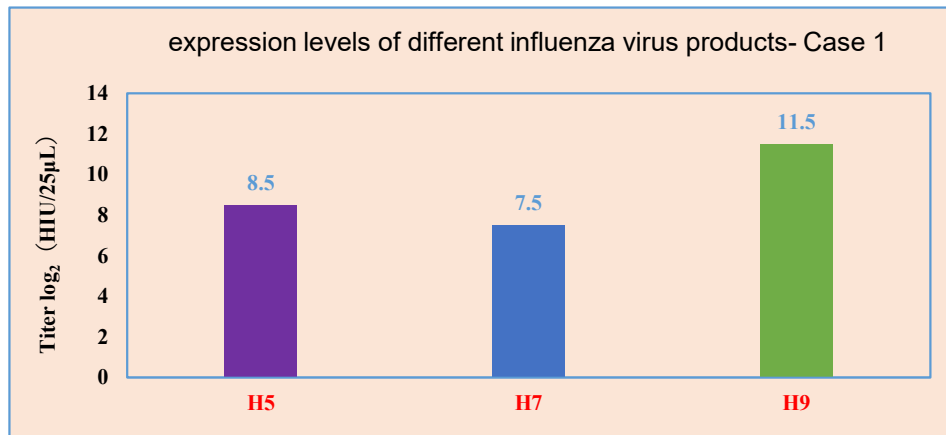
Cell Culture Media

Case 1: HEK293 CDM26 Pro for AAV



Cell Culture Media

Case 2: MDCK SFM01 -Influenza vaccine



Sterilizing-Grade Filter

Saipress® Hydrophilic Sterile Filter

Filter type		Disk filter	Capsule filter						Cartridge filter				
Nominal size		Dia 50mm	1"	2.5"	5"	10"	20"	30"	2.5"	5"	10"	20"	30"
Effective filtration area	Single layer	13.8cm ²	0.04m ²	0.16m ²	0.32m ²	0.65m ²	1.32m ²	1.98m ²	0.16m ²	0.32m ²	0.65m ²	1.32m ²	1.98m ²
	Double layer	13.8cm ²	0.04m ²	0.14m ²	0.28m ²	0.57m ²	1.14m ²	1.71m ²	0.14m ²	0.28m ²	0.57m ²	1.14m ²	1.71m ²
Membrane pore size		0.1µm / 0.22µm / 0.45µm / 0.65µm											

Saipress® HF Hydrophilic Sterile Filter

Filter type		Syringe filter	Capsule filter						Cartridge filter				
Nominal size		--	1"	2.5"	5"	10"	20"	30"	2.5"	5"	10"	20"	30"
Effective filtration area	Single layer	2.8cm ²	380cm ²	0.16m ²	0.33m ²	0.65m ²	1.30m ²	1.95m ²	0.16m ²	0.33m ²	0.65m ²	1.30m ²	1.95m ²
	Double layer	2.8cm ²	350cm ²	0.14m ²	0.28m ²	0.55m ²	1.10m ²	1.65m ²	0.14m ²	0.28m ²	0.55m ²	1.10m ²	1.65m ²
Membrane pore size		0.1µm / 0.22µm / 0.45µm / 0.65µm											



Filgiant® Hydrophobic Sterile Filter

Filter type		Disk filter	Capsule filter					Cartridge filter			
Nominal size		-	1"	2.5"	5"	10"	20"	2.5"	5"	10"	20"
Effective filtration area	Single layer	13.8cm ²	0.04m ²	0.16m ²	0.32m ²	0.65m ²	1.30m ²	0.16m ²	0.33m ²	0.65m ²	1.30m ²
	Double layer	13.8cm ²	0.04m ²	0.14m ²	0.28m ²	0.57m ²	1.14m ²	0.14m ²	0.28m ²	0.57m ²	1.14m ²
Membrane pore size		0.22µm / 0.22+0.22µm									

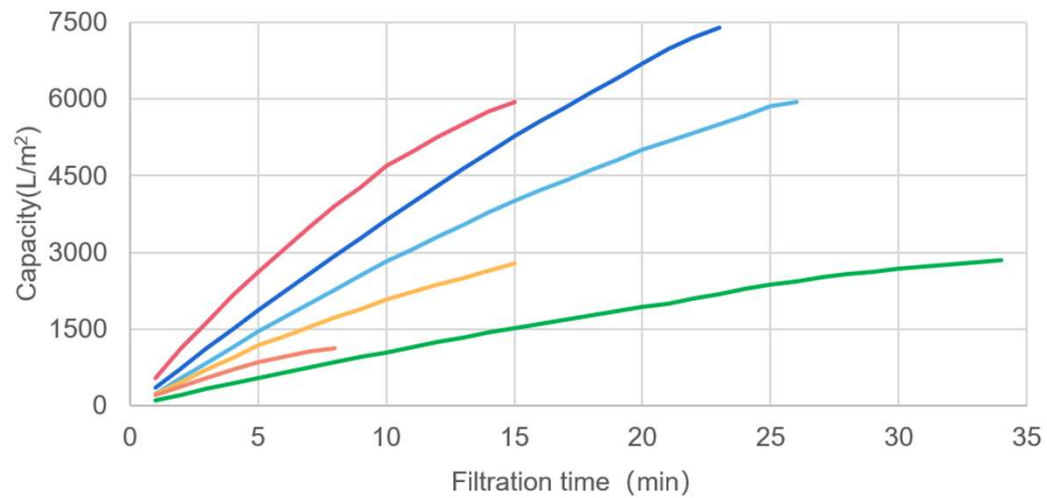
Tofflon

Sterilizing-Grade Filter

Media Filtration Case Show- Saipress® HFP

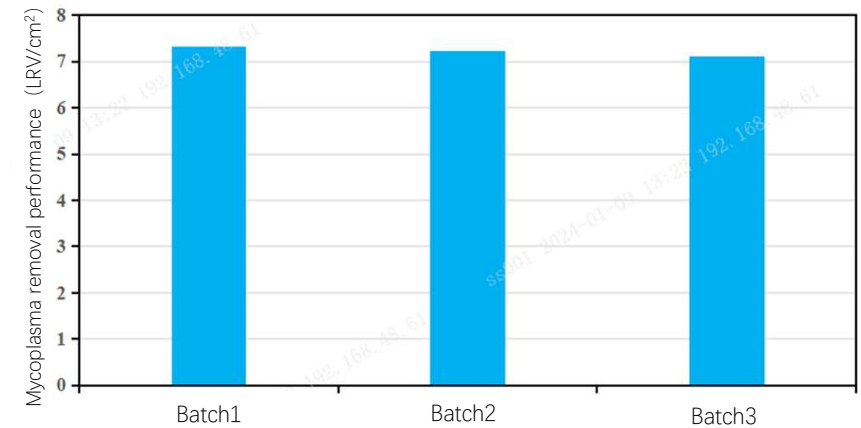
Filter: PES, 0.45+0.22μm

Filtration Flux Trend



Chinese brand B S&P Saipress HF S&P Saipress HFP
Chinese brand A Imported brand B Imported brand A

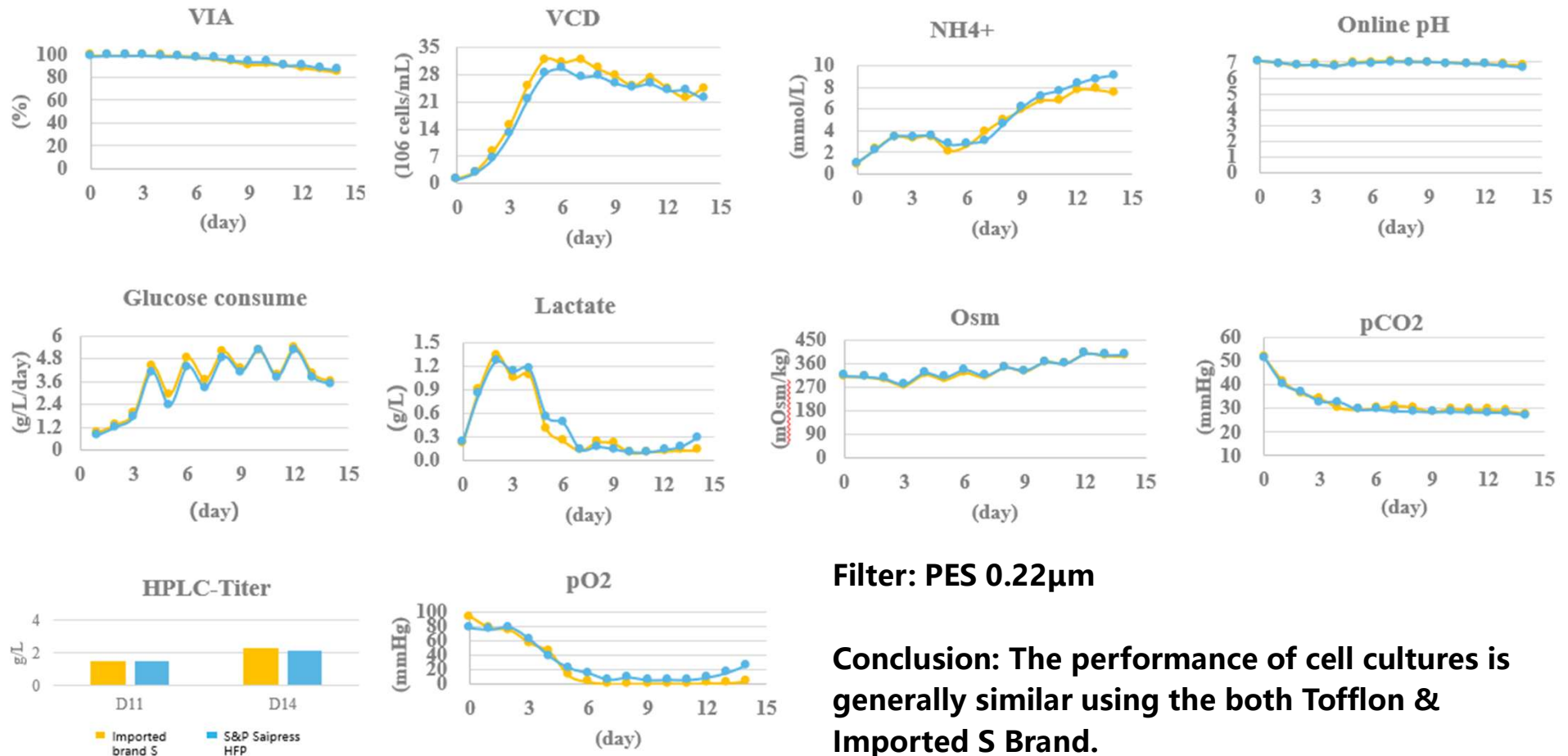
Mycoplasma retention test - Saipress 0.1μm



