

VACCINE PRODUCTION PLATFORM BASED ON BHK-21 CELLS

Simple, reproducible, scalable.

High virus production in large scale stirred tank bioreactors with BHK-21 cells in a synthetic medium.



One platform for production of many viruses – no repetitive media and process development.



BENEFITS

Developed to maximize virus production with BHK-21 cells. The platform consists of several modules which are integrated to each other and finetuned for maximal virus production in large scale stirred tank bioreactors.

One platform for many viruses: One cell bank, one medium, one bioreactor setting for all viruses you wish to produce. No repetitive media development and process development necessary.

Scalable: Scalability is demonstrated from shake flask to stirred tank bioreactors.

Simple: Ideal from bench to manufacturing scale.

Highest regulatory quality: No risk for animal derived contaminants in culture media or cell bank.

High reproducibility: Minimal human interference into the process, thus highly reproducible.

PRODUCT INFORMATION

BHK-21 platform is developed for maximal animal or human virus production in large scale bioreactors in an economical way.

Cells and media are developed for maximal viral infection and replication in suspension BHK-21 cells in serum free environment. The platform is dedicated for production of for example, foot and mouth disease or rabies virus.

If basal medium is combined with the specific feed media, viable cell concentration up to 3×10^7 /mL is achieved in stirred tank bioreactors.

Cell thaw and stock culture is implemented in shake flask. Cell expansion and virus production is performed in stirred tank bioreactors in batch or fed-batch process.

BHK-21 PLATFORM MODULES

THE BHK-21 CELL LINE

The cell line is obtained from Public Health of England and adapted to serum free suspension growth. Cell line is further adapted to resist high shear forces in large scale stirred tank bioreactors. Fully adapted suspension cells are frozen in serum free, animal component free media. Long term cell bank stability is proven over years in performance testing. Cell bank history and development reports are part of cell bank delivery package for high regulatory acceptance.

