Exbumin™

Guidelines for Use

Exbumin™
Recombinant Human Serum Albumin
Approved for use as an excipient by EMA and FDA
Blood-Free/Animal-Free
Made in USA
cGMP

Introduction
Exbumin® stabilizes virus and other biologics such as vaccines, gene therapies and whole-cell therapies in final formulation and during manufacturing. It is a lyophilized animal component free (ACF) recombinant human serum albumin (rHSA). Exbumin® is used as a media component to improve viral titer during inoculation and as an excipient added to final formulations to enhance viral stability prior to injection.

Exbumin® is regulatory friendly and has been shown to be safe in more than 250,000 human injections. Both the EMA and FDA have approved the use of Exbumin® in final formulations of injectable biologics and have approved biologics that incorporate Exbumin® in the manufacturing process. Due to its recombinant DNA manufacturing method, Exbumin® does not have donor-to-donor variability or risk of human or bovine adventitious agent contamination compared to blood-derived products. Exbumin® is cGMP and manufactured in an ISO9001:2015 certified facility. Exbumin® is manufactured in the USA and is available for distribution worldwide.

Figure 1 demonstrates the results after the addition of Exbumin® to virus-producing cultures. As expected, Exbumin® enhanced the production of an influenza virus over unsupplemented cultures. Thus, Exbumin® recombinant albumin is an attractive and cost-effective alternative for virus stabilization compared to using human serum-derived albumin.

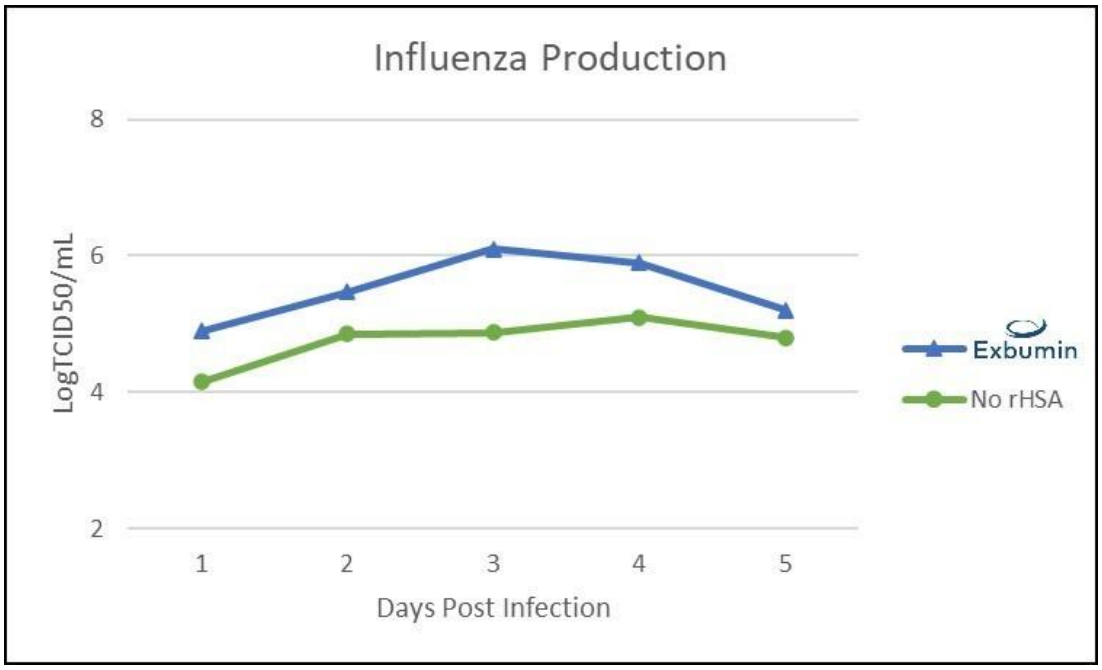

Figure 1. Enhanced virus production in cell cultures supplemented with Exbumin®. *VERO cells were allowed to adhere on microcarrier beads and expanded in spinner flasks. Cells were subsequently infected with an influenza virus and the culture medium was partially exchanged for the same formulation with and without Exbumin®. Culture samples were obtained every day and the pH of the cultures were maintained between 6.8 and 7.2 by the addition of NaOH. Agitation of the cultures was kept constant throughout the process. The effect of Exbumin® addition to the cultures was beneficial to viral titers.*

Storage

Recommended storage at -20°C, tightly sealed, and protected from light.

Instructions for Use

To prepare concentrated liquid stocks of Exbumin®, gently dissolve Exbumin® powder in cell culture grade DPBS, PBS, or basal media to between 50-100mg/mL. Use gentle mixing or inversion to minimize the formation of bubbles. Allow Exbumin® to completely dissolve overnight at 4°C in a dark environment. Liquid stocks should be sterile filtered prior to use. To sterile filter, a pre-filtration step with a 0.8µm filter is recommended prior to final sterile filtration with a 0.2µm filter. Liquid solutions should be stored at 4°C in the dark and are stable for 4 weeks after solubilization.

Virus Stabilization During Manufacturing

Exbumin® inclusion between 2-30mg/mL is found to be effective for virus stabilization during viral production. However, different virus types and cellular substrates will have optimal inclusion levels of Exbumin ® to enhance virus titer and should be empirically determined. Once the cells have reached the desired confluency, initiate virus production by transfecting with plasmid DNA or infection with the virus to be expanded (See OptiVERO 2D Virus Expansion Application Note). Once the infection/transfection media has been removed, exchange the media for virus production media of choice containing 2-30mg/mL Exbumin®. Perform the virus production run and harvest with Exbumin® incorporated with virus product.

Formulation Excipient Guidelines

Exbumin® inclusion between 1-50mg/mL is reported to be effective in final formulation excipient use. Optimal inclusion levels of Exbumin® will depend on characteristics of the formulation and manufacturing process and needs to be empirically determined in each case. Exbumin is soluble in water and common buffers such as DPBS and PBS at a wide range of concentrations (See Exbumin® Reconstitution Application Note). Below are suggested inclusion ranges based on the type of application:

Formulation Excipient Guidelines

Application	Inclusion (mg/mL)
RNA Virus Formulation	2-30[1][2]
DNA Virus Formulation	10-50[3]
Cell Therapy Formulation	20-50[4][5]
Therapeutic Protein/Antibody Formulation	1-10[6]

Exbumin® Application Notes

Stabilizing Virus with Albumin to Improve Yield

Exbumin® References

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