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Plasma proteins matter a lot for India

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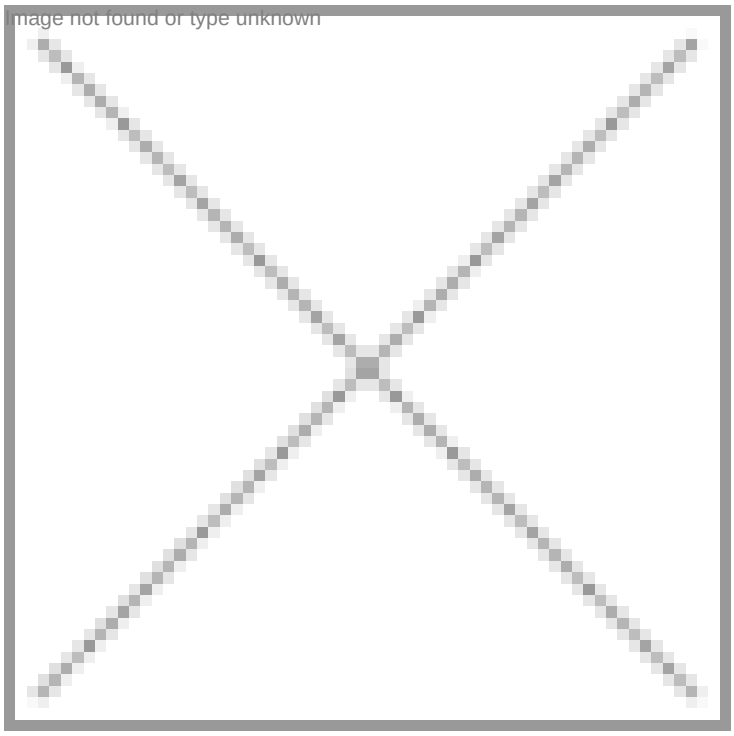
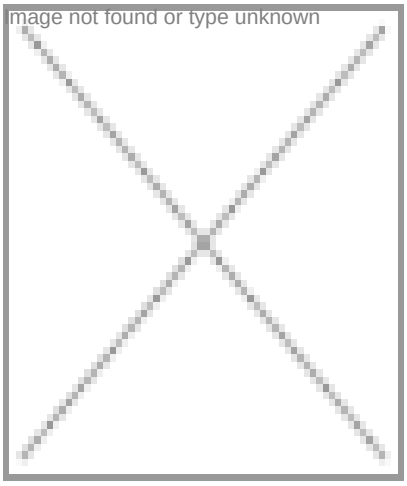
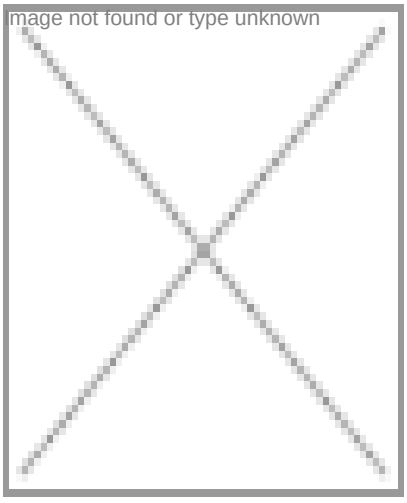


Plasma proteins matter a lot for India

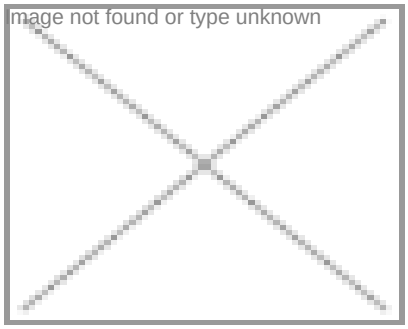
AlbuRel is a Plasma Volume Expander (PVE) used to increase the circulating plasma volume in blood. Albumin is the most abundant protein in human plasma and is synthesized by the liver. Dialysis, burns, cerebral oedema, cirrhosis of the liver are some the many indications where Albumin preparations can be used. It is available in 20%, 5% concentrations in 100 ml and 50 ml pack sizes.



