# Problem and Prospectof Pharmaceuticals Industryof Bangladesh amid LDC Graduation

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## ABSTRACT

**Aims:** The paper aims to identifythe prospects and challenges of the pharmaceutical sector of Bangladesh after graduation and explores potential areas of market and product diversification. Addressing the upcoming graduation challenges, the paper sheds light on pharmaceutical sector-based trade-related challenges and potentials and digs out a way forward.

**Study design:**The study is conducted using primary data from the Key Informant Interview (KII) andsecondary data from different publications and sources. A qualitative survey tool is used for assessing the view of stakeholders and graduation challenges in the pharmaceutical sector.

**Methodology:**The study uses qualitative tools to evaluate the area of market and product diversification of thepharmaceutical industry and finally usesthe Autoregressive Integrated Moving Average (ARIMA) model to forecast what the export figure after 2032 and what interventions need to be taken to reach the expected level of growth amid graduation challenges.

**Results:** The pharmaceutical industry will confront significant hurdles in terms of value addition, paying for patents, and license fees for the production of pharmