Original Article

Presence of Indian pharmaceutical industries in US market: An empirical analysis

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ABSTRACT The United States is the largest pharmaceutical market in the world with generic sales accounting for US$58.5 billion and is India's largest export destination. India accounts for one out of every four Abbreviated New Drug Application (ANDA) approvals in the years 2007 and 2008, ranks first in total Type II active Drug Master Files (DMFs) with US Food and Drug Administration and it also received 31 per cent of all tentative approvals (as on 11 December 2008). In 2008, the exports of formulations from India to top 28 regulated countries surpassed Active Pharmaceutical Ingredient (API) exports firmly demonstrating the shift in credibility and Quality Compliance. India has rich vendor base with 3.75 DMFs per molecule and has filed more than 450 different APIs. Has India tapped the US market to its fullest potential? Where do the opportunities for further growth for India lies in this market? To answer this question, a comprehensive study of DMFs and ANDAs filings by their therapeutic categories, dosage forms, strengths, companies, countries and other key parameters like patents was undertaken. The study reveals that ANDAs from India are confined to small number of highly competitive molecules, and has to move into the new orbit of working in complex chemistry, Biotech-based medicines, and advanced formulations.

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INTRODUCTION

India currently has significant expertise in process chemistry, reverse engineering, designing and managing CGMP manufacturing facilities and enjoys the advantages of lower capital expenditure, plant operating expenses, costs of innovation which enabled it to foray into the global generic markets. Third world countries as well as developed countries are increasingly looking towards India as a source for affordable medicines to solve their increasing health-care costs. The recent anti-retroviral revolution to help millions of AIDS patients across the world was possible only due to India.

In the past, India exported majority of its pharmaceutical products to other developing countries having similar disease profiles. By contrast, in 2008, India exported drug and pharmaceuticals to more than 228 countries with 45 per cent of it by value[1] going to regulated markets.[2]

The study of exports of drugs and pharmaceuticals products from India[3] shows that over the past 5 years (2003–2008) the pharmaceutical exports have increased from US$1.90 billion to $7.52 billion with a compound annual growth rate of 23.42 per cent. The exports of formulations to regulated market grew at an impressive rate of 31.55 per cent. In the year 2008, India for the first time exported more formulations than Bulk Drugs to regulated markets (Figure 1).

The United States being the largest pharmaceutical market in the world at $286.5 billion in the year 2007, with generic market accounting for $58.5 billion,[4] continues to be India's largest export destination followed by Germany and Russia. Although India's exports to the United States have nearly tripled during the past 5 years, the country's share in pharmaceutical imports of the United States remains below 2 per cent. Top Indian companies like Ranbaxy entered US market in mid-1990s and currently Indian companies have 1100 products in prescription and Over The Counter (OTC) markets of the United States. Their successful penetration into the United States, Europe and African markets has encouraged a growing number of Indian companies to enter these markets.

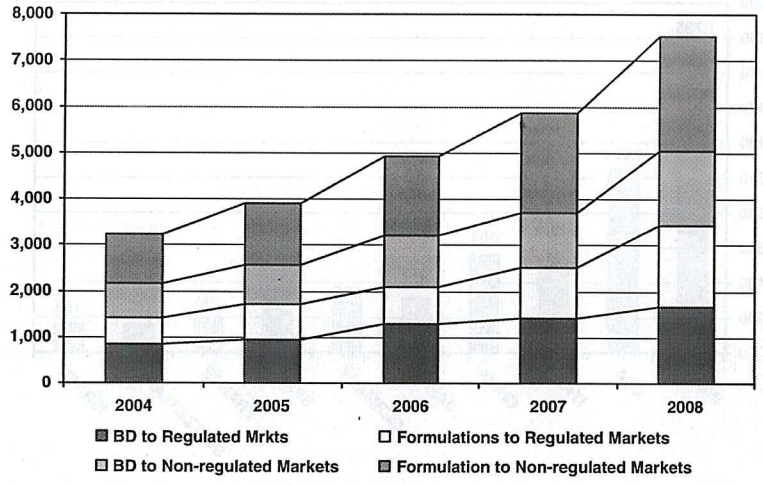

Figure 1: India's exports of pharmaceutical products to regulated markets alongwith compositions *vis-a-vis* ROW (figures in US$million).
Source: Research based on CMIE India trades database.