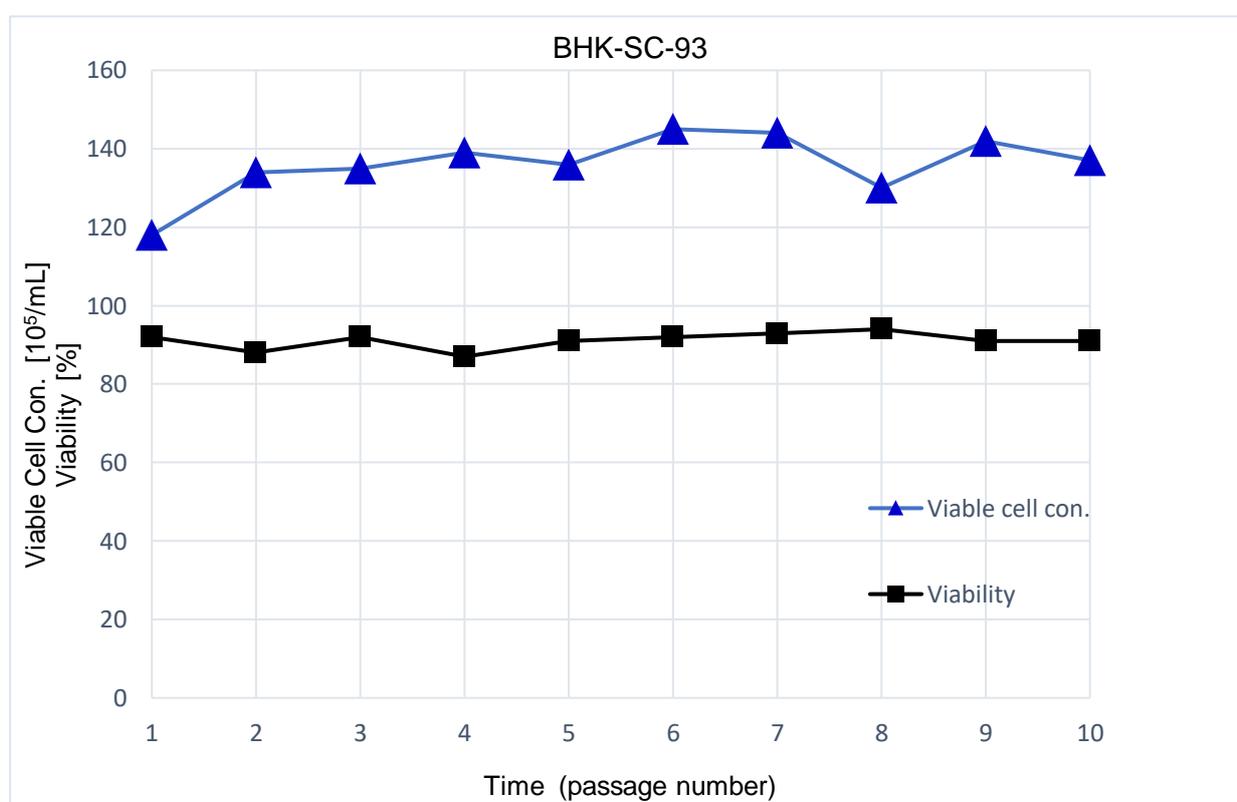


Figure 1: BHK-21 suspension cells are cultured in stock culture in shake flasks in ROSE culture medium for 10 passages (30 days). Shake flasks were inoculated with a cell concentration of 3×10^5 /mL and cultures were splitted every third day.



ROSE - BHK-21 CULTURE MEDIA AND FEEDS

ROSE medium is free of serum, animal components, growth factors and hydrolysates. The medium is developed for maximal virus and recombinant protein production in suspension BHK-21 cells. If combined with ROSE FEEDs the media supports a viable cell concentration up to 3×10^7 /mL. Suspension BHK-21 cells have been carried for more than 3 years in ROSE medium with no loss of viability.

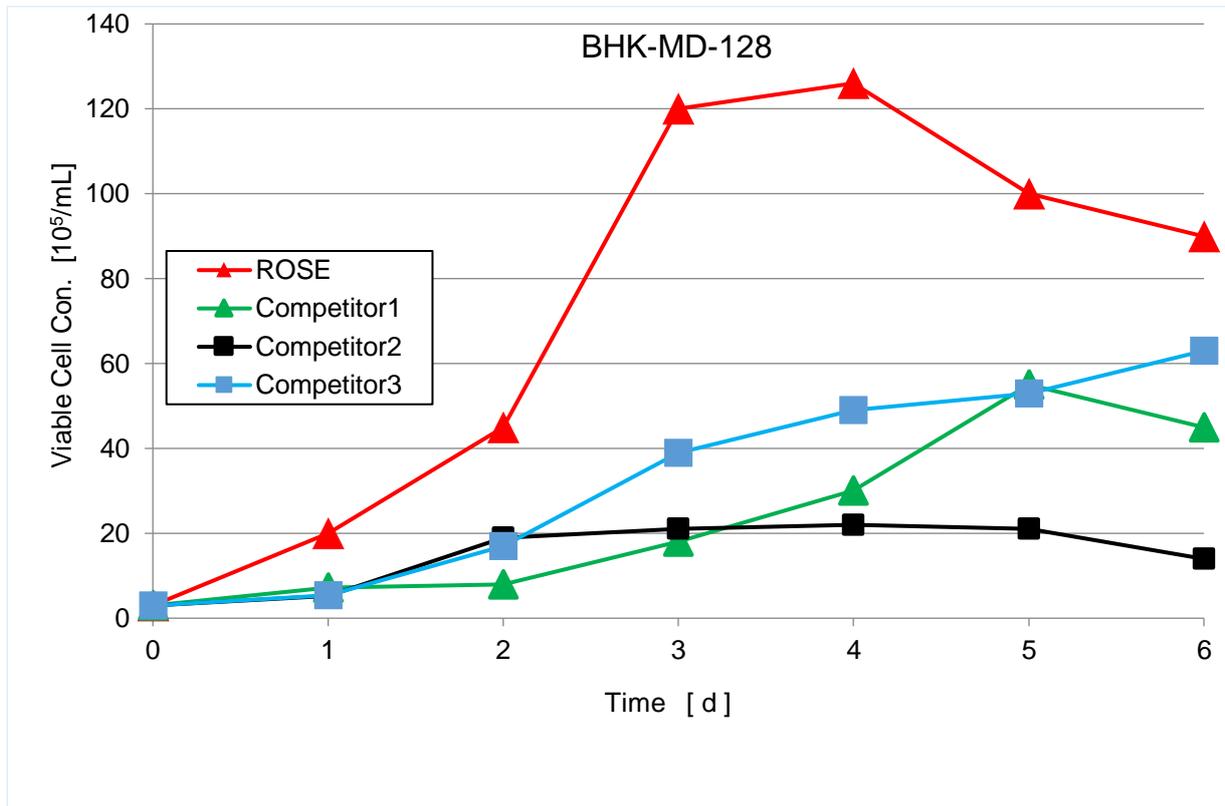


Figure 2: Growth performance of BHK-21 suspension cells in commercially available media. Cells are adapted to corresponding media for 4 passages before testing the growth performance. Experiment is performed in batch in shake flask.

