



2014

Sera Report



INSTITUTO BIOLÓGICO ARGENTINO S.A.I.C.



According to the WHO the snakebite envenoming is a common but neglected public health problem, especially in the poorest rural regions of Africa, Asia and Latin America.

“The only validated treatment for these bites is passive immunotherapy with safe and effective animal-derived antivenoms”¹

Notwithstanding this global situation **the development of Antivenoms is far below the real needs of many developing countries.**

Due to economic issues a large part of the first centers destined to the production of Antivenom serum have closed their doors while others were privatized.

The **Antivenom Serum is a biological product** with a complex manufacturing process and requires several steps, including:

- Hyperimmunization of Horses
- Blood collection and plasma separation
- Mixture of raw plasma
- Digestion of immunoglobulins with pepsin
- Globulin Purification
- Purified bulk concentrate sterilization
- Concentrate dilution
- Lyophilisate
- Packaging



***Bleeding and collection
of plasma***



***Ultrafiltration System
for tangential ultrafiltration***



Reactors for purification

Furthermore, a major investment in facilities, highly trained personnel with experience in the production of biological products and maintenance of healthy blood-donor animals is also necessary.

In **1998** we launched our **first polyvalent lyophilized antivenom serum** in the Argentinean market. This product joined a number of heterologous equine sera already marketed by the company, such as **tetanus toxoid, diphtheria antitoxin and antivenom in its liquid form.**

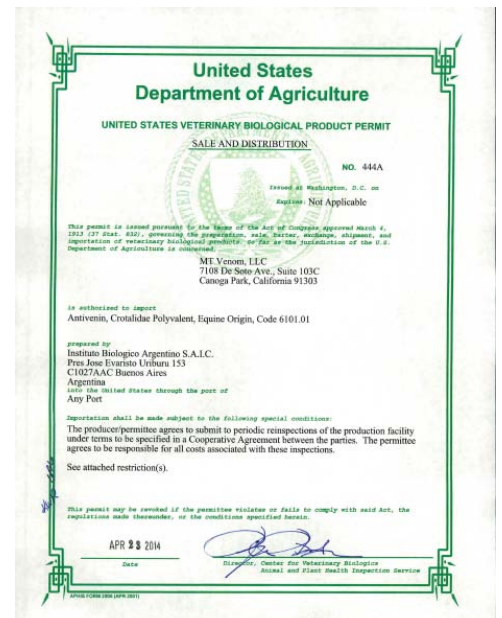
The presentation of the **lyophilized antivenom serum** was developed to allow the **conservation outside the cold chain** which provides a significant benefit for those users who develop business or tourist activities in areas where accidents are likely to happen and its refrigerated storage cannot be assured.



The development of a series of regional antivenoms, now marketed in several countries in Latin America and which are specific against the snakes for each region, was possible thanks to the technology platform for producing heterologous lyophilized sera, the knowledge acquired by our technicians in production and biological control, and the importance that the Latin American markets have gained.

Over recent years we have made great progress in the development of this product:

- **NEW SEGREGATED PLANT:** We built a new plant segregated from production of heterologous sera for the domestic and the international market
- **DEVELOPMENT OF SPECIFIC FORMULATIONS**
 - VENOM FOR HUMAN USE:** We developed a specific formulation for the Amazon Region and Central American Region.
 - VENOM FOR ANIMAL USE:** In 2014 we gained the registration for the Exportation of VENOM VET product (Antivenom Serum for Animal use) for the United States.
- **OWN BIOTERY:** We have our own biotery certified by ISO 9001/2008 where animals are bred and kept for the realization of quality controls related to the product.
- **NATIONAL AND INTERNATIONAL AUDITS:** Our products and facilities are being audited by ANMAT (Argentina) and by USDA (United States).



Nowadays we export antivenom serum to the following countries:

- Belize
- Paraguay
- Bolivia
- Nicaragua
- Guatemala
- Honduras
- Ecuador
- United States (for animal use)



We are also in advanced stages of registration in Peru and Panama

Our goal is to conquer new markets and position ourselves as leaders in the region with a high quality biological product.

We have the support of our partners in each country in order to move to the next stage related with the increase and optimization of the production in order to supply the various markets promptly and efficiently.

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