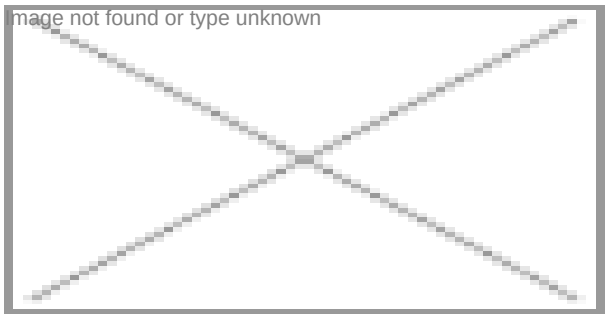
ImmunoRel is a solvent/detergent treated, sterile preparation of chromatographically purified immunoglobulin G (lgG) derived from pooled human plasma. The US Food and Drug Administration (USFDA) has approved IVIG for the use of primary immunodeficiences, Kawasaki disease, immunemediated thrombocytopenia, chronic B-cell lymphocytic leukemia, pediatric HIV Type 1 infection and haematopoietic stem cell transplantation in patients older than 20 years of age (Gamimune-N only). The normal immunoglobulin
is meant for intravenous use. ImmunoRel is available in 5% concentrations in 100 ml and 50 ml pack sizes.



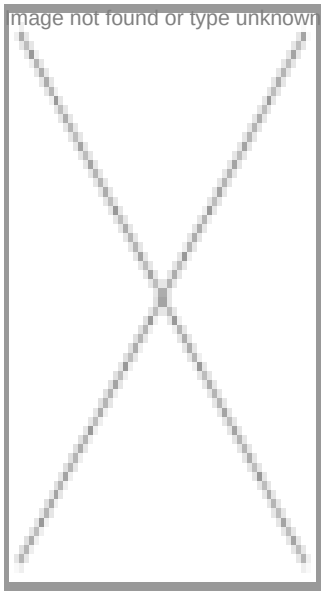
ReliSeal is a biological glue and hemostatic agent, which can be used in a variety of surgical procedures to arrest bleeding, seal tissues and as an adjunct to wound healing. A quick acting surgical fibrin sealant derived from human blood plasma, with hemostatic sealing and adhesive properties, ReliSeal mimics the final stage of the natural clotting mechanism. The kit is available in 1 ml pack size.



HemoRel A is a clotting factor VIII 250 I.U. preparation. It is indicated for replacement of Factor VIII in blood in patients in whom deficiency of Factor VIII activity is demonstrated i.e. patients diagnosed with Hemophilia A. Factor VIII replacement is the therapy of choice for clotting disorder in Hemophila A. The product pack is user-friendly and includes one 20 ml syringe, 2 needles, water for injection, syringe filter and spirit swab. It is administered by slow intravenous injection after reconstitution in 15 ml sterile water.

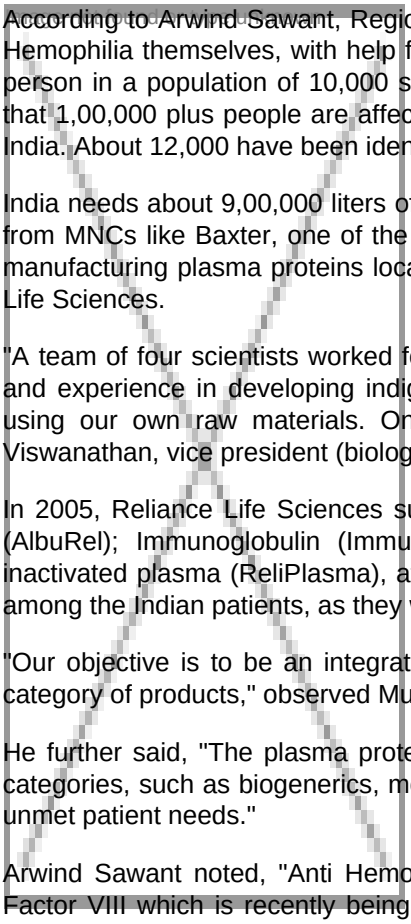


ReliPlasma is a pooled viral inactivated plasma for transfusion and is a safer substitute for fresh frozen plasma used for plasma protein replacement therapies. It is available in 100 ml bags in A, B, O and AB blood groups. ABO compatibility is a must for administration of ReliPlasma. It is safe due to the virus inactivation technology used in its production. It is the only brand of solvent detergent treated plasma in the country and does not require replacement donation.



