

Indian Drugs & Pharmaceutical Industry in the Post-TRIPs Period



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Abstract

During the first two decades of the planning period (1950 to 1970), growth of Indian drugs & pharmaceutical industry was very slow and more than 90 per cent of the industry was dominated by Foreign Companies. With a view to develop a self-reliant indigenous industry, the Government took various protective steps in 1970s. The protective environment has induced the establishment of large numbers of domestic units during the periods of 1970s and 1980s. Besides the increase in the number of manufacturing units, volume of production and exports from this industry has increased manifold. But, after the formation of WTO, the industry has witnessed a dramatic change with respect to policy environment. India, being a signatory member of WTO, adopted TRIPs Agreement. It was expected that the introduction of this new agreement may adverse effect on the Indian Drugs & Pharmaceutical industry. But the results of the study suggest that TRIPs have no adverse effect on the performances of the industry.

Keywords: Drugs, Pharmaceutical, TRIPs, Patent.

Introduction

Drugs & Pharmaceutical industry is life line for any society or any country and this is rightly too for Indian society. During the first two decades of the planning period (1950 to 1970), growth of this industry was very slow and more than 90 per cent of the industry was dominated by Foreign Companies. With a view to develop a self-reliant indigenous industry, the Government took various steps in 1970s. Among these, the significant step was the introduction of the 'Indian Patent Act' of 1970. Since then the Indian Drugs & Pharmaceutical industry was provided immense protection and the industry has remained heavily protected from foreign competition for about three decades (1970s, 1980s and 1990s). During this period the industry transformed itself and witnessed remarkable growth in industry's turnover. The industry turnover reached up to Rs. 95275 crores in 2009 from just Rs. 10 crores in 1947, with annual growth rate of 18.65 percent.¹ Industry is ranked at top position among the India's science based industries and ranked very high amongst all the third world country², with wide range of capabilities in the complex sector of drugs manufacturing and technology.³ Also prices of drugs produced by domestic manufacturer have remained fairly low as compared to international market during this period. This served not only the interest of common people of the country but also provided competitive advantage in the export market for domestic manufacturer of drugs. As a result the industry, which was dependent on imports of bulk drugs and formulation in the pre-1970 period, has become net foreign exchange earner in the recent past. Also the protective environment has induced the establishment of large numbers of domestic units during the periods of 1970s and 1980s. Besides the increase in the number of manufacturing units, volume of production and exports from this industry has increased manifold.

But, after the formation of WTO, the industry has witnessed a dramatic change with respect to policy environment. In addition to old issues, the WTO includes a large number of new issues. Among these new issues, there is an issue viz. TRIPs (Trade Related Intellectual Property Rights) agreement. India, being a signatory member of WTO, adopted TRIPs Agreement. This agreement represents an essential break with the past in which India had only weak level of patent protection. Under the new agreement patent has been granted both for product and process for all inventions in all fields of technology and the term of patent has been granted for 20 years from the date of application. Whereas, under the Indian Patent Act of 1970, only the process of manufacturing of drugs was protected and the terms of Patent was granted for only for 7 years. With the

signing of the WTO agreement, India committed to itself to reform its patent law in accordance with the TRIPs Agreement. In this context the first initiative of the Government was the adoption of Patents (Amendment) Act, 1999 for granting the Exclusive Marketing Rights (EMRs) to an international company to market a product in the field of pharmaceutical and agricultural chemical products in the Indian market. The second initiative was the passing of Patents (Amendment) Act 2002. Finally, the Patents (Amendment) Act 2005 was passed by the Parliament in March 2005 and this Act was the third amendment of Indian Patent Act of 1970 to bring it in line with the provisions of TRIPs. With the passing of the New Patent Act the country has now ushered in a product patent regime. The New Patent Act is likely to pose some certain serious challenges for the industry. This new framework may cause to prices of drugs to increase, reduction in the volume of production and employment and decline in exports from Indian pharmaceutical market. The new framework may also affect the R&D behaviour of the industry. In this background, it becomes relevant to examine that whether the introduction of TRIPs Agreement of WTO has any adverse effect on the Indian Drugs & Pharmaceutical industry. In this background this paper attempts to examine the current changes in the structure and performances of the Indian drugs & pharmaceutical industry in post-TRIPs period.

Data and Methodology of the Study

Current changes have been observed in terms of the variables like market size, market concentration, financial performance, global activities like export and import, domestic consumption, and R&D expenditure of the industry. Data relevant for this analysis has been collected from the annual reports of Department of Pharmaceuticals, Government of India, the database of Economic Intelligence Service⁴ and the database of Annual Survey of Industries (ASI) for the period starting from the year 1995 till the year 2015.

To fulfill the objective of the study, performance of the industry was examined on the basis of data covering the period 1995-2011. Keeping in view the significance of study, the entire period was divided into three sub-periods – 1995 to 1999 (considered as pre- TRIPs period), 1999 to 2004

(considered as transition period) and 2005 to 2015 (considered as post- TRIPs period)⁵.

Growth of the Industry

The growth momentum that the sector received during the 1980s continued even in the 1990s. The pharmaceutical sector witnessed a consistent growth of around 16 percent since 1995 onward. The bulk drug and the formulation sector also experienced a growth rate of between 15 percent and 20 percent during this period⁶. Because of the competence gained by the Indian pharmaceutical firms in process engineering, they also emerged as the major players in the domestic market. This resulted in a further fall in the share of multinationals in the country⁷. The country also gained reputation in the international market as low cost producer. In a recent case of supplying anti- retroviral drugs to South Africa, the price quoted by Indian firm was the lowest at \$350 per year per person compared to \$1679 per year per person of multinationals.⁸ The number of production units in the Indian pharmaceutical sector also exhibits increasing trend in the recent phase. The growth performance in number of production units is shown in the Table-1.

Table-1
Growth of Production Units of Indian Pharmaceutical Industry

Year	No. of Unit	Year	No. of Units
1953	1752	1984	9000
1970	2257	1985	9234
1978	5201	1986	9540
1980	5126	1990	16000
1981	6417	2001	20053
1983	6631		

Source: Organization of pharmaceutical producers in India (OPPI).

Market Structure

Market structure of Indian Pharmaceuticals is determined by the degree of market concentration and the market size. Market concentration is measured by Hirschman-Herfindahl Index, widely known as H-Index⁹ whereas market sized is expressed in terms of total sales of the industry over the year. Table-2 shows the extent of concentration (i.e. H-Index) and the market size of drugs and pharmaceutical industry in India.

Table-2
H-Index of Concentration and Market Size (Values of Market Size in crores)

	Pre TRIPs Period					TRIPs Period											
						Transition Period					Post TRIPs Period						
Year	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
H-Index	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.02	0.01	0.02	0.01	0.01	0.01	0.01
Market Size	15118.5	18189.3	23641.8	23837.1	27615.2	29316.2	33011.8	35376.6	40365.2	44208.0	46919.4	57100.9	70901.6	81962.9	98174.8	106209	119075.7

