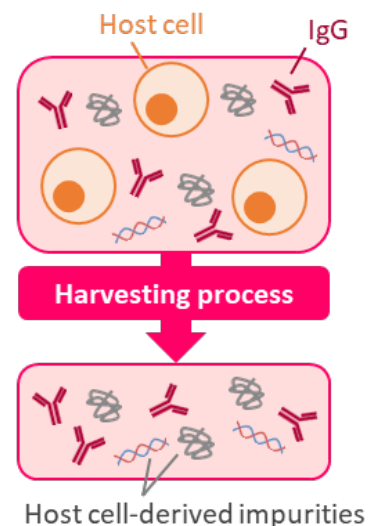


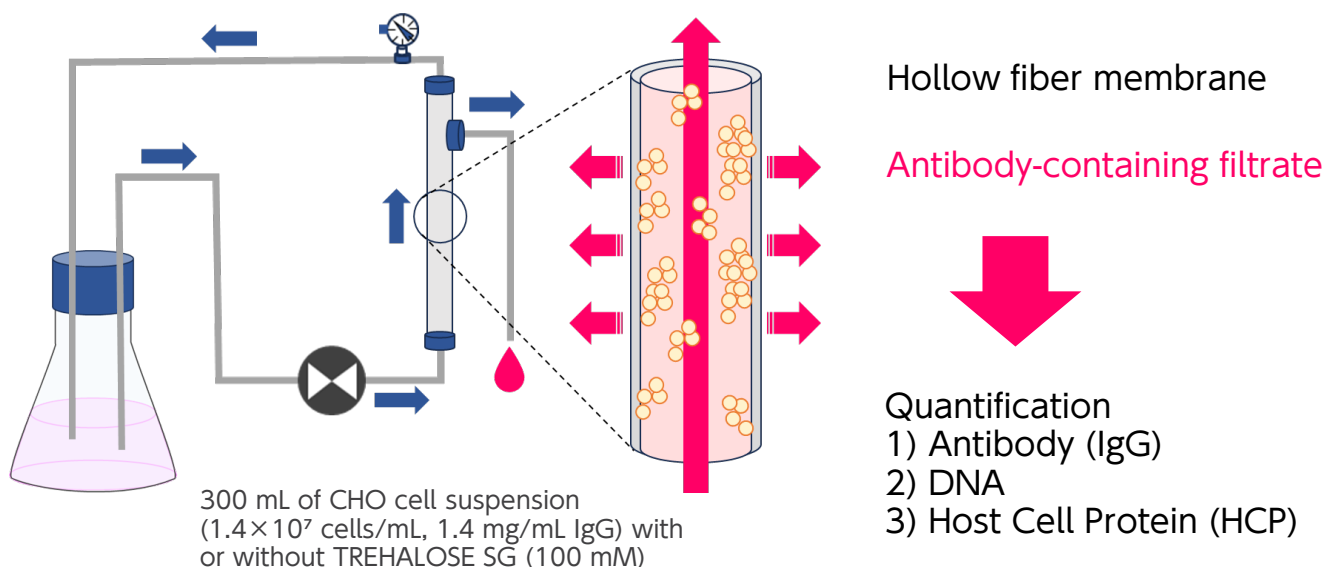
# For Antibody Harvesting Use

## Challenges in managing host cell-derived impurities

- Over the past decades, advancements in upstream processing of therapeutic antibody production have led to an increased carry-over of host cell-derived impurities into downstream processing, presenting a significant challenge.
- Centrifugation and depth filtration are commonly used in the harvesting process, but tangential flow filtration (TFF) has recently been proposed as a suitable method for perfusion culture.
- Trehalose is known to protect cells and proteins from various physical stresses, but its role in reducing impurities during antibody harvesting process remains unclear.



## Experimental model of harvesting process using the TFF system



### Materials & Methods

IgG-producing Chinese hamster ovary (CHO) cells were cultivated for 5 days. Just before sampling the culture filtrate, 100 mM trehalose (TREHALOSE SG) was added to the cell suspensions ( $1.4 \times 10^7$  cells/mL, 1.4 mg/mL IgG). Then, 300 mL of the cell suspension was filtered using the TFF system for 3 hours (Pore size : 0.45  $\mu\text{m}$ , Permeate flux : 5.7 L/m<sup>2</sup>/h). IgG in the filtrates was quantified by HPLC. Residual DNA and HCP were measured using QuantiFluor® ONE dsDNA System (Promega) and the CHO HCP ELISA Kit, 3G F550-1(Cygnus).

