

Analysis of market trend of Human Albumin and Coagulation factors in India

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Abstract

The present study has been conducted at National Institute of Biologicals (NIB), NOIDA to analyse the status of Human Serum Albumin (HSA) and other human plasma derived products and their availability in Indian market. The samples of albumin, human coagulation factor VIII and factor IX, both indigenously manufactured and imported, which were received in the Institute during financial years FY 2012-13 to 2017-18. The present study showed that there was no change in the number of indigenously manufactured HSA samples received in 2013-14 and 2014-15 afterwards the data showed gradually decline in viz. of 29% in the 2015-16 and further by 84% in 2016-17. It was observed that there is a gap between supply and demand of plasma fractionation products as most of them are imported. The non-availability of quality domestic plasma fraction has led to dependence on imported plasma for production of indigenously manufactured plasma products. Strong reforms in regulations and Health Policies within the country as well as globally is the key to address the situation and achieve the target of self-sufficiency in indigenous production of plasma based medicinal products.

Keywords: Human serum albumin, Factor VIII, Factor IX, Plasma fractionation products.

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1. Introduction

Human serum albumin is the most abundant plasma protein which acts as a carrier protein synthesized in liver. HSA has high molecular weight (66,500 Daltons) and it accounts for 50% of total plasma protein.

The macro-molecular structure and ligand binding capacity of albumin enables it to maintain the plasma osmotic pressure. It can bind to therapeutic compounds and toxins present in the circulatory fluid, and help in their transport. It is also useful for the treatment of haemolytic disease by lowering bilirubin content present in plasma [1].

Factor VIII, on the other hand, is an important blood coagulation glycoprotein and enhances the catalytic efficiency of other components in blood coagulation system.

It has been widely used for the treatment of Haemophilia and other bleeding problems [5].

Similarly factor IX is also a key component of blood coagulation system and plays an important role in maintenance of haemostasis [6].

The major market of human serum albumin is expanding in India and other Asian countries with the global rise in blood plasma fractionation industry. After closing down of various plasma fractionation facilities functional during 1990s a unit was established in Ahmedabad by a collaborative effort of Celestial biologicals, an associate of Intas pharmaceuticals and GE healthcare Biosciences Ltd in 2009 [2].

A short supply of life saving drugs such as HAS, Immunoglobulin was reported after their price was cut by regulating authorities in 2013, as most of the indigenous manufacturer started to export the drugs instead of selling it in Indian market [3, 4].

Poor quality of domestically fractioned plasma has forced the manufacturers to import the plasma or send the collected plasma to foreign countries for the contract fractionation. As quoted by RS Ajmani "India's production capacity is less than 1% of the total requirement of human serum albumin, factor VIII and factor IX for fulfilment of demand of evergrowing population of the country". Sadly, the increased global consumption of plasma products has already been started to hamper the supply of imported plasma to the India [13].

NIB, an Autonomous Institute under Ministry of Health and Family Welfare, Government of India is notified Central Drug Laboratory as per Drugs and Cosmetic Act, 1940 and it evaluates various biologicals and diagnostic kits, before their release in the Indian market. NIB receives the samples forwarded from Government regulatory bodies, indigenous manufacturers, State Medical Services Corporations and Drug Inspectors.

2. Material & Methods

Compiled and analysed the data of Human albumin for Coagulation Factor VIII and Factor IX for FY 2012-13 to 2017-18.

This study has been conducted to connect the available market reports to the actual data available with NIB that has been prepared by combining all the batches of albumin, factor VIII and factor IX received for their Quality Evaluation as per regulatory requirements of our country. No software was used for conducting the present study.

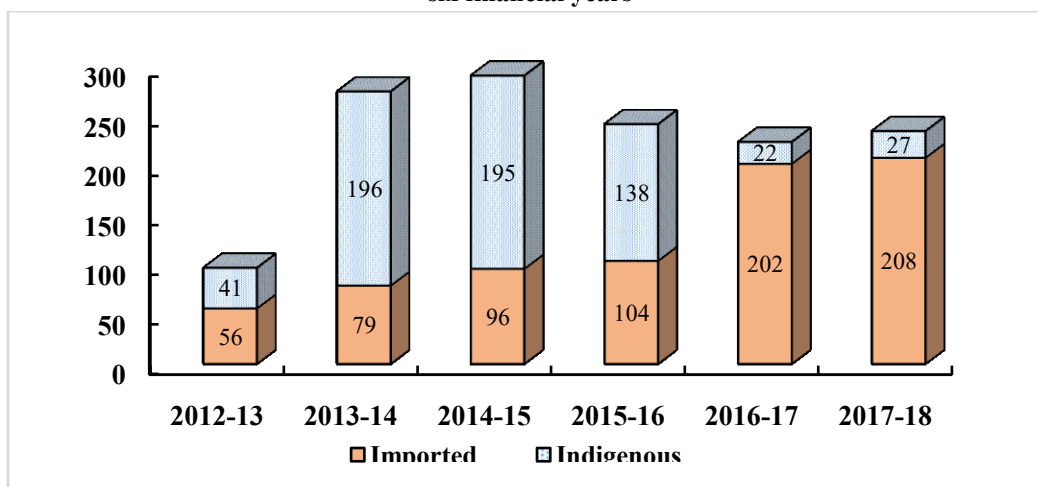
3. Results

A total of 1364 batches of indigenously and imported HAS were received in the Institute during FY 2012-13 to 2017-18. During this study it has been observed that Institute received more than 200 HSA every year from FY 2013-14 to FY 2017-18. Out of these 1364 batches 619 were indigenously manufactured and 745 were imported. In this time duration the total number of HSA samples received were 97, 275, 291 242, 224 and 235 respectively.

It has been observed that there were no changes in the seen number of indigenously manufactured HSA samples received in FY 2013-14 and 2014-15 but afterwards the data showed gradually decline viz. 29% in FY 2015-16 and further by 84% in FY 2016-17.

It has been observed that the decline found in indigenous HSA was mainly due to increase in the imported HSA during the FY 2014-15 to 2017-18 as shown in Figure 1.

Figure 1: Comparison of Human serum albumin both indigenous and imported samples received for testing during six financial years



HSA 20% is the most widely applicable albumin concentration for treatment. The trend of HSA 20% samples received in the Institute has been recorded for last six financial years (Figure 2). It has been observed that there was an increment of 180% in number of HSA samples received in the FY 2013-14 in comparison to FY 2012-13.

The samples number further increase by 14% in FY 2014-15. Interestingly, a significant decline by 29% has been seen in HSA 20% samples received in FY 2015-16 and a further decrease by 11% in FY 2016-17. An insignificant increase of 13% has been recorded during FY 2017-18 with respect to its preceding year.

Figure 2: Human serum albumin 20% samples received for testing during six financial years