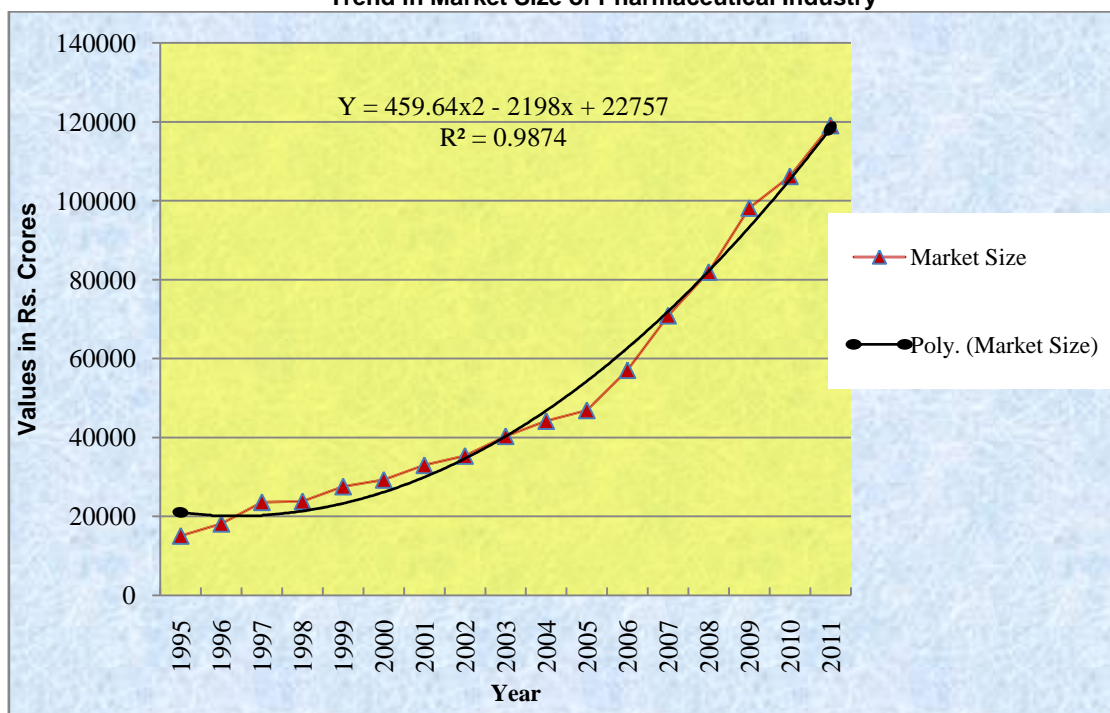
Source: CMIE proress database of Economic Intelligence Service.

Table-2 reflects that market size of Indian Pharmaceuticals has increased 7.88 times by the 2011 as compared with the value of market size in the year 1995. It shows that growth momentum has continued even in the post- TRIPs period. The low value of H-Index shown in the third row of Table-2 exhibits that the extent of concentration in the pharmaceutical industry has been very less or the

level of competition has been very high during the entire post – TRIPs period.

The growth performance of market size is also presented by polynomial trend line, shown in the figure-1. This trend line exhibit the significant increasing trend in market size during the period 1995 – 2011.

Figure-1
Trend in Market Size of Pharmaceutical Industry



Source: Growth line and trend line has been obtained by the data presented in the table-2.

A Comparison between the market size of pre-TRIPs and post- TRIPs is presented in the Table-3. This table shows that market size has increased significantly with the average value of Rs. 82906.32 crores during post- TRIPs period (2005-2011) which is 3.82 times greater than the average value of Rs.

21680.38 crores during pre TRIPs period (1995-1999). This result reflects that the market size of the industry has not been adversely affected after the implementation of TRIPs agreement, rather there is favorable effect in this regards.

Table-3
Comparative Analysis of Market Size (Average value in Crores)

Indicator	Pre TRIPs Period (1995-1999)	TRIPs period		t-statistic [#]	t-statistic [§]
		Transition (2000-2004)	Post TRIPs (2005-2011)		
Market Size	21680.38	36455.56	82906.32	-5.59691 [*]	4.650424 [*]

Source: CMIE proweas database of Economic Intelligence Service

#. Values of t-statistic are obtained under the Null Hypothesis $H_0: (MRS_{2000-2004} - MRS_{1995-1999}) = 0$ and alternative Hypothesis $H_1: MRS_{2000-2004} \neq MRS_{1995-1999}$.

#. Values of t-statistic are obtained under the Null Hypothesis $H_0: (MRS_{2005-2011} - MRS_{2000-2004}) = 0$ and alternative Hypothesis $H_1: MRS_{2005-2011} \neq MRS_{2000-2004}$.

*. Significant at 1 % level

Domestic Consumption of Drugs and pharmaceutical

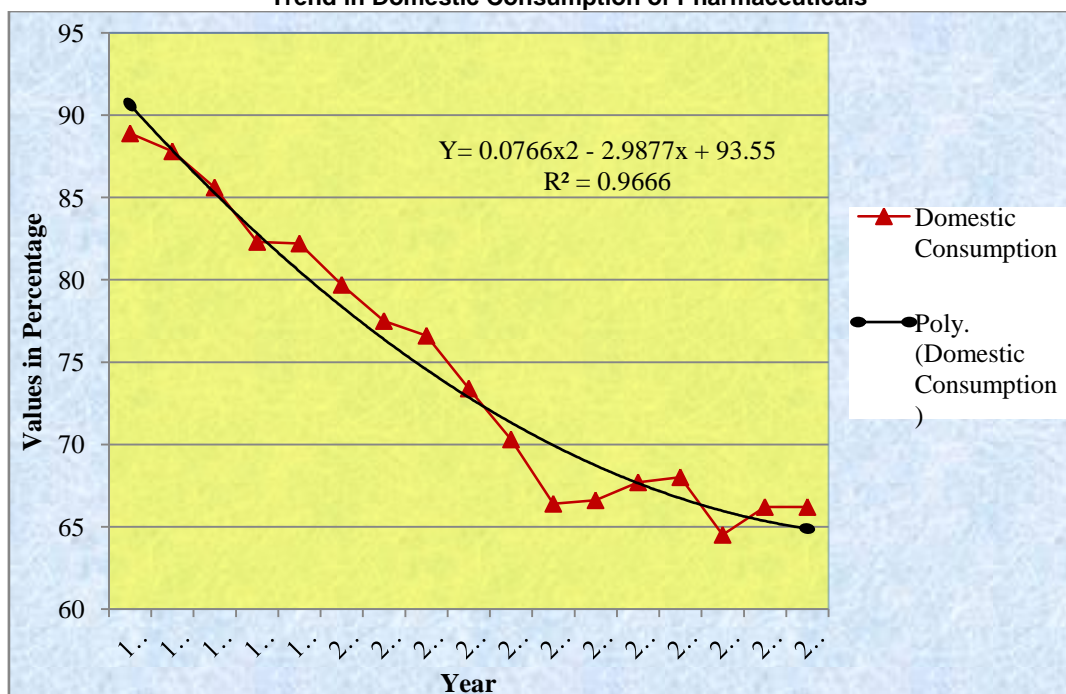
Domestic consumption measured in terms of domestic consumption as a percentage of total sales. The computed values for different years during the entire period are presented in Table-4. This table exhibits that the values of domestic consumption keep on declining.

Table-4
Domestic Consumption of Drugs (Values in Percentage)

Year	Pre- TRIPs Period					TRIPs Period											
	1995	1996	1997	1998	1999	Transition Period					Post- TRIPs Period						
D.C.	88.9	87.8	85.6	82.3	82.2	79.7	77.5	76.6	73.4	70.3	66.4	66.6	67.7	68.0	64.5	66.2	66.2

Source: Values calculated on the basis of data collected from the CMIE database of Economic Intelligence Service. The computed values of domestic consumption are also shown by polynomial trend line, presented in the figure-2. This figure shows that the domestic consumption has been declining throughout the entire period. This means that with the passes of time Indian pharmaceutical firms are selling less in the domestic market and exporting more to the rest of world. This trend shows that Indian pharmaceutical companies are utilizing the harness opportunities driven by the policy of globalization.

Figure-2
Trend in Domestic Consumption of Pharmaceuticals



Source: Growth curve and trend line has obtained on the basis of data presented in the table-4. Comparative values of domestic consumption are presented in Table-5. This table exhibits that the average domestic consumption has declined significantly during post - TRIPs period as compared to the pre- TRIPs period.

Table-5
Comparative Analysis of Domestic Consumption (Average value in percentage)

Indicator	Pre TRIPs Period (1995-1999)	Post TRIPs period		t-statistic [#]	t-statistic [§]
		Transition (2000-2004)	Post TRIPs (2005-2011)		
D. Consumption	85.36	75.5	65.51	5.984006	20.73376

Source: Computed from CMIE Prowess database of Economic Intelligence Service.