BHK-21 BIOREACTOR PROCESS

A whole process is developed starting with cell thaw, stock culture, culture expansion and bioreactor steps. All process steps are reproduced up to 10 times to demonstrate the robustness. The bioreactor process can run in batch or fed-batch modus depending on what is planned to produce. The process is designed for large scale. Detailed process description and support in process transfer are parts of the package.



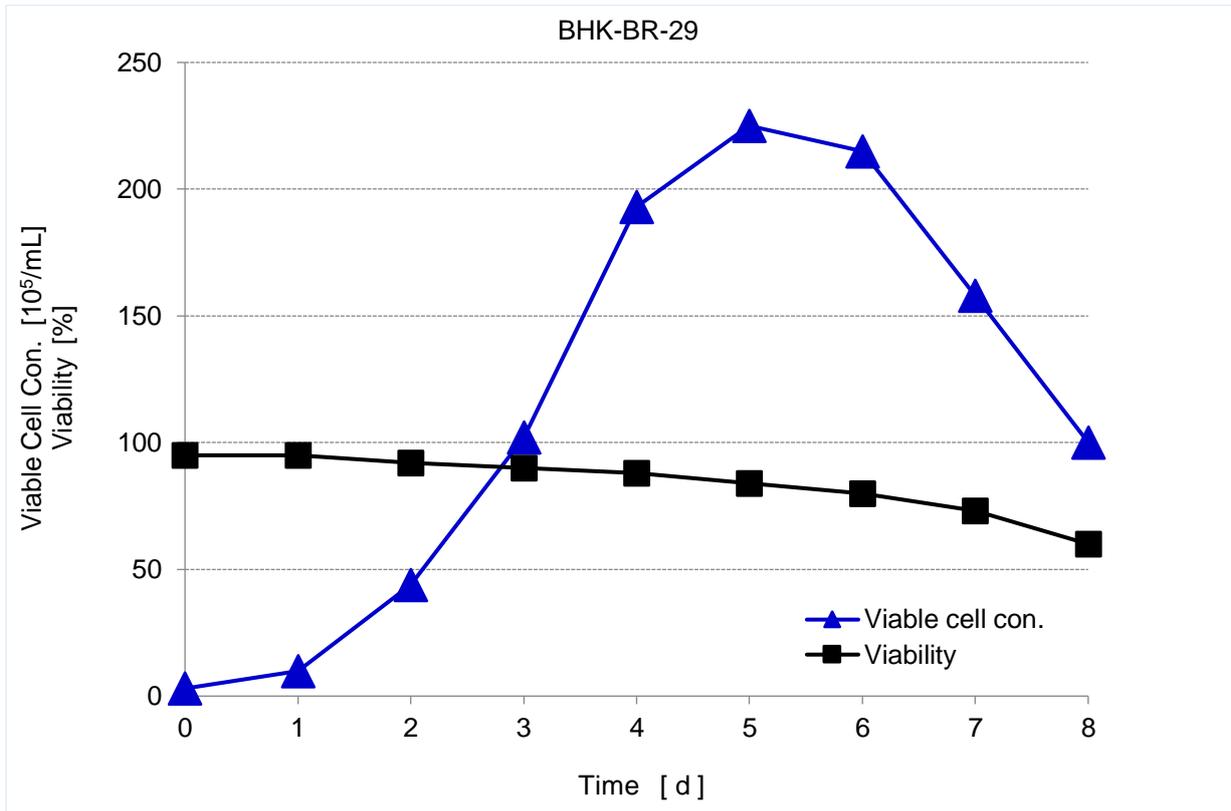


Figure 3: BHK-21 suspension cells cultured in 4 L stirred tank bioreactor in fed-batch process. Cells are cultured in ROSE basal medium and fed with ROSE FEEDs.

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