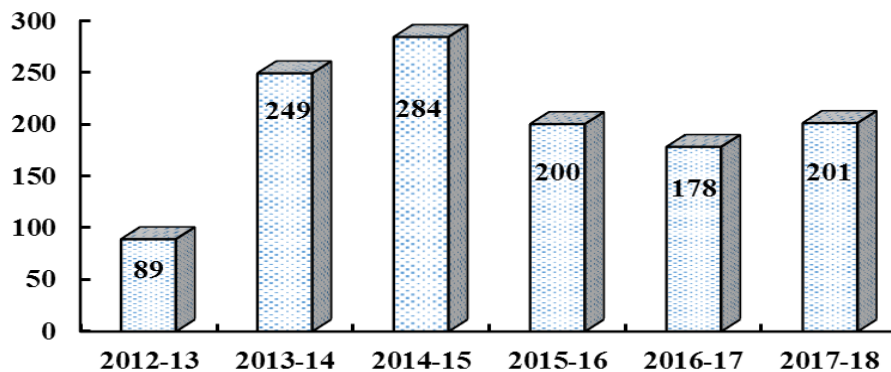
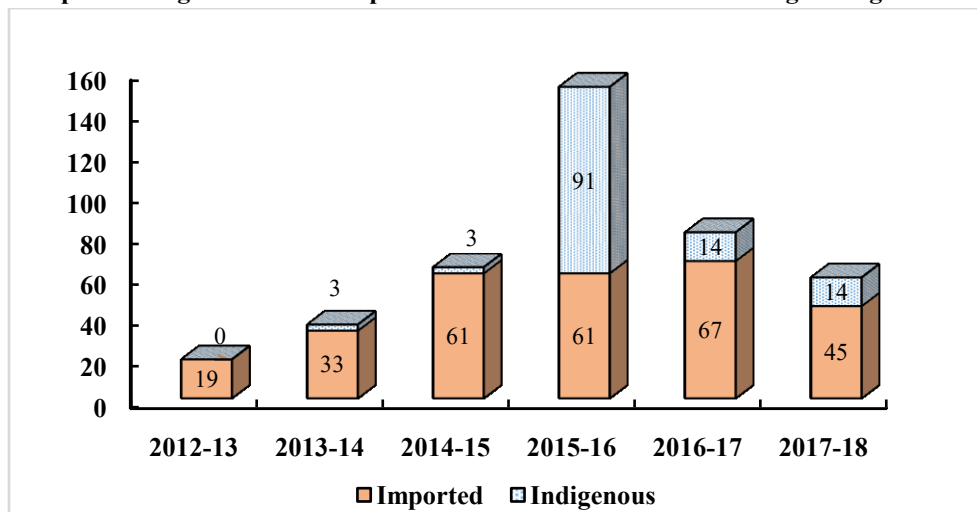


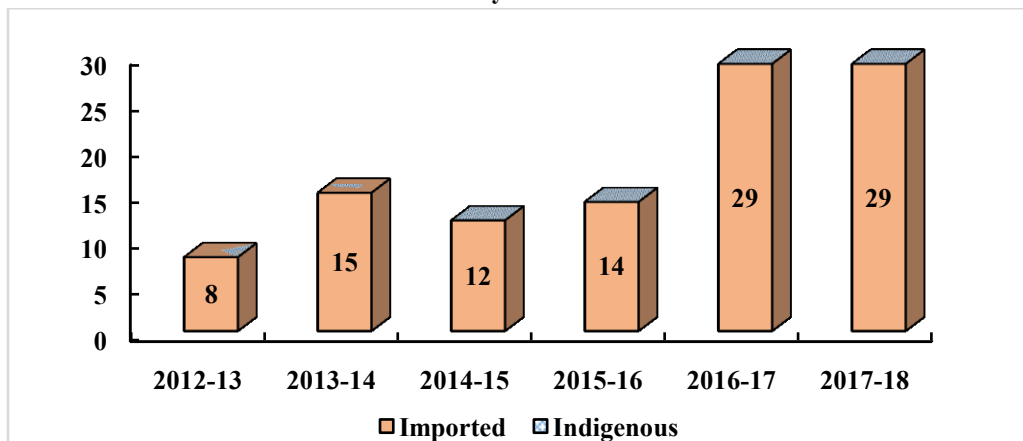
Figure 3: Graph showing number of samples of factor VIII received for testing during six financial years



The numbers of samples of factor VIII, another important product of plasma fractionation system received in the Institute has been calculated for last six financial years and shown in Figure 3. During the present study it has been identified that the number of factor VIII samples has increased 8 times from FY 2012-13 to FY 2015-16 but it further decreased consecutively by 46% in FY 2016-17 and

by 61% in FY 2017-18 respectively. The number of indigenous factor VIII sample has increased by 91% in FY 2015-16 as compared to FY 2012-13 but it decreased further by 84% in FY 2016-17 and 2017-18 respectively. The trend of factor VIII samples both indigenous and imported received was not promising at all.