#. Values of t-statistic are obtained under the Null Hypothesis $H_0: (DC_{2000-2004} - DC_{1995 - 1999}) = 0$ and alternative Hypothesis $H_1: DC_{2000-2004} \neq DC_{1995 - 1999}$.
 §. #. Values of t-statistic are obtained under the Null Hypothesis $H_0: (DC_{2005-2011} - DC_{1995 - 1999}) = 0$ and alternative Hypothesis $H_1: DC_{2005-2011} \neq DC_{1995 - 1999}$.
 *. Significant at 1 % level

Financial Performance

Financial performance of Indian pharmaceutical industry has been measured by the indicator 'Income Intensity' in which income of the industry has computed as a percentage of total sales. The observed results are presented in Table - 6. It is evident from the table that income intensity does not exhibit any clear trend. Income intensity of the

industry was 2.68 percent in 2001, while it was 0.94 percent in 2002, 3.30 percent in 2006 and 4.52 percent in the year 2011.

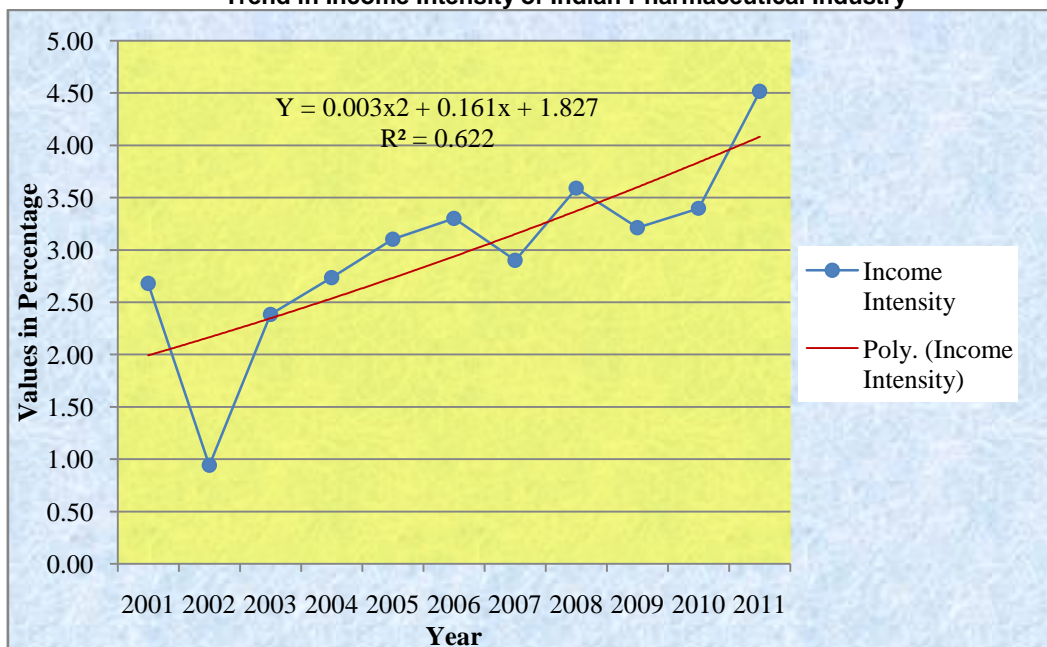
Table-6
Income Intensity of Indian Pharmaceuticals
(Values in Percentage)

Year	Pre TRIPS Period				Post TRIPs Period						
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Income Int.	2.68	0.94	2.39	2.74	3.10	3.30	2.90	3.59	3.21	3.40	4.52

Source: Computed from the database of ASI

These ups and downs in income intensity figures of the industry have clearly evident by the line chart, presented in the Figure-3. However, polynomial trend line (see thin black line) in the figure, depicts increasing trend over the year from 2001 to 2011.

Figure-3
Trend in Income Intensity of Indian Pharmaceutical Industry



Source: Growth line and trend line has been obtained on the basis of data presented in the table-6

The comparative analysis of financial performance between pre- TRIPs period (2001-2004) and post - TRIPs period (2005-2011) is presented in the Table-7. This table reflects that Indian pharmaceutical industry performed better during the post - TRIPs period as compared to the pre- TRIPs period. The computed value of t-statistic shows that differences are statistically significant.

Table-7
Comparative Analysis of Income Intensity
(Average value in percentage)

Indicator	Pre-TRIPs Period	Post-TRIPs period	t-statistic [#]
	(2001-2004)	(2005-2011)	
Income Intensity	2.19	3.43	-6.27128*

Source: Computed from the database of ASI.

[#]. Values of t-statistic are obtained under the Null Hypothesis $H_0: (IIT_{2005-2011} - IIT_{2001 - 2004}) = 0$ and alternative Hypothesis $H_1: DC_{2005-2011} \neq DC_{2001 - 2004}$.

*. Significant at 1 % level

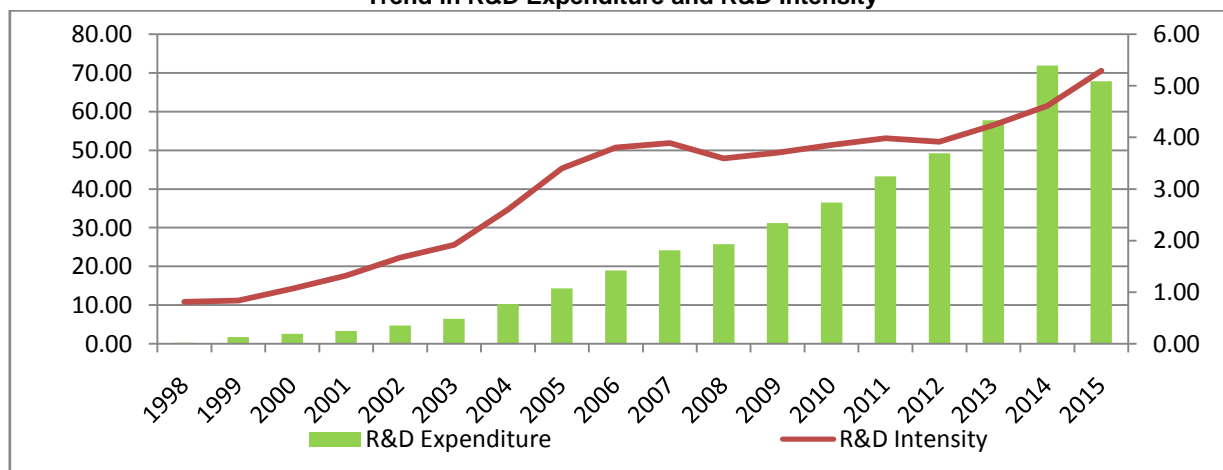
R & D Performance

Data on R&D expenditure of pharmaceutical firms operating in India is depicted in figure-4 and

Table-8. This figure and table shows that R&D expenditure has increased from Rs .023 billion in 1998 to Rs 67.81 billion in 2015 while R&D intensity

has increased by 0.81 percent in 1998 to 5.29 percent in 2015.

Figure-4
Trend in R&D Expenditure and R&D Intensity



Source: Computed from PROWESS database

A comparative data on R&D expenditure and R&D intensity are shown in Table -8. This table also shows that both R&D expenditure as well as R&D intensity in post TRIPs period are significantly greater than that of pre TRIPs period.

Table-8
Comparative Analysis of Research and Development Expenditure
(Values are in Rs. billions)

Indicator	Pre- TRIPs Period	Post- TRIPs Period	t-statistic [#]
	(1998-2004)	(2005-2015)	
R&D Expenditure	4.14	40.07	-5.9351008 [*]
R&D Intensity	1.46 (%)	4.02 (%)	-8.7646504 [*]

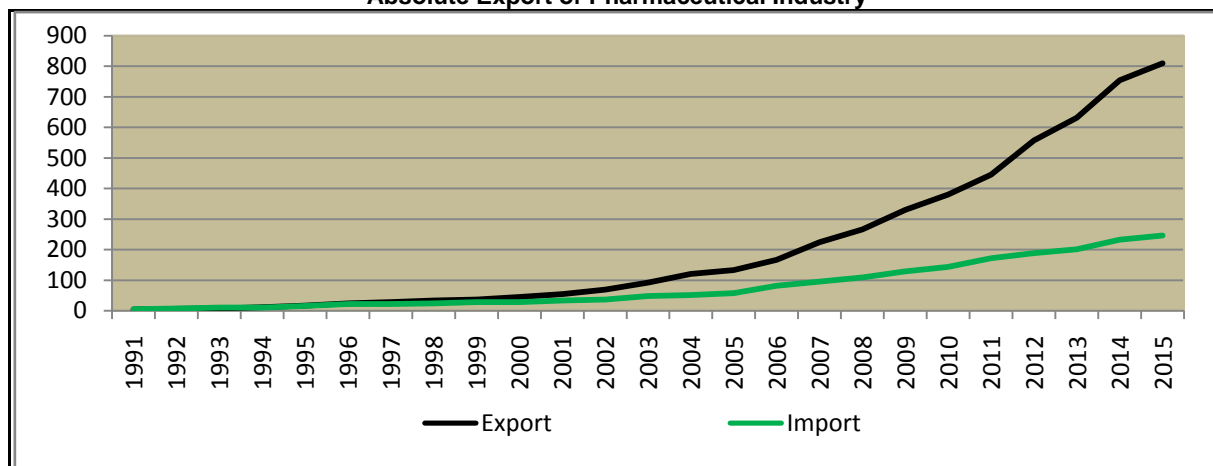
Source: Computed from PROWESS database

Export and Import Performance

Absolute Exports and imports are depicted in Figure - 5. This figure shows increasing tendency of export and import over the entire period. Exports in

drugs and pharmaceuticals has increased from Rs. 4.15 billion in 1991 to Rs. 36.21 billion in 1999, Rs. 120.10 billion and Rs. 809.16 billion in 2004 and 2015 respectively.

Figure-5
Absolute Export of Pharmaceutical Industry



Source: Computed from PROWESS database of 'Industry Outlook'

Conclusion

On the basis of above description it may be concluded that in the growth momentum that the industry received during the 1980s and 1990s continued even in the post-TRIPs period. Apart from

the growth in production and production unit, the industry exhibits phenomenal growth in many other aspects such as market size, export, trade balance and R&D activity during the post-TRIPs period. These

results suggest that TRIPs have no adverse effect on these performances of the industry.

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Footnotes

1. *Annual Report 2011-2012*, Government of India Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals.
2. The term is used to describe the developing countries of Africa, Asia, Latin America and Oceania. Many poor countries who have struggled to attain steady economic development adopted the term to describe themselves.
3. *Brief report on Pharmaceutical Industry in India (Corporate Catalyst India-March 2013)*
4. *Economic Intelligence Service is the CMIE prowess database, provides data of different industries including drugs and pharmaceutical industry, where 32 major firms of pharmaceutical industry are included in the database.*
5. *The justification for this subdivision lies in the fact that it was the year 1999 in which the New Patent Act was introduced by the Government of India. But it was finally passed in the year 2005.*
6. Majumdar M. (2013).
7. Majumdar M. (2013).
8. *Final report on 'Impact of TRIPS on Pharmaceutical prices with specific focus upon generics in India', NIPER, Mohali, 2006.*
9. *H-Index is the some of the squares of the relative sizes (i.e. market shares) of the firms in the market, where the relative sizes are expressed as proportion of the total size of the market. The range of the value of H is from 1 (monopoly case) to 1/n (for n equal sized firm). With perfect competition when n tends to ∞ the value of H is zero.*