REVIEW OF DATA FROM EUROPEAN DIRECTORATE OF QUALITY MEDICINE (EDQM)

Data from EDQM website reveal that the highest number of Certificate of Suitability (CEPs) is granted to India. As on 3 December 2008, India has 461 CEPs (19.78 per cent) of the total 2330 granted by EDQM. The country has 153 EDQM approved facilities for 195 molecules out of the total 693 molecules approved by EDQM.

RESEARCH METHODOLOGY

To understand strategic penetration of Indian pharmaceutical industry in US generic market, a descriptive and comprehensive study of product registration pattern of Indian pharmaceutical companies in the United States was undertaken.
A complete study of Type-II Active Drug Master Files (DMFs), New Drug Applications (NDAs), Biological Licensing Applications (BLAs) and Abbreviated New Drug Applications (ANDAs) for all the human products approved by Centre for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA) was done.

However, the research methodology does not consider foreign subsidiaries of Indian multinational companies and also includes Ranbaxy and Matrix laboratories among Indian companies (in spite of their acquisition by Daichi Sankyo and Mylan, respectively). The study was carried out in three segments:

1. Country-wise and molecule-wise study of DMFs filed with US FDA (available from www.fda.gov/cder, updated to September 2008) was conducted in the first segment.
2. Comprehensive study of all products including NDAs, ANDAs and BLAs approved by CDER, US FDA was carried out in the second stage. (Data collected from FDA Orange Book and Drug@FDA as updated till 12 November 2008.)
3. Further, combined study of above two databases was carried out based on molecules, therapeutic categories and

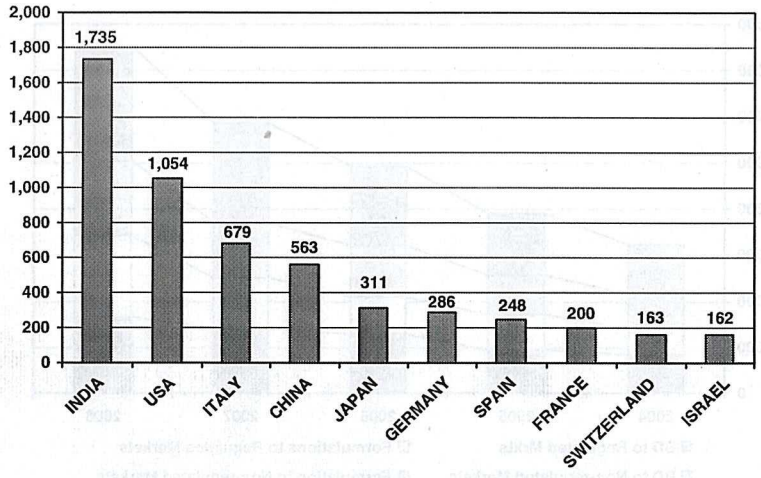

Figure 2: Country-wise number of Type-II active DMFs with US FDA (September 2008) (figures in numbers.) (World total 6482).
Source: Research based on CDER, US FDA database.

dosage forms to understand strategic position of Indian pharmaceutical industry.

REVIEW OF DMFs WITH US FDA

The total number of Type-II Active DMFs with US FDA stood at 6482 at the end of September 2008 by a total of 1004 companies from 55 countries. The top 10 countries accounted for 83.55 per cent of all DMFs filed with US FDA.

India is the holder of largest number of DMFs with 1735 followed by the United States (1054) and Italy (676) (see Figure 2). As per our study, these DMFs have been filed for a total 464 of different APIs from 169 facilities in India. Many of them have already been approved by US FDA, making India as the holder of largest number of US FDA approved plants outside the United States.

India has been aggressively filing of DMFs over the past 7 years and as at the end of September 2008 holds 26.76 per cent of Total Type-II Active DMFs (Figure 3).

In its 1735 DMFs, India has a total of 464 different molecules out of which 26.3 per cent have five or more DMFs while another 61.2 per cent have two or more DMFs. India has more than 10 DMFs for 40 high value molecules (for example, Atorvastatin, Omeprazole, Clopidogrel, Simvastatin, Amilodipine and so on) positioning itself as a potential supplier of these molecules (Table 1).

CHINESE COMPETITION TO INDIAN BULK DRUGS EXPORTS

Our study reveals that strategically India has not positioned itself well in comparison with other competing countries. The ratio of number DMFs per molecule for India is 3.73 while it is 1.75 for China. This indicates that Indian companies are competing not only with top exporting countries, but also among themselves. As per reports, China is currently the world's largest exporter of Bulk Drugs followed by Italy and India.[5] China is the global leader in production of several pharmaceutical products like Penicillin (60 per cent of world's production), Vitamin C, Cephalosporins, Doxycycline Hydrochloride and Terramycin.[6]

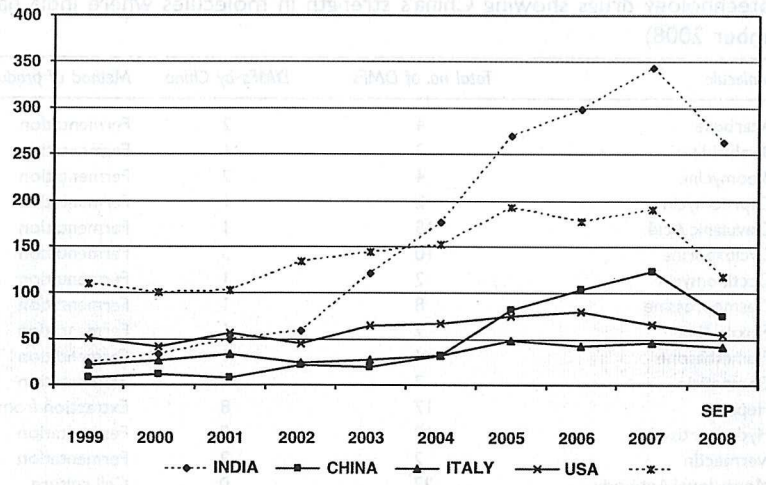

Figure 3: Year-wise number of Type-II active DMFs with US FDA by top four countries and ROW (figures in numbers).
Source: Research based on CDER, US FDA database.

Table 1: List of molecules having more than 14 DMFs from India

Sl. No.	*Subject*	*No. of DMF*	*Global sales (US$ bn.)*
1	Metformin	20	0.76
2	Amlodipine	19	0.87
3	Venlafaxine	18	2.76
4	Omeprazole	16	0.34
5	Cefuroxime Axetil	15	—
6	Ranitidine	15	0.46
7	Simvastatin	15	0.91
8	Clopidogrel	14	7.21
9	Pantoprazole	14	4.24
10	Quetiapine	14	4.57
11	Sertraline	14	0.57
12	Zolpidem	14	2.19

Source: Research of CDER US FDA data.

According to[7] Pricewaterhouse Coopers, China is likely to beat India as one of the world's largest pharmaceutical exporting country by 2010. The report also indicates that China has already surpassed India in the exports of Bulk Drug during the year 2007.

China is a large-scale producer of several Bulk Drug Intermediates. It produces several patent protected molecules up to a pre-API stage (a strategy China uses to escape patent violation) and exports them to other countries.[6] China is also lead exporter of drugs and pharmaceuticals to India (2007).[1] Strategically China is making it difficult for Indian Bulk Drug manufacturer to obtain intermediates at reasonable prices. India is more efficient in converting APIs into finished products and is significantly ahead of China in export of formulation. China lags behind in formulation manufacturing expertise with the first US FDA approval of a product (ANDA) fully manufactured by China only in the year 2007.[8]

Comparison of molecules filed from India and China reveals that India is absent in several fermentation and biotech products (Table 2).

Study of the chemistry of the molecules filed from India shows that India has significant presence in Small Molecular Chemistry; however, it is almost absent in Peptides, Biopharmaceuticals and Biotech products. China is strongly placed in fermentation technology and biotech products, which according to IMS-Health is growing at double the rate of the pharmaceutical market. The biotech drugs increased by 12.5 per cent in the year 2007, which is double the growth rate of global pharmaceutical markets (6.4 per cent) during the same year.[9]

Table 2: List of biotechnology drugs showing China's strength in molecules where India has no DMFs (DMFs as on September 2008)

Sl. No.	Molecule	Total no. of DMFs	DMFs by China	Method of production
1	Acarbose	4	2	Fermentation
2	Bivaluridine	2	1	Fermentation
3	Bleomycine	4	2	Fermentation
4	Capreomycin	2	1	Fermentation
5	Clavulanic Acid	15	1	Fermentation
6	Cyclosporine	10	3	Fermentation
7	Dactinomycin	2	1	Fermentation
8	Desmopressine	8	1	Fermentation
9	Floxuridine	2	1	Fermentation
10	Flumethasone	4	1	Fermentation
11	Gentamicin	3	2	Fermentation
12	Heparin	17	8	Extraction from animal intestine
13	Hydrocortisone	19	5	Fermentation
14	Ivermectin	2	2	Fermentation
15	Monoclonal Antibody	27	0	Cell culture
16	Mupirocin	6	1	Fermentation
17	Prednisolone	29	4	Fermentation
18	Thiostrepton	1	1	Fermentation
19	Vancomycin	6	2	Fermentation
20	Various salt of Penicillin	20	4	Fermentation

Source: Research of data available at Drug@FDA (CDER US FDA).

A tally of generic drug applications processed in 2007 by US FDA shows reference to over 1000 foreign establishments for API manufacturer and India and China together account for 94.7 per cent of them.[10] This amply demonstrates the role of India and China as leading suppliers of Bulk Drugs to the United States as also the competition between them.

In view of the large number of filings by China and India and in realisation of the importance of these two countries in bringing down the health-care costs, the US FDA has opened its first overseas office in Beijing on 19 November 2008 with another two coming up at Guangzhou and Shanghai and it has also decided to open two offices in New Delhi and Mumbai, for close monitoring of product approvals to generic companies of these countries.[11]

REVIEW OF ANDA APPROVALS FROM INDIA BY US FDA

A comprehensive study of Orange Book and also Drug@FDA updated to 12 November 2008 was undertaken, which collects information on human drug products along with their dosage forms, strengths, marketing status, sponsor applicant and their therapeutic categories that are approved in US pharmaceutical markets.

Study shows that CDER, US FDA granted marketing approvals to a total number of 24611 pharmaceutical products. Of these 10194 products were discontinued. The remaining 14417 products are active products that include Prescription Products, OTC Products as also Tentative Approvals (Figures 4 and 5).

Prescription products accounts for maximum 13206 products coming from 758 different companies, followed by discontinued products (10194) where India is fortunate to have minimum presence.

Often more than one strength is approved in US FDA through single application (NDA, ANDA or BLA). FDA does not require separate bioequivalence study for each strength if certain guidelines given by it are met.[12] Each application will carry a unique application number leading to approval of one or more strengths, which have been considered as different product. Most of the

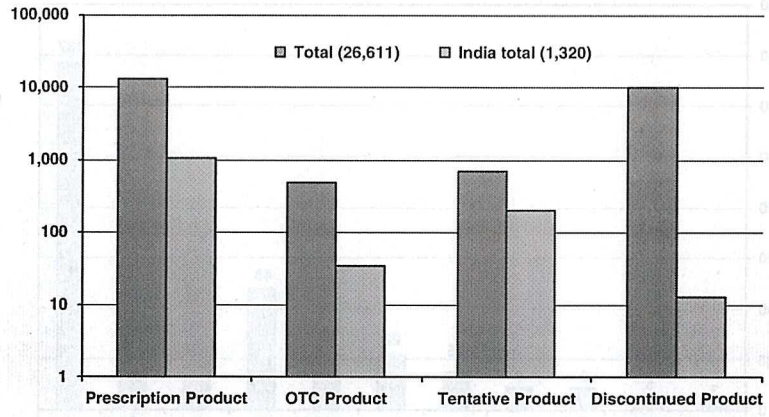

Figure 4: Product-wise breakup of pharmaceuticals registered with US FDA based on marketing status (as on 12 November 2008).
Source: Research based on CDER, US FDA database.

