

GMP Storage of Cell and Virus Banks

The storage of pharmaceutical products and materials for their production such as cell banks (MCB/WCB) and virus banks (MVSS/WVSS) up to their point of use is a fundamental and essential aspect of the GMP Banking System. A Qualified GMP compliant storage environment protects the Cells or Virus Stocks and guarantees constant storing conditions thus ensuring integrity of the biological material over the life span of the product. GMP storage encompasses the following attributes:

- Fully qualified storage units that use a segregation policy/strategy for different biological materials
- Controlled access to storage zones restricted to authorized personnel.
- Every storage container is adequately sealed, clearly labelled and kept at an appropriate temperature.
- Storage temperature is continuously recorded and connected to a validated alarm system that triggers a 24 hr alarm call-out system whenever temperature excursions and deviations occur
- Any deviation from the set temperature limits is carefully evaluated and any corrective and preventive action taken is recorded.
- Back-up systems in the event of power failures or failures in the cooling device

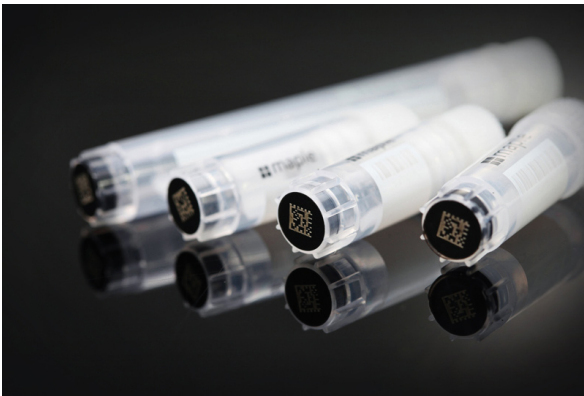


Storage in - 65 °C Freezers

Storage of virus and bacterial seed banks is performed to GMP standards using the controls detailed above. The banks are stored in fully validated -80 °C freezers (with an alarm setting at <-65°C).

Cell Banks Storage in Ultra-Low Freezers

For the storage of mammalian cell banks that require ultra-low temperatures, VirusSure offers storage in validated ultra-low deep freezers. Storage in liquid nitrogen tanks bears the risk of cross contamination, especially if the vials are stored close to or in the liquid phase and not in the vapour phase. Liquid nitrogen is known to contain low levels of microbiological contaminants, and during transport and storage can become further contaminated by ice, inanimate debris, and viable microorganisms. Furthermore, the filling of liquid nitrogen tanks must be carefully controlled, and failures of e.g. automated filling systems can result in either too little liquid nitrogen or an overfilling of the tank resulting in failure of the vapour phase storage conditions.



Because of these known risks with liquid nitrogen, an alternative strategy which avoids the requirement for liquid nitrogen completely is the use of Panasonic ultra-low freezers, which operate efficiently down to cryogenic temperatures. Such systems are fully compliant with GMP storage requirements and result in a stable and well controlled low temperature for the long-term maintenance of GMP cell and virus banks. Ultra-low freezers are also compliant with ICH Q5D: Quality of Biotechnological Products: Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products and the WHO TRS 822: Annex 2- WHO good manufacturing practices for biological products. Many companies, including VirusSure, have been storing cell banks using such ultra-low freezers for a significant period of time without any impact on viability or performance of the cells. The use of ultra-low deep freezers therefore presents a safer and more secure environment for GMP cell banks with none of the handling issues associated with liquid nitrogen.

