

Animal-free recombinant Proteins



Using animal-free proteins and antibody products has been a new trend in the field, especially since the U.S. Senate unanimously passed the "FDA Modernization Act 2.0" on September 29, 2022, which amended the FDA's regulatory guidance on animal testing of drugs and bio-similars. More and more researchers are now incorporating ethical considerations into the design and conduct of their research involving animals, and they are looking for ways to replace, reduce, and refine the use of animal models in research^[1].

What are animal-free recombinant proteins?

Animal-free means that neither the raw material nor the production process involves animal components. Thus, proteins produced under animal-free conditions using standard laboratory techniques are animal-free recombinant proteins[2].

The production process requires two preparation steps. First, the culture system for prokaryotic and eukaryotic cells are modified to enable a culture process without peptone and bovine serum. Then, specialized laboratory vessels, fermenters, filters, and lyophilizers are constructed to ensure that there are no trace amounts of animal proteins or mammalian pathogens present.

Why are animal-free recombinant proteins needed?

Recombinant proteins require eukaryotic or prokaryotic cells for expression, and the medium for culturing cells needs to be supplemented with animal-derived ingredients such as tryptone. This procedure inevitably mixes the recombinant protein products with many known or unknown animal ingredients, which causes the following potential risks:

- . Transmission of animal pathogens (e.g., mad cow disease virus and other unknown pathogens)[3].
- · Allogeneic rejection or allergic reactions in humans and animals.

	Animal-free Recombinant Proteins	Traditional Recombinant Proteins
Species	Human, Rat, Mouse	
Expression System	E. coll, Eukaryotic cells	
AA Sequence	Same	
Biological Activity	Same	
Pros	Compared with traditional recombinant proteins, animal-free recombinant proteins have the following advantages. No introduction of animal-derived pathogens into the culture system No xenoblotic rejection or allergic reactions in animals or humans No ethical and moral issues	

What kind of study needs to be animal-free?

- Clinical and pre-clinical studies with the potential to enter clinical trials.
- Studies that require defined culture conditions are particularly concerned with experimental variables caused by trace animal components or mammalian. Studies in which there are concerns about animal-derived ingredients due to ethical issues.
- In conclusion, when possible it is better to use animal-free recombinant proteins for applications such as cell therapy and in vivo experiments using animals.

Cat. No.	Product Name	Classification
HY-P73052AF	Animal-Free FGF-2, Mouse	FGF Family
HY-P7044AF	Animal-Free IL-6, Human	Interleukin & Receptors
HY-P700084AF	Animal-Free GDNF, Human	TGF-beta Superfamily
HY-P700033AF	Animal-Free BMP-9/GDF-2, Human	TGF-beta Superfamily
HY-P700051AF	Animal-Free EGF, Human	EGF Superfamily
HY-P700178AF	Animal-Free G-CSF, Mouse	CSF & Receptors
HY-P700143AF	Animal-Free Noggin, Human	Cytokines and Growth Factors
HY-P70426AF	Animal-Free TNF-alpha/TNFSF2, Human	TNF Superfamily

References:

[1] FDA Modernization Act 2.0.

[2] Nat Biotechnol. 2020 Nov;38(11):1234-1239.

[3] J Toxicol Environ Health A. 2009;72(17-18):1096-105.