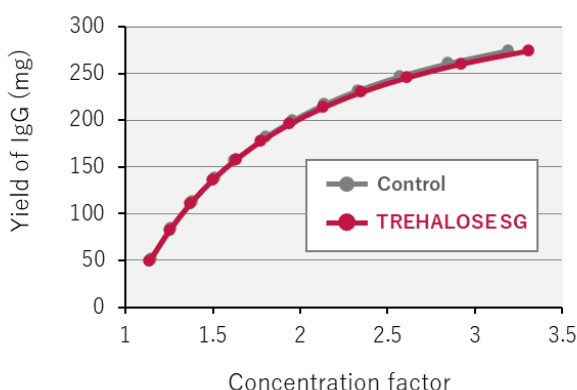
**Effects of TREHALOSE SG in TFF process**

- Addition of TREHALOSE SG during the harvesting process using TFF system did not affect the yield of IgG (Table a, Figure b).
- However, addition of TREHALOSE SG reduced residual DNA and HCP levels in the filtrates by 34% and 21%, respectively, compared to the control (Table a, Figure c, d).

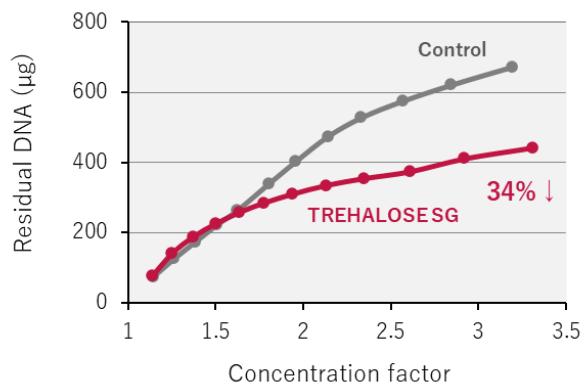
**a**

	Control		TREHALOSE SG	
	Input	Output	Input	Output
IgG	423.2 mg	274.6 mg	421.3 mg	274.9 mg
(Output/Input)		(64.9 %)		(65.3 %)
DNA	605.0 µg	672.5 µg	571.4 µg	442.1 µg
(Output/Input)		(111.2 %)		(77.4 %)
HCP	28.3 mg	12.3 mg	24.9 mg	9.66 mg
(Output/Input)		(43.5 %)		(38.8 %)

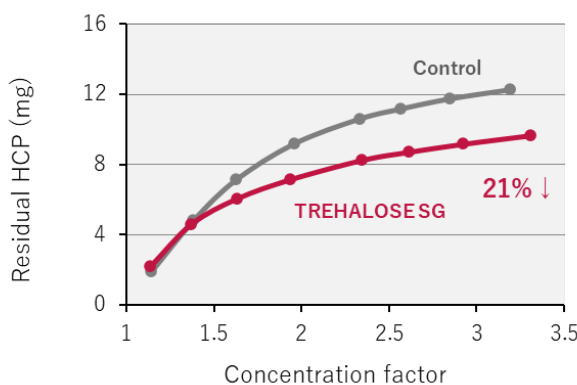
**b IgG levels in the filtrates**



**c DNA levels in the filtrates**



**d HCP levels in the filtrates**



**Table & Figures**

(a) Amounts of IgG, DNA and HCP in the cell suspension before TFF (Input) and in the filtrate after 3 hrs of the TFF (Output). The Output/Input ratio shows the yield based on the Input amounts. (b) The yield of IgG was not affected by adding 100 mM TREHALOSE SG. (c) The DNA levels in the filtrate after TFF were reduced by 34 % by adding 100 mM TREHALOSE SG, compared to the control. (d) The HCP levels in the filtrate after TFF were reduced by 21 % by adding 100 mM TREHALOSE SG, compared to the control.

MANUFACTURER : **Nagase Viita Co., Ltd.**  
 CONTACT : **Nagase & Co., Ltd.**

Life & Healthcare Products Department  
 E-mail: [dnfct@ex.nagase.co.jp](mailto:dnfct@ex.nagase.co.jp)

⚠ The information provided herein is intended only for reference purposes. It is the customer's responsibility to determine that the ingredients meet all legal requirements in the country where they are used, and that they do not infringe on any third party patents. Unauthorized reproduction of this brochure is prohibited.