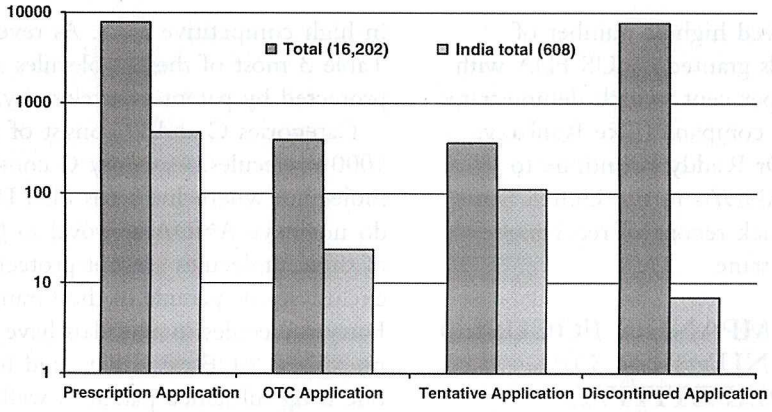

Figure 5: Application-wise breakup of pharmaceuticals registered with US FDA based on marketing status (as on 12 November 2008).
Source: Research based on CDER, US FDA database.

filings by Indian companies are for ANDAs (generics) with the exception of 19 NDAs (17 Ranbaxy + 1 Dr Reddy's + 1 Glenmark), which mainly includes new formulations approved under 505(b), of Federal Food, Drug, and Cosmetic Act.

A comparison of US FDA approved prescription products and applications between India and rest of world (ROW) reveals that on an average, Indian companies have received approvals in for 2.29 formulation dosage strengths for every application filed while the ratio is 1.65 in the case of the ROW. This signifies that Indian companies are filing for multiple strengths that help to maximise their product basket and to optimise revenues. India during the past 10 years has made rapid strides growing from just three ANDAs to the present 137 in 2008 (Figure 6).

During the past 2 years (2007–2008) one out of every four ANDA approvals came to Indian companies and the share stands at 27.73 per cent of all ANDA approvals granted in 2008.

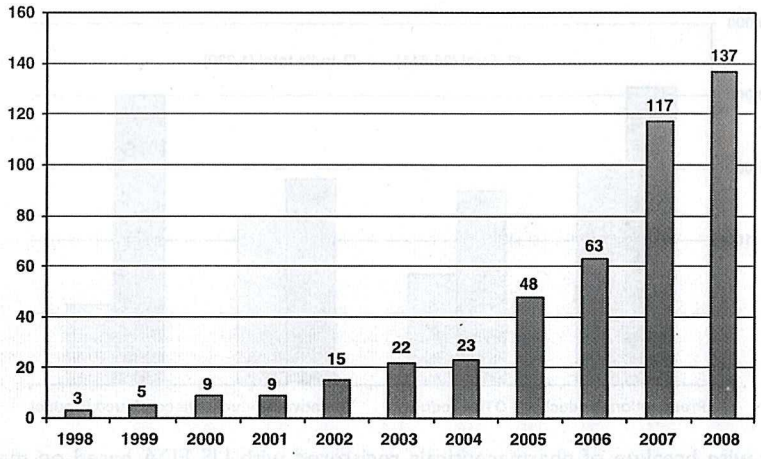

Figure 6: Number of approved applications from India (1998–2007) (figures in numbers).
Source: Research based on US FDA Orange Book and Drug@FDA.

India has received highest number of tentative approvals granted by US FDA with a share of 30.91 per cent, which demonstrates that many Indian companies like Ranbaxy, Aurobindo and Dr Reddy's continue to aggressively file ANDAs in the United States and have good track record of receiving approvals for the same.

INDIAN COMPANIES FOCUSED ON SMALL NUMBER OF HIGHLY COMPETITIVE MOLECULES

Study of FDA databases reveals that a total of 1198 drug molecules are approved in US market. The data were analysed for number of competing companies for each molecule, first Drug Substance patent expiry, first Patent Use Code expiry and New Chemical Entities (NCE) exclusivity expiry to make the study comprehensive. The above information was further analysed molecule-wise in context of Type-II Active DMF held by India (Table 3).