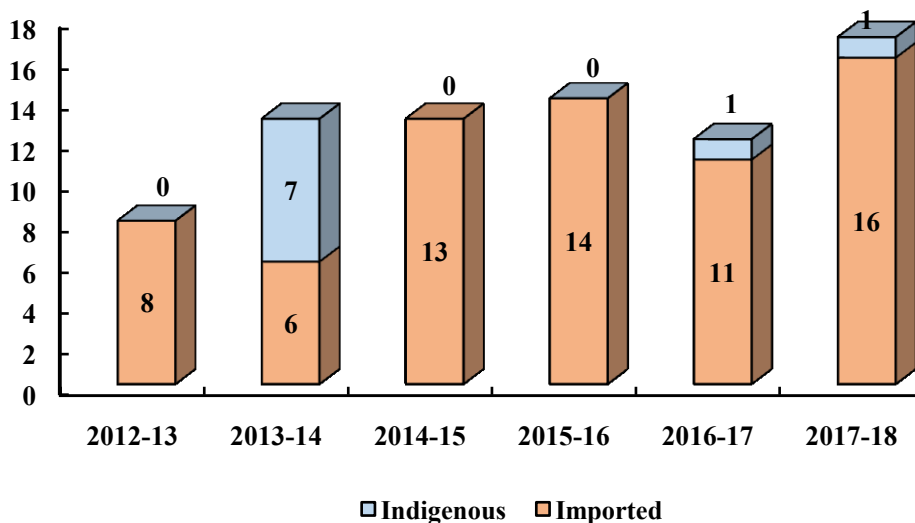
Figure 4: Graph showing number of samples of recombinant factor VIII received for testing during six financial years



The trend of recombinant factor VIII samples received in the Institute has also been analysed and it has been found that the samples have been increased by 262% in FY 2016-17 and FY 2017-18 as compared to FY 2012-13 as shown in Figure 4. Since the availability of plasma for

fractionation of factor VIII was acting as limiting condition so the number of recombinant factor VIII samples has shown a remarkable increase. It has been observed during the present study that all of the recombinant factor VIII samples received for testing were imported.

Figure 5: Graph showing samples of factor IX received for testing during six financial years



The number of samples of anticoagulant protein, factor IX received in the Institute for quality testing has been evaluated for consecutive six financial years.

It has been observed that although the total number samples of factor IX remains the same for FY 2013-14, 2014-15, 2015-16 and 2016-17, a slight increase has been noticed during FY 2017-18. The number of factor IX indigenous samples have shown sharp decline of 85% in FY 2016-17 & 2017-18 in comparison to FY's 2013-14 (Figure 5).

The present study has established the less availability of indigenous samples of factor IX in India during recent years.

4. Discussion and Conclusion

Human serum albumin is one such product among the other plasma derived biologicals, whose severe shortage in past decade has raised many concerns for public health. It had essential application in treatment of cancer, liver ailments. Albumin is a crucial lifesaving drug hence its price has been cut down to 58% by National pharmaceutical pricing authority [7].

As quoted by S. Nautiyal "after the price control it has been observed that hospitals and market of many parts of the country are facing the shortage of this vital drug. The reason behind this decline could be the less availability of imported plasma, lack of plasma fractionation facilities in

the country and reduction in price of albumin by Indian Regulatory Authorities"[8].

As quoted by Francis "It has been observed that the indigenous manufacturers are not maintaining the adequate supplies of albumin in domestic market rather they export their products for obtaining higher profits" [9].

According to several reports, 60% of the blood plasma collected in India got wasted since there were no functioning plasma fractionation facilities till 2009 as quoted by Francis [9].

Though a model was proposed in 1997 under the roof of National Plasma Fractionation Centre (NPFC), but it had been failed due to variety of reasons, mainly because it was not capable of meeting mandatory GMP (Good Manufacturing Practices) norms. It has been reported that 4,000 units of blood plasma were discarded as Biomedical Waste in 2012 [10].

To combat with the deficiency of plasma products in Indian market, the Union Health Ministry had decided to enhance the production of indigenous plasma up to 4 lakh liters till 2018 [11].

The permission has been granted by government to the Blood Banks (having separation facility) for selling plasma to fractionators under the condition that they will supply the fractioned products first to the Indian market. The blood donation practice has been significantly increased in recent years in India but this supplementary

blood has not been utilised for manufacturing of plasma products. One of the few challenges faced in this context was related to the Indian Laws that restrict the facility of source plasma collection in India, i.e. voluntary collection of plasma from healthy donors therefore domestic plasma production largely depends on domestically available recovered plasma.

Lack of effective administrative control has been clearly indicated by the case of the lone plasma fractionation machine of 18,000 litres per day capacity set up in Shatabdi Hospital, Govandi, and Mumbai, India in 2006 by NPFC which has never been used after its installation because of the inability to provide the infrastructure to house the machine as reported by Karam. [12].

Another challenge is contributed by lack of coordination between Blood Banks and hospitals in India leading to huge blood wastage, the scenario had been worsened by poor quality control management of blood transfusion facilities leading to increased scope of contamination in domestic plasma implied by cases of HIV transmission through blood transfusion [13].

Conflict of Interest Statement

The authors have no financial interest in any drugs manufacturer, including any arising from employment, consultancies.

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References

[1]. Caironi P. Point: Should intravenous albumin be used for volume resuscitation in severe sepsis/septic shock? *Yes. Chest.* 2016 Jun 1; 149(6):1365-7. doi:10.1016/j.chest.2016.03.048

[2]. First Plasma Fractionation Facility in India to Meet Self-sufficiency. GE biosciences. 2009. https://www.asiabiotech.com/13/1302/0041_0041.pdf

[3]. Albumin in short supply, patients, doctors on edge. Available online: <https://timesofindia.indiatimes.com/city/mumbai/Albumin-in-short-supply-patients-doctors-on-edge/articleshow/48520664.cms>

[4]. Quinlan GJ, Martin GS, Evans TW. Albumin: biochemical properties and therapeutic potential. *Hepatology.* 2005 Jun; 41(6):1211-9.

[5]. Pisarek A.M., Plucienniczak G., Ciach T., Plucienniczak A., The factor VII protein and its function. *Acta Biochimica Polonica,* 2016; 63:1. doi: 10.18388/abp.2015_1056

[6]. Osterud B., Bouma B.N. and Griffing J. H. Human blood coagulation factor IX purification, properties and mechanism of Activation by activated Factor IX. *The Journal of Biological Chemistry* 1978; 254. 17.

[7]. Nautiyal S., Only 45 Blood Banks provide plasma to produce human albumin in state, Pharmabiz. com. 2015. <http://www.pharmabiz.com/NewsDetails.aspx?aid=87186&sid=1>

[8]. Nautiyal S., Human albumin serum not available across India post NPPA price cut, Pharmabiz.com. 2014. <http://www.pharmabiz.com/NewsDetails.aspx?aid=84266&sid=1>

[9]. Francis P.A., Albumin Shortage, 2015. <http://www.pharmabiz.com/ArticleDetails.aspx?aid=86664&sid=3>.

[10]. Most govt Blood Banks don't comply with best healthcare standards: reports. <https://www.livemint.com/Politics/B5j4i8W4VRNVsqOFFm7YbJ/Most-govt-blood-bank-dont-comply-with-best-healthcare-stan.html>.

[11]. Plasma fractionation market global forecast to 2023. Research and market. Dublin/ PRNewswire. 2018. <https://www.prnewswire.com/news-releases/plasma-fractionation-market--global-forecast-to-2023-300596977.html>

[12]. Karam N, Mumbai: Procured in '06, Rs 3.5-cr plasma fractionation machine never used. 2016. <https://indianexpress.com/article/cities/mumbai/mumbai-ai-procured-in-06-rs-3-5-cr-plasma-fractionation-machine-never-used/>

[13]. Sanchez-Aranguren L, Ahmed A. Indian plasma fractionation industry: challenges and opportunities. *Annals of Blood.* 2018 Apr 29; 3(4).