As per a market research bureau survey, the glo- bal plasma sales for the year 2005 was estimated at $6.9 billion dominated

mainly by five players-CSL Group, Baxter, Talecris, Grifols and Octapharma. These five account for over 60 percent of the global plasma sales.



According to Arwind Sawant, Regional Manager (West), Hemophilia Federation (India), a self-help NGO run by persons with Hemophilia themselves, with help from medical fraternity, the prevalence of Hemophilia is the same all over the world, i.e. 1 person in a population of 10,000 suffers from Hemophilia. India having a population of more than 100 crore, it is estimated that 1,00,000 plus people are affected with Hemophilia. Unfortunately 25 percent of the world Hemophilia population lives in India. About 12,000 have been identified by us till now and registered with Hemophilia Federation (India).

India needs about 9,00,000 liters of plasma proteins per year as per WHO estimates. India has been sourcing these proteins from MNCs like Baxter, one of the major suppliers of plasma proteins in the world. India has the market potential to look at manufacturing plasma proteins locally. But due to various factors no company has looked at this huge market until Reliance Life Sciences.

"A team of four scientists worked for over three years on developing indigenously the plasma proteins. We have knowledge and experience in developing indigenously the plasma products by sourcing raw materials from the US, Europe and also using our own raw materials. On the technology front, we have the IP for these plasma proteins," said Dr Chandra Viswanathan, vice president (biologics), Reliance Life Sciences, who led the team in the development of plasma proteins.

In 2005, Reliance Life Sciences successfully launched its indigenously developed first set of five plasma proteins-Albumin (AlbuRel); Immunoglobulin (ImmunoRel); Anti Hemophilic Factor VIII (HemoRel); Fibrin Sealant (ReliSeal) and Virus inactivated plasma (ReliPlasma), at 30-40 percent lesser cost compared to the imported ones. This will bring in some cheer among the Indian patients, as they will now be able to receive the blood proteins at competitive price.

"Our objective is to be an integrated global biotechnology player and the first stop in this direction is the plasma proteins category of products," observed Mukesh Ambani, Chairman and Managing Director, Reliance Industries Ltd.

He further said, "The plasma proteins range of products from Reliance Life Sciences will be followed by products in other categories, such as biogenerics, monoclonal antibodies, novel recombinant proteins and siRNA molecules, aimed at meeting unmet patient needs."

Arwind Sawant noted, "Anti Hemophilic Factor is the lifeline of hemophilics and is not manufactured in India (Except for Factor VIII which is recently being manufactured by Reliance Life Sciences) and at present, we are importing from Baxter USA. We import factor VIII & IX. Since the cost is high, we are giving it at a subsidized rate of Rs 5.50 to Rs 6 to hemophilics. In the open market, Factor VIII is available at Rs 10 to 12. Factor IX is not available in the open market freely."

On making the plasma proteins available at affordable prices, KV Subramaniam, president, Reliance Life Sciences, said, "These are indigenously developed proteins. There is no tech transfer involved. Even the scaling up has been done at our state-of-art facility. Moreover, it is our objective to offer the quality products at an affordable price to the patients."

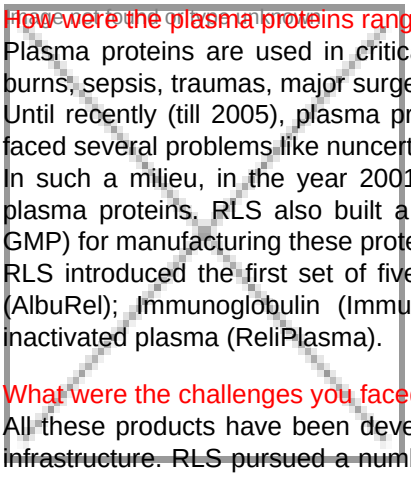
He continued, "At present our facility is equipped to produce 1,20,000 liters of plasma proteins per year. We are working on expanding the facility five-fold so that we can meet the unmet needs of the Indian patients and also patients from abroad."

