

BalanCD[®] CHO FEED 4

Maximize productivity in large-scale, fed-batch cultures

- Enriched feed improves productivity and cell growth
- Advanced, concentrated formula achieves protein quality and provides flexibility to meet specific user needs
- Simple three-step, pH neutral, hydration protocol saves labor and facilitates a more robust process
- Fulfills regulatory requirements: chemically-defined, animal-component free

BalanCD[®] CHO Feed 4 is a nutrient-rich supplement designed to enable high-performing CHO cell lines achieve their full production potential while maintaining protein quality and functionality. Optimized for use with BalanCD CHO Growth A medium, BalanCD CHO Feed 4 is part of the scalable BalanCD media and supplements platform used to produce high yields of high quality recombinant proteins.



Improve performance compared to other commercially-available feeds

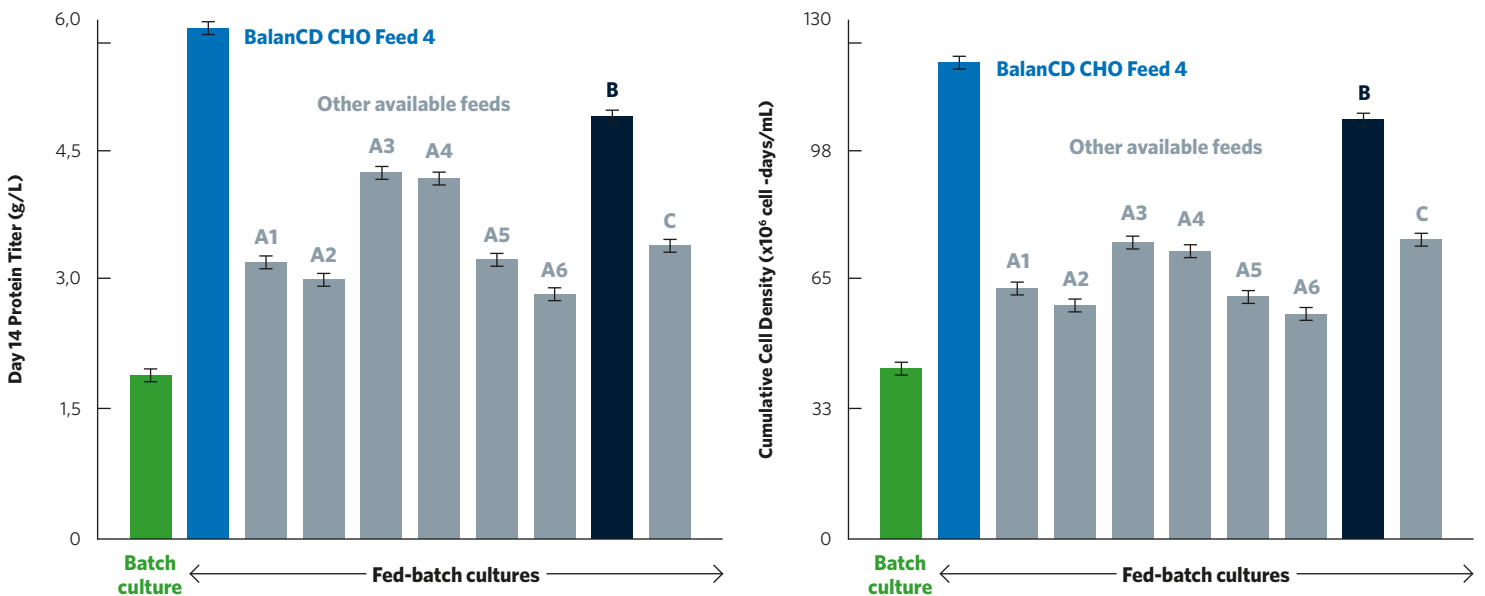


Figure 1 CHO cells were grown in 125 mL shaker flasks with 30 mL working volume. Cells were seeded at 3×10^5 cells/mL in BalanCD CHO Growth A medium in duplicate. Each feed medium was added on days 5 through 9 at equal volumes per event (total volume for each feed determined in prior experiment). Temperature shift was performed from 37° C to 33° C on day 7. Glucose was monitored every other day and supplemented to 8 g/L when levels dropped below 3 g/L. Final titer (A) and cumulative cell density (B) were measured. Supplier B Feed was progressed for additional comparative studies.