Categories A and B consist of a total 156 molecules for which India has got products in US market. Analysis shows that in these two classes, average numbers of companies per molecule are 12.39 and 9.04, respectively. This signifies that India has presence in limited number of molecules that too mostly in high competitive areas. As revealed by Table 3 most of these molecules are not protected by patent or exclusivity.

Categories C and D consist of more than 1000 molecules. Category C consists of 272 molecules where India has filed DMFs but do not have ANDA approval so far. Several of these molecules are not protected by exclusivity or patents in the Orange Book. Forty molecules in this class have no unexpired NCE exclusivity and has at least one drug substance patent as well as patent use code expired. In all these 40 molecules there are only two to four companies and present an opportunity to generic companies.

Category D is the largest with 770 molecules where India neither has DMF nor ANDA. These include several exclusivity and patent protected molecules, NDAs and all 65 BLAs. One hundred and twenty-eight molecules are marketed by five or more companies, and this list includes several anti-cancer drugs, hormonals, controlled substance and corticosteroids.

Above analysis identifies that India has confined its ANDA/NDAs to limited number of molecules (156), whereas top generic companies like Teva, Sandoz and Watson have presence in more than 200 molecules each. With over 1000 molecules left out

Table 3: Analysis of India's DMFs and products among human drugs in US market

Analysis of DMFs & ANDAs by India	*Total number of molecules in the category*	*Average no. products*	*Average no. of competing companies for the molecule*	*Average no. of Indian companies*	*Molecules not protected by drug substance patent*	*Molecules not protected by patent use code*	*Molecules protected by NCE*	*No. of molecules with more than 4 companies*	*No. of molecules with 4 or less than 4 companies*
A. India has product as well as DMF to the US	134	43.26	12.39	2.28	119	86	Nil	121	13
B. India does not have DMF but got product	22	23.94	9.04	1.41	Nil	21	Nil	16	6
C. India has DMF but no product	272	10.72	4.11	0	200	143	21	82	190
D. India does not have either DMF or product	770	6.66	2.74	0	596	499	80	254	516

Source: Research based on CDER US FDA database.

(categories C and D), there exists enough opportunity for India to expand their presence in US market. Category C molecules present better opportunity to India as they have DMFs for the same.

INDIA'S PRESENCE IN VARIOUS THERAPEUTIC CATEGORIES

All the products in the US market were categorised into 24 different therapeutic categories. The study reveals that India is fairly strong in five therapeutic categories namely, anti-HIV, anti-microbial, CVS, anti-diabetic and CNS, which account for 68.78 per cent of all products approvals. India has insignificant presence in corticosteroids/ hormones, respiratory, musculo-skeletal, ophthalmics and biologics (Table 4). The maximum number of products from India is anti-microbials, which is in line with the country's domestic market where anti-microbials are the top selling category.

INDIA'S PRESENCE IN VARIOUS DOSAGE FORMS

Study of dosage forms reveal that 204 different types of dosage forms are marketed in various prescription and OTC medicines. India has filed products only in 24 types of dosage forms (Table 5). For the purpose of analysis, all the dosage types have been classified into five broad categories, that is, oral, injectable, topical, non-conventional and advanced formulations. Advanced formulation consists of controlled release products, implants, patches, depot preparation, inhalations and so on. Non-conventional dosage forms include products meant for rectal, vaginal and urethral routes. Oral, topical and injectable are self-explanatory.

Study of products approved from India reveals that 83 per cent are oral, mostly conventional tablets (690) and capsules (137). India has very little presence in advanced formulations accounting for just 3 per cent of its total products. India is also completely absent from non-conventional dosage form.

