

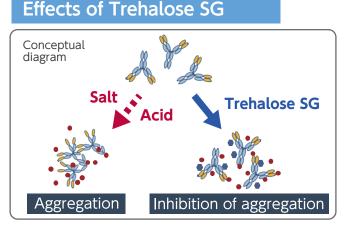
NAGASE Group

TREHALOSE SG JP, USP-NF, Ph. Eur., CP

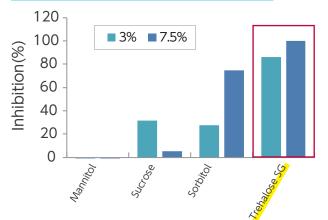
For antibody purification use

Antibody manufacturing process and aggregate formation

- While there are various stressors that cause antibody aggregation during the antibody manufacturing process, use of acidic buffers and high concentrations of salt solutions are the major stressors leading to aggregate formation.
- The resulting aggregates may also act as nuclei for further aggregate growth, possibly creating antigenicity of the aggregates, raising quality and safety concerns.



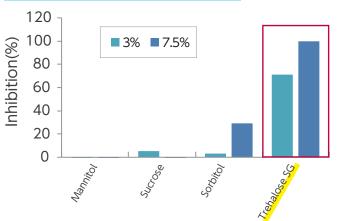
Acidic buffer (glycine-HCl pH 2.7)



Manufacturing **Stress** conditions process Agitation Cell culture Affinity Acidic buffer purification Virus Low pH inactivation Mid to final Salt purification Absorption Filtration Increase the amount of aggregates High Storage concentration /Shipping Freeze-Thaw

- Trehalose SG is suitable for use as an additive for antibody chromatography buffers because it suppresses antibody aggregation due to acids and salts, which is a particular problem during antibody purification.
- Addition of Trehalose SG in the purification buffer prevents loss of active antibody yield without affecting the interaction with the carrier used for chromatography.

Salt (5 mol/L lithium chloride)



*Monoclonal antibody was incubated with Trehalose SG, sucrose, mannitol or sorbitol in glycine-HCl buffer (0.1mol/L, pH2.7) or lithium chloride buffer (5 mol/L) for 30 min at 25 °C. The percent inhibition of aggregate formation in the antibody solutions were determined using dynamic light scattering and presented as a relative value when compared with the inhibition percentage when 7.5% Trehalose SG is added. It was shown that the addition of 7.5% Trehalose SG efficiently inhibits antibody aggregation in the chromatography buffers containing acid and salts.

Manufacturer : HAYASHIBARA CO., LTD. CONTACT : NAGASE & CO., LTD.

Life & Healthcare Products Dept. Pharma-Medical Div. TEL: +81-3 (3665) 3333 (TOKYO JAPAN) TEL: +81-6 (6535) 2327 (OSAKA JAPAN) E-mail: 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.

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