Achieve protein quality attributes

Day 14 antibody samples of fed-batch cultures that resulted in the highest titer (Figure 1) were collected and purified for further analysis. Quality of the monoclonal antibodies was evaluated for glycan profiles and ADCC activity.

TARGET GLYCAN PROFILE CONFIRMED

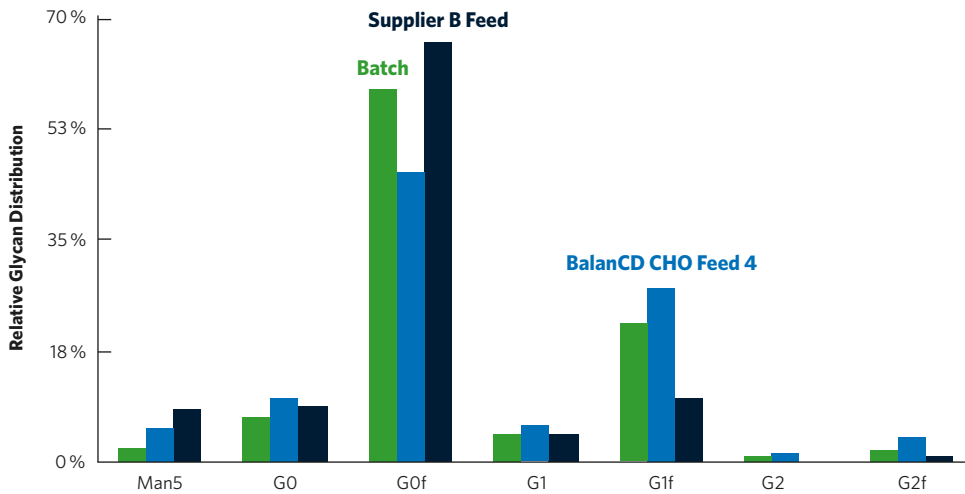


Figure 2 Comparison of glycan profiles of biosimilar harvested from fed-batch cultures of BalanCD CHO Feed 4 and Supplier B Feed. Relative abundance of each glycoform was determined.

