RECOMBUMIN®

Vaccine stabilization

The natural properties of albumin can help to overcome critical challenges in vaccine development and Albumedix rHA has been used in both marketed vaccines and a range of clinical and pre-clinical programs. rHA can protect from shear stress, prevent surface adsorption and provide thermal stability to sensitive vaccines.

PROVIDING SOLUTIONS THROUGHOUT THE VACCINE PRODUCTION PROCESS

- Readily coats surfaces and prevents non-specific adsorption of sticky vaccines during DSP and final formulation
- Prevents aggregation formation during DSP and final formulation
- Protects fragile particles from shear stress during processing
- Stabilizes vaccines during freeze and thaw
- May increase long-term stabilization and improve cold chain process

INCREASE LONG-TERM STABILITY & IMPROVE COLD-CHAIN PROCESS

As the development of a COVID-19 vaccine has highlighted, getting viable vaccines to patients is not only about their manufacture but also the critical challenges with supply chain which especially more novel vaccines such as mRNA vaccines pose.

We have optimized nature’s own stabilizing and provide a rHA product that may improve this process significantly.

CASE EXAMPLE IMLYGIC®:

IMPROVING HSV VECTORS WITH ALBUMIN

Problems: Stability, Storage and handling
- HSV Vector is very sensitive to temperature changes, unstable when stored at temperatures higher than -80°C.
- Must not be exposed to ambient temperature for longer than 60 seconds.
- This translates in operational challenges leading to an increase of costs across manufacture, storage and transportation.
- Must only be thawed immediately before use and only draw into syringe immediately prior to administration.

Solution: Each rHSA grade had different levels of purity and other components intended to stabilize rHSA. The three grades from Novozymes (now Albumedix) (Alpha, Abix and Prime) were of significantly higher purity. The Novozyme rHSA grades provided greater stability than the Sigma grade, but there was no difference between the Novozyme rHASAs.

CUSTOMER CASE STORY

Recombbumin® is used in the manufacture of Merck’s M-M-PR® II and ProQuad® vaccines for immunization against measles, mumps, rubella, and varicella virus infections in children 12 months through 12 years of age.

Consequently, a very high level of safety was imposed by the regulatory authorities for this product.

As each dose contains up to 0.5mg of albumin, Merck decided to incorporate Reombumin® in the M-M-PR® II vaccine in 2006.

Albumedix recombinant human albumin (rHA) products are manufactured at cGMP ICH Q7 standards at our own manufacturing site in Nottingham, UK. The products are produced using a proprietary yeast strain (Saccharomyces cerevisiae) with very high batch-to-batch consistency. We have more than 25 years of manufacturing experience.

PwC Health Research Institute

Developing a COVID-19 vaccine may not be enough.