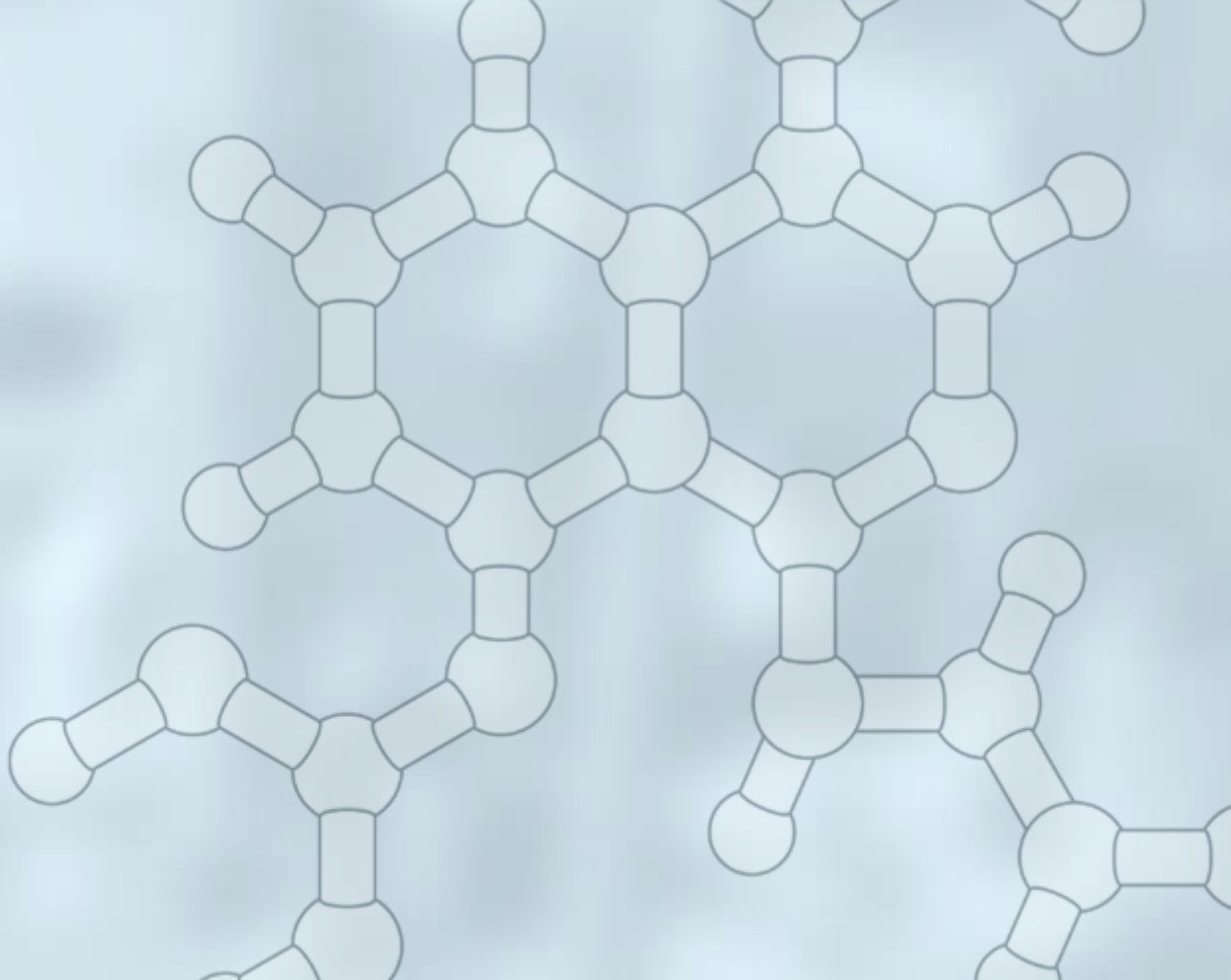


# J.T.Baker® HPLC Sugars



*Life Sciences*

# J.T. Baker® HPLE Sugars

HIGH PURITY,  
LOW  
ENDOTOXIN  
CARBO-  
HYDRATES

## IMPROVE YIELDS

### Galactose

- Monosaccharide used in upstream processing as cell culture nutrient
- Improved purity increases performance and yields

## REDUCE API DEGRADATION

### Sucrose

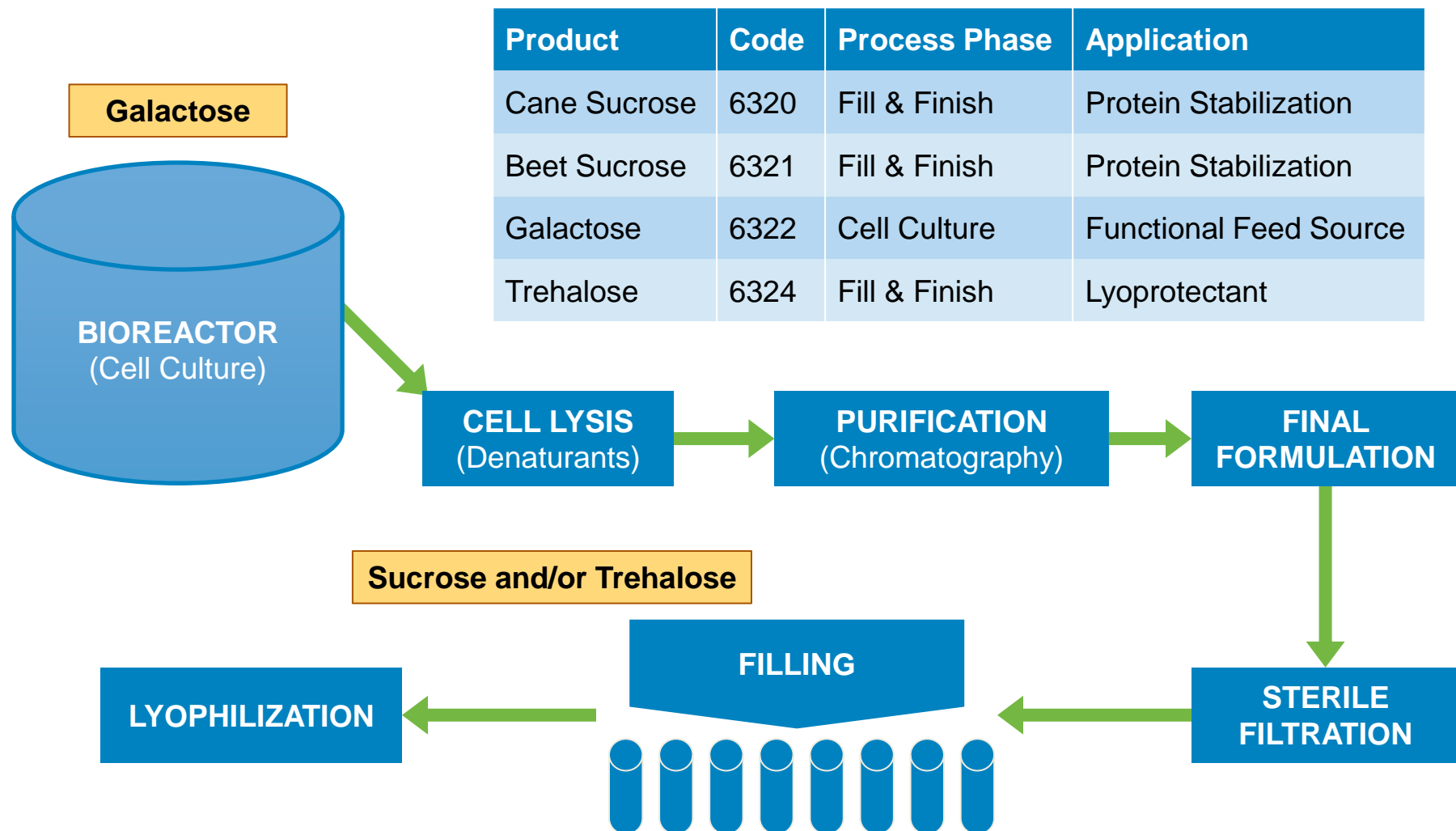
- Bulking agent and stabilizer in parenteral formulation
- Non-reducing sugar. Good lyoprotection for API

## REDUCE API DEGRADATION

### Trehalose

- Bulking agent and lyoprotectant in parenteral formulation
- Non-reducing sugar . Best lyoprotection: Low hygroscopicity, very low chemical reactivity and higher Tg

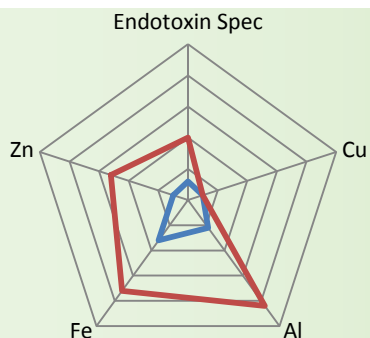
# J.T. Baker® HPLE Sugars: Product Line Overview



# J.T. Baker® HPLE Sugars Benchmarking

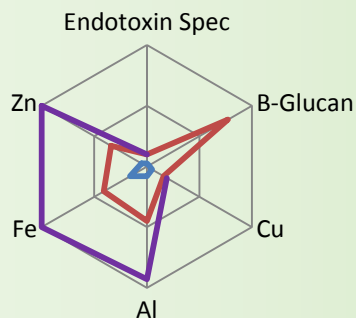
— J.T.Baker® brand — Competitor 1 — Competitor 2

## CANE SUCROSE



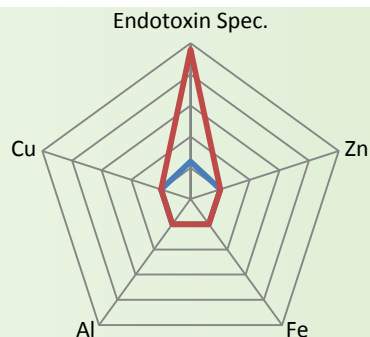
- J.T.Baker® HPLE Cane Sucrose has superior endotoxin specifications, below industry standards excipients.
- Proprietary purification technologies provide lowest trace metal impurities of materials tested to date.
- Further benchmarking and impurity profiles are being developed such as B-glucan and reducing sugars.

## GALACTOSE



- J.T.Baker® HPLE Galactose has superior endotoxin specifications, below industry standards for excipients.
  - We are evaluating further decreases in this endotoxin specification
- Competitors 1 and 2 have consistently higher impurities such as trace metals and B-glucan.
- Competitor 2 is off the chart for Zn and Fe with levels 56X higher than J.T.Baker® brand product.

## TREHALOSE



- J.T.Baker® HPLE Trehalose has superior endotoxin specifications, below industry standards for excipients.
- Proprietary purification technologies provide lowest trace metal impurities of materials tested to date.
- Further benchmarking and impurity profiles are being developed, including B-glucan and reducing sugars.

# Demonstrated Value : HPLE Sugars

## Savings and yield efficiencies

### Cell Culture Step

#### High Purity:

- Yield improvement with high-purity Galactose
- Capacity relief benefits from increase yield
- Testing reduction from consistent lot-to-lot quality

#### Low Endotoxin:

- Endotoxin levels below current regulatory requirements
- Potential new regulatory requirements addressed

### Fill & Finish Step

#### High Purity:

- Reduction in protein degradation from higher purity
- Molecular weight impurities clearly identified in specifications
- Support to identify impurity parameters for different APIs
- Consistency in lot-to-lot impurity levels

#### Low Endotoxin:

- Patient safety: Endotoxin levels below current regulatory requirements
- Ability to leverage the lower endotoxin levels in formulation to address total endotoxin levels per vial

## Demonstrated Value

Next-generation purity levels and industry-leading endotoxin specifications provide:

Reduce API degradation in certain parenteral formulations **up to 2%\***

An Avantor customer that is piloting the product has seen **improvements in cell culture yield up to 10%\*\*** when using our HPLE Sugars as nutrients

Endotoxin levels that are consistently below regulatory requirements

Maximizes patient safety

\* Impact of Residual Impurities and contaminants on Protein Stability, *Journal of Pharmaceutical Sciences*, 103, 1315-1330, 2014; Screening for stability and compatibility conditions of recombinant human epidermal growth factor for parenteral formulation: Effect of pH, buffers, and excipients. *International Journal of Pharmaceutics*, 452, 52-62, 2013

\*\* Cell Culture Medium Comprising Transition Metals or Trace Elements, US Patent, US20050287666 A1, May 25, 2010