CORRELATION OF GLYCAN ANALYSIS TO ADCC ACTIVITY CONFIRMED

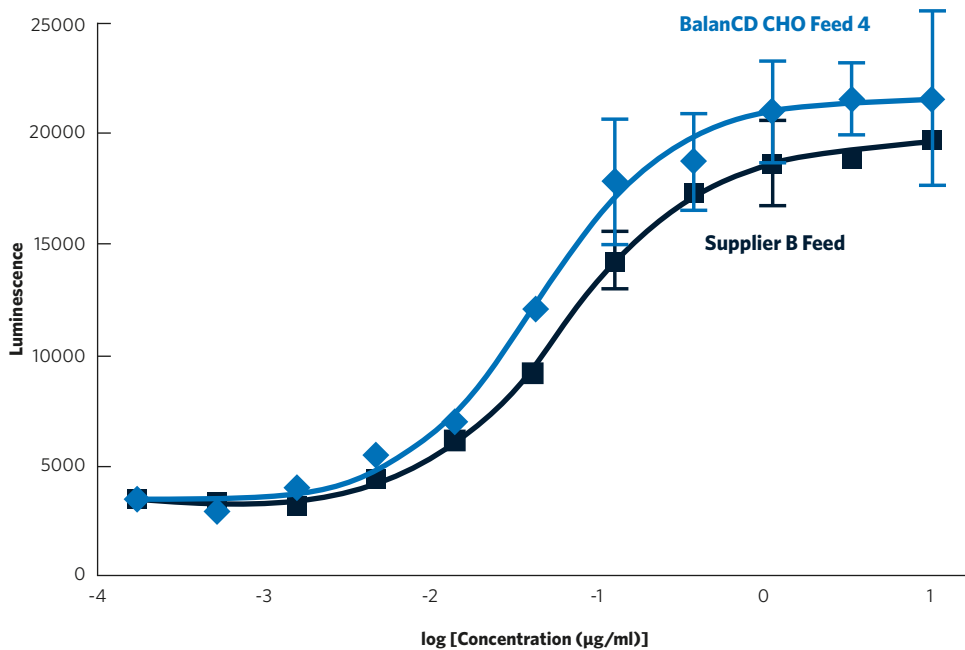


Figure 3 Comparison of ADCC activity of a biosimilar harvested from fed-batch cultures of BalanCD CHO Feed 4 and Supplier B Feed. Activity of the purified antibody was measured by ADCC reporter bioassay, triplicate per concentration.

FEED	EC ₅₀ (ng/mL)	% AFUCOSYLATED
BalanCD Feed 4	44	18.5%
Supplier B Feed	64	15.3%

$$\% \text{Afucosylated} = \frac{(\% \text{G0} + \% \text{G1} + \% \text{G2})}{(\% \text{G0} + \% \text{G0f} + \% \text{G1} + \% \text{G1f} + \% \text{G2} + \% \text{G2f})}$$

Cut hands-on time compared to alternative, best-performing feed

Nutrient rich feeds can be difficult to dissolve and require complicated, time-consuming preparation protocols. The BalanCD CHO Feed 4 is rich in amino acids and vitamins, yet dissolves easily when following the simple, three-step protocol. Typically there is no need for multiple pH adjustments and the pH remains stable in culture.

MULTI-STEP PREPARATION OF SUPPLIER B FEED

1

Add feed A powder to liquid, stir until dissolved

2

Add sodium bicarbonate, stir

3

Adjust pH with NaOH to 7.0-7.5; stir

4

Sterile filter through 0.2µm PES filter

5

Add feed B powder to liquid, stir until dissolved

6

Add sodium bicarbonate, stir

7

Adjust pH with NaOH to 11.0-11.4; stir

8

Sterile filter through 0.2µm PES filter

9

Mix A:B, 9:1 parts before feeding

READY TO FEED

THREE-STEP PREPARATION OF BalanCD CHO FEED 4

1

Add feed powder to liquid and stir until dissolved

2

Add sodium bicarbonate and stir until clear

3

Sterile filter through 0.2µm PES filter

**READY TO FEED,
STABLE UP TO
4 WEEKS**

Reduce development times and ensure process consistency

Success in biologics development and manufacture is highly dependent on determining optimal culture conditions – in particular the quality and content of the growth and feed media.

The BalanCD platform of cell-specific growth media and feeds has been developed to avoid many of the challenges faced during cell line development through process optimization and into commercial production. These serum-free, chemically-defined media and their supplements ensure process consistency by utilizing a common media backbone. Beginning with the BalanCD medium best suited for an application reduces development and optimization times, rapidly achieving the required yield and quality of end-product.

Transition smoothly into to commercial production

Irvine Scientific products and services are developed according to the highest medical standards. Every BalanCD product is subject to stringent Quality Systems unrivalled in the industry. To fulfill quality and reliability requirements, proprietary and customized media are manufactured under fully cGMP compliant conditions in dedicated animal-component free facilities. Comprehensive documentation, including information from Supply Chain Management through to Drug Master Files, is available to help minimize the regulatory burden.

Be sure of rapid, uninterrupted deliveries

State-of-the-art facilities in California and Japan provide replication of media manufacture and Quality Systems and offer a responsive, flexible production capacity.

cGMP compliant
manufacturing
FDA-regulated
ISO13485 certified
EN 13485:2012 certified

Ordering information

ITEM	CATALOG #	SIZE*	ADDITIONAL INFORMATION
BalanCD CHO Feed 4, powder	94134	1 L	Chemically-defined, animal-component free formula Drug Master Files submitted to US FDA
	94134	10 L	
BalanCD Growth A, liquid	91128	1 L	
BalanCD Growth A, powder	94120	10 L	

*Custom sizes and packaging available on request

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