Sharing her views on the product reach, Medha Dhargalkar, vice president, business development, Reliance Life Sciences, said, "We were able to serve about 50,000 patients on an annual basis by reaching out to 10,000 doctors in India by offering the first set of five plasma proteins. We wish to reach out to five times of the present patient reach in the coming years."

"The Award came as a surprise to us as we never expected this. However, compliments will encourage us to move ahead. We feel that it's beginning in the right direction," a delighted Dr Chandra Viswanathan said.

Narayan Kulkarni

"Plasma proteins are indigenously developed, leading to import substitution"



How were the plasma proteins range of products conceived?

Plasma proteins are used in critical life-saving conditions and situations such as Guillain Barre Syndrome, liver cirrhosis, burns, sepsis, traumas, major surgeries and clotting factor deficiencies.

Until recently (till 2005), plasma proteins were almost entirely imported into India. Patients in dire need of plasma proteins faced several problems like nuncertainty in availability, short expiry of imported products and high price.

In such a milieu, in the year 2001, Reliance Life Sciences (RLS) embarked on indigenous research and development of plasma proteins. RLS also built a pilot scale facility in Mumbai, compliant with Indian and international standards (WHO-GMP) for manufacturing these proteins indigenously. This is the only facility in India manufacturing these proteins.

RLS introduced the first set of five plasma proteins from the year 2005 in the market place. These proteins are: Albumin (AlbuRel); Immunoglobulin (ImmunoRel); Anti Hemophilic Factor VIII (HemoRel); Fibrin Sealant (ReliSeal) and Virus inactivated plasma (ReliPlasma).

What were the challenges you faced during the development phase of each of these products?

All these products have been developed indigenously and the major challenge was in building the basic competencies and infrastructure. RLS pursued a number of developmental activities rights from identifying and getting on board the right set of competencies, instituting a rigorous quality assurance and quality control program, building a GMP compliant manufacturing facility, instituting appropriate molecular testing for viruses and incorporating viral inactivation technologies.

Tell us about the team that developed these products.

The team that RLS brought together under the leadership of Dr Chandra Viswanathan encompasses competencies in research, animal testing, manufacturing, quality assurance, quality control, validation, project management, product development and business development. The team was highly motivated with the mission of meeting unfulfilled patient needs and looks forward to developing many more products in this domain.

How have these products made a difference to the country?

These products are indigenously developed, leading to import substitution. Patients can get them at a short notice. Patients can be sure of the quality since it is coming from Reliance. Also, these products are 30-40 percent cheaper when compared with international price points for similar quality products.

What are the USPs of these products and the market potential in India and abroad?

The salient features of this indigenous research, development, commercial manufacture and clinical use are:

- Virus inactivated plasma introduced for the first time in India. This product, based on solvent detergent treatment process, developed by RLS, assures safety from transfusion transmitted infections such as HIV and Hepatitis B or C, which are critical issues in patient management.
- Fibrin Sealant introduced for the first time in India.
- Product safety with PCR screening at every major stage of production from raw materials to final product.
- Each and every batch of these products manufactured by RLS is released by the National Institute of Biologics (NIB), the governmental arm that is responsible for ensuring quality.

At what competent price range are these available in the market in India against the existing products in the market?

The product prices are typically 30 to 40 percent lower when compared to imported products from multinational companies.

What are the future plans of Reliance Life Sciences in product development in the area of life sciences and biotechnology?

RLS is now building a larger scale plasma protein manufacturing facility compliant with USFDA and EMEA standards. This facility would be operational in the second half of the year 2007. This facility would not only fully meet India's requirement, but would also cater to the needs of other geographies. RLS is also working on a range of specialty plasma proteins.

When can we expect the next range of products from Reliance Life Sciences?

Our scientists are working on recombinant therapeutic products, stem cell therapies, specialty plasma proteins, monoclonal antibodies, and also siRNA molecules. And we are hopeful of making them available to the patients by launching about eight products during the next financial year.