Consistent performance for mycoplasma clearance

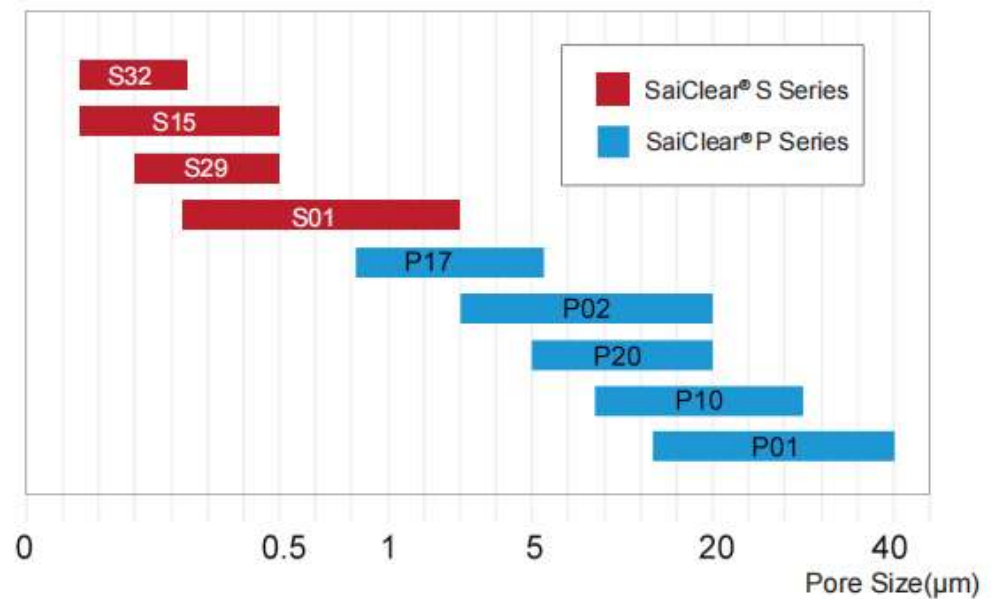
Sterilizing-Grade Filter

Medium Filtration Show Case - Saipress®



Tofflon

SaiClear® Depth Filter

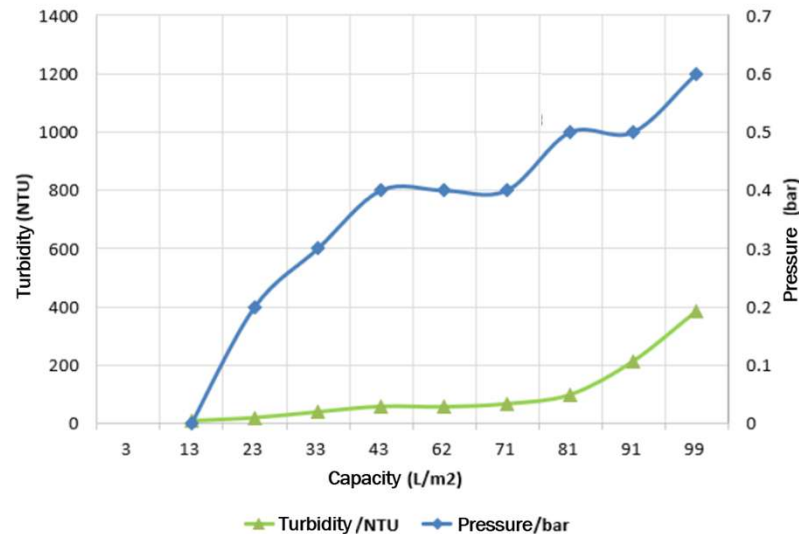


- ✓ A wide range of filter sheet combinations for a variety of material and liquid challenges
- ✓ Highly efficient removal of HCP and HCD
- ✓ Compatible with imported brand fixtures
- ✓ Unique structural design ensures good amplification consistency
- ✓ Complete validation and quality system

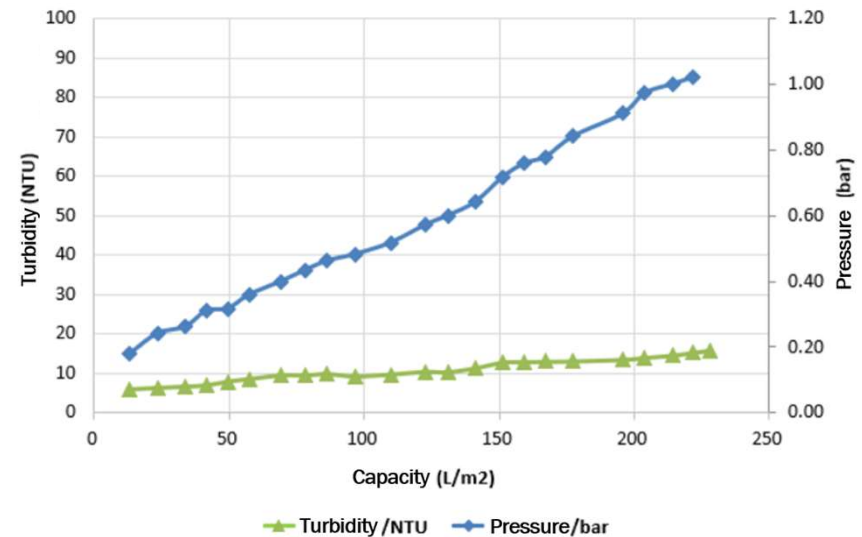
SaiClear® Depth Filter

SaiClear® application in Recombinant Protein Cell Harvest Solution

SaiClear P20-First Clarification



SaiClear S15-Second Clarification



Recombinant protein cell harvest solution

- Initial turbidity: 1400NTU
- Cell density: $10 \times 10^6/\text{mL}$
- Cell viability: >85%
- Solid content: 4%

SaiClear P20-First Clarification

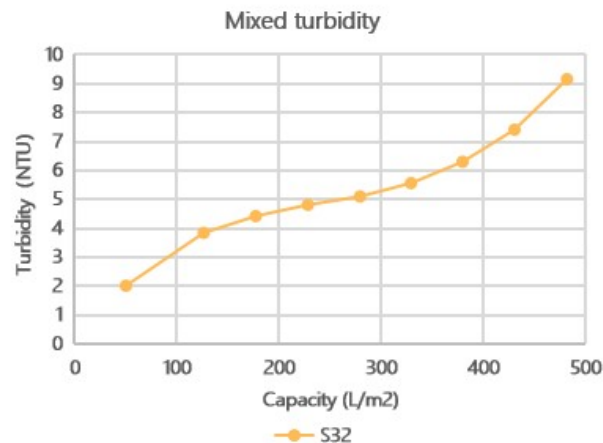
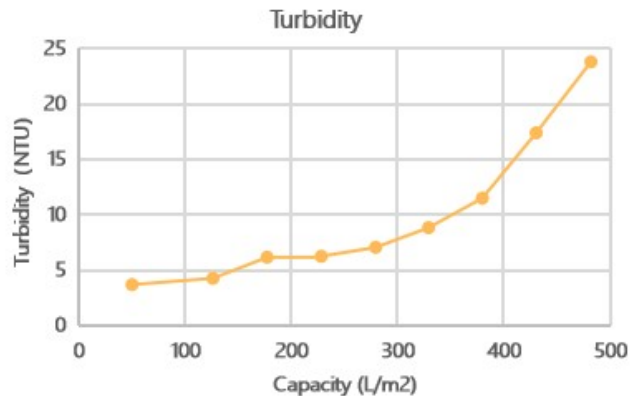
- **Capacity: 99L/m²**
- Pressure:<0.6 bar
- Filtrate turbidity: 109NTU

SaiClear S15-Second Clarification

- **Capacity: 228L/m²**
- Final Pressure:<1.0 bar
- Filtrate turbidity: <10NTU

SaiClear® Depth Filter

SaiClear® application in CHO Cell Fermentation Centrifuge Harvest Solution



Fusion protein

Initial turbidity: 119NTU (post-centrifuge)

Current process: Centrifuge + M# Depth filter,
Capacity > 240 L/m²

Alternative process : Centrifuge+ **SaiClear S32**

Filtration flux: 300LMH;

Terminal: Prompt turbidity ≤ 20NTU

Mixed turbidity < 20NTU

(Pressure ≤ 1.5 bar)

S32 performance:

Capacity: **485.96 L/m²**

Terminal pressure: 16.3psi

Mixed turbidity: **9.16 NTU**

Configuration: 2100L sample solution,
filtration 1.5h, with 5m² (1.35)

UFDF - Tanflux® TFF Cassette

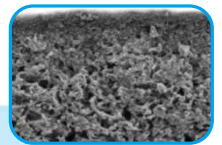
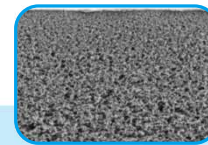
Tanflux®



Tanflux® II



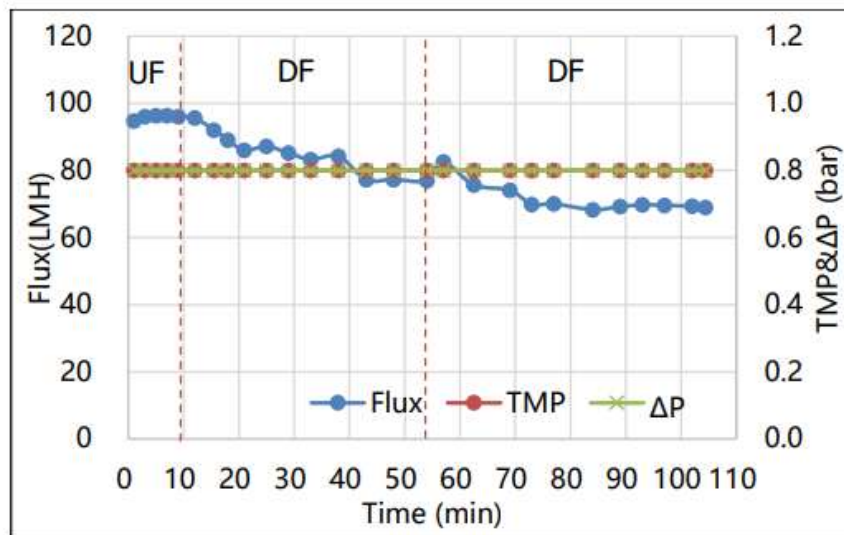
- **Total Solution for TFF:**
 - From 1kd to 500kd UFTFF
 - 0.1 to 0.45um MFTFF
 - 0.01m²; 0.1m², 0.5m², 2.5m²
- **Stable supply chain:**
 - From membrane making to final filter
- **Thermal welding technology:**
 - Low E&L level
 - Excellent NaOH compatibility, long service life cycle
- **Compatible with various kinds of holders**



Membrane Material	Modified PES (polyethersulfone)		CompositeFlawless RC (regenerated cellulose)
Filtration Type	Ultrafiltration	Microfiltration	Ultrafiltration
Molecular weight cutoff	5/8/10/30/50/70/100/300/500KD	0.1/0.22/0.45µm	1/2/3/5/10/30/100/300KD

UFDF - Tanflux® TFF Cassette

Tanflux® II Cassette application in HPV Vaccine



Basic Info

HPV Vaccine

Process Step: 2*UF + 5*DF + 5*DF

Cassette: TanFlux® RC 30KD

Process Volume: 20L

Process Duration: 1h

Concentration average flux: **96 LMH**

Permeation average flux: **75LMH**

TMP: 0.8 bar

Recovery rate: **98%**

NWP recovery: **98.95%**

Process Configuration:

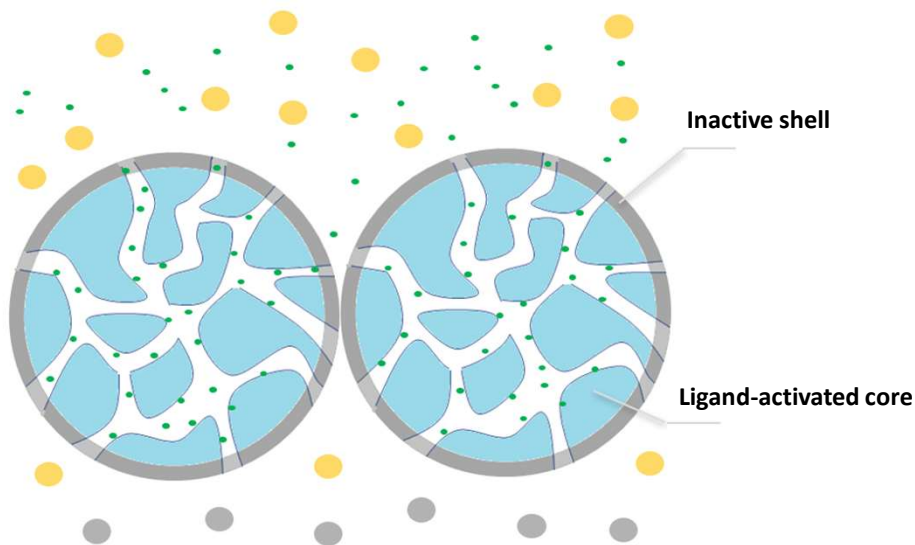
1.5m² RC 30KD Cassette (0.5m²*3)

Chromatography Resin

MMC

Rigose Shell 400
For 20-35 nm

Riose Shell 700
For Larger than 35nm

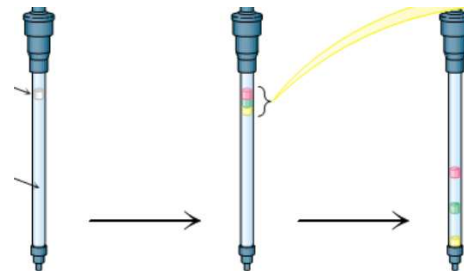
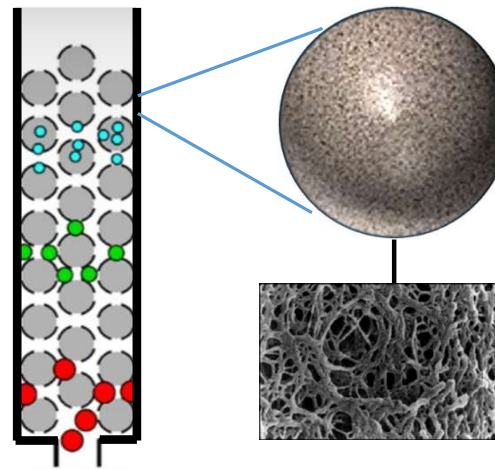


● Virus, plasmid DNA, VLPs, etc

● BSA, ovalbumin, HCP, DNA fragments, endotoxin, etc

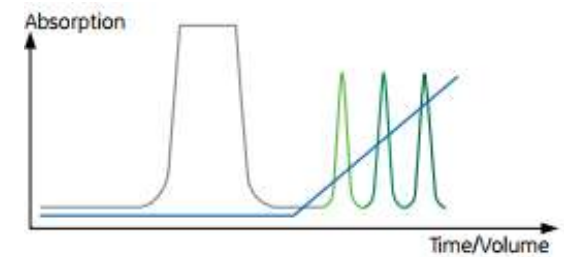
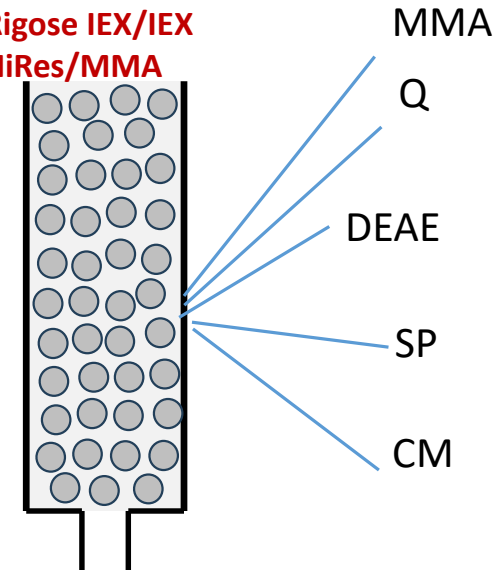
GFC

Purose 4 FF, Purose 6FF



IEX

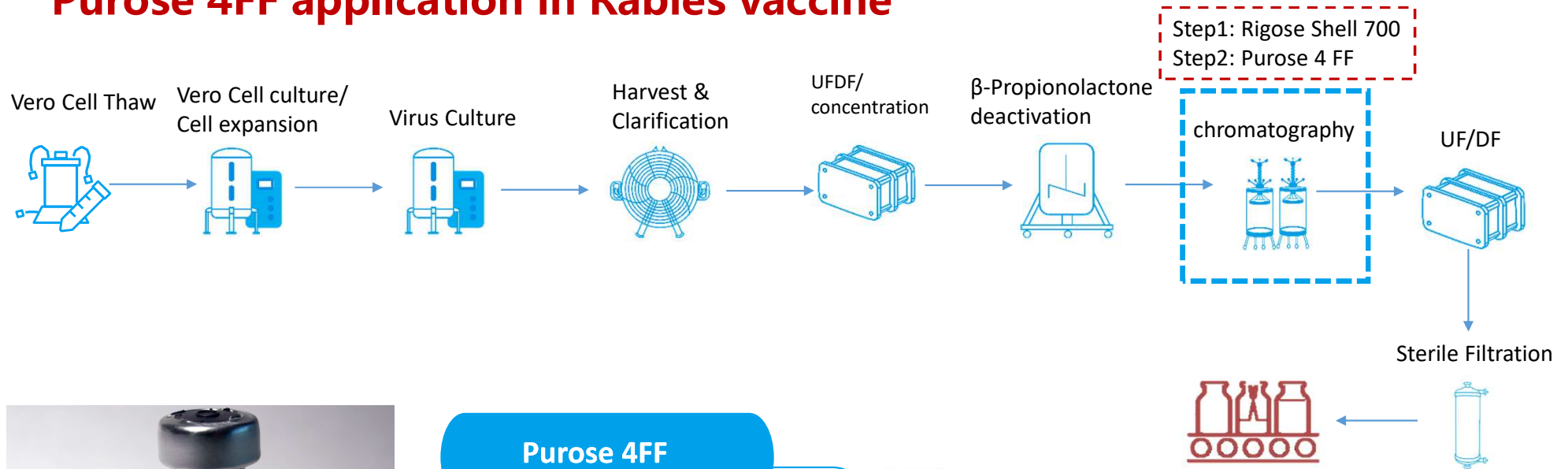
**Rigose IEX/IEX
HiRes/MMA**



Tofflon

Chromatography Resin

Purose 4FF application in Rabies vaccine



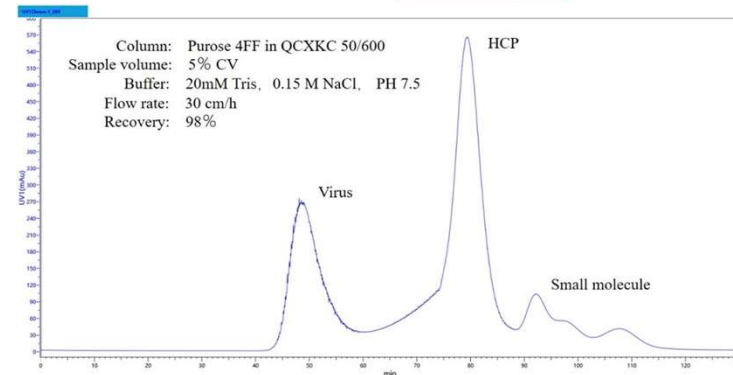
Purose 4FF

Process Target :

- Total protein removal
- DNA fragments removal

Main Spec. :

- Protein removal rate



Tofflon

Thank You