Table 4: Comparison of therapeutic category-wise product approvals of India *vis-à-vis* ROW (prescription products) (as on 12 November 2008)

Sl. No.	*Therapeutic category (product-wise)*	*ROW total*	*India total*	*Percentage share of India*
1.	Anti-HIV	59	13	18.05
2.	Anti-microbial	1581	274	14.77
3.	CVS	2029	254	11.12
4.	Anti-diabetic	313	37	10.57
5.	CNS	2158	247	10.27
6.	Dermatological	79	9	10.22
7.	GI tract	547	60	9.88
8.	Other anti-viral	120	12	9.09
9.	Anti-allergic	127	10	7.87
10.	Analgesic	1000	53	5.03
11.	Hormonals	456	21	4.40
12.	Anti-cancer	534	24	4.30
13.	Renal function	445	20	4.30
14.	Drugs acting on blood	227	9	3.81
15.	Musculo-skeletal	134	3	2.18
16.	Ophthalmic	114	2	1.72
17.	Corticosteroid	839	13	1.52
18.	Respiratory	263	4	1.49
19.	Electrolyte replenishers	423	0	0
20.	Local anesthetics	205	0	0
21.	Diagnostics	193	0	0
22.	Monoclonal antibody	37	0	0
23.	Others	257	1	0.39
	Total	12140	1066	—

Source: Research of CDER US FDA data.

Table 5: Classification of products registered with US FDA into various dosage forms (prescription & OTC products)

Categories	*Types of dosage forms (total)*	*No. of products (ROW)*	*Types of dosage form from India*	*No. of products (India)*
Oral	40	7130	10	913
Injectable	41	3083	4	130
Advanced formulation	56	1289	3	35
Topical	45	982	7	22
Non-conventional	22	114	0	0
Total	204	12598	24	1100

Source: Research based on US FDA Orange Book, Drug@FDA.

PRESENCE OF INDIA IN COMBINATION PRODUCTS

Analysis of combination products in US market identifies that out of total 13206 prescription products 1805 are combination products. All these combination products consist of 287 different types of molecular combination. India has filed a total of 54 combination products accounting for just 3 per cent of total combination products as compared to 8 per cent in total prescription products. The majority of combination products as well as advanced formulation are from Ranbaxy; other companies include Dr Reddy's, Zydus Pharms, Sun Pharm, Lupin, Wockhardt and Unique Pharm.

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ROAD AHEAD FOR INDIAN COMPANIES

As above statistics reveal, high volume and efficient production of generics and APIs remain India's core competitive advantage in the global pharmaceutical sector. However, Indian companies need to achieve their full potential in this segment. One way to achieve this could be to improve their operating efficiency and improve their presence in untapped markets (for example, Brazil, Canada, Australia, Japan and so on). Further, they need to build up their product basket to have broader offerings.

US generic market is undergoing significant price erosions and diminishing profitability mainly because of high competition and trend of authorised generics.[13] To overcome these factors, Indian companies need to select new expansion avenues such as speciality generics and Biotech-based medicines, as these are high-value and difficult to manufacture and often are less prone from high competition. India has just 48 products in speciality generics, which is miniscule in the scope of US market that is close to 1250 products. Speciality generics involve value added products and novel formulations that could earn 3 years exclusivity following approval through 505(b)(2) Application.

Over a period of time, India has learnt the art and science of production of finished APIs that meet regulatory requirements and has higher profitability, leaving commodity-oriented intermediates to other countries. China with its focus on scale, cheap carbohydrate source and economical energy supply captured lot of fermentation and intermediates business in the world. On an average, API accounts for 45 per cent of the cost of finished formulation and therefore India should develop self-sufficiency in its API requirements, as the dependence on other countries like China may, with time, erode the country's competitiveness in providing affordable generics to the global market.

All these changes require heavy investments and entirely new capabilities in manufacturing. Further, investments required for drug registration and distribution in foreign countries like that of European Union may prove to be a time consuming and costly affair for Indian companies. Hence, they need to get into consolidation or strategic alliances and expand their intellectual property to more number of countries.

CONCLUSION

The study shows that India has made phenomenol progress in both DMF and ANDA approvals over the past 7 years. The country's share in ANDA approvals and tentative approvals during the past years clearly demonstrates its aggressive ambition. There are over 1000 molecules that provide great opportunity for India to expand its presence in US pharmaceutical market. India is weak in various segments such as corticosteroids, respiratory, musculo-skeletal, ophthalmics and so on and has to develop its capabilities in bio-generics for its future growth. The pharmaceutical products from India are mostly confined to conventional tablets and capsules with very little presence in advanced formulations and completely absent from non-conventional dosage forms. India has to, therefore, urgently take corrective action to move into higher orbit of complex chemistry, Biotech-based medicines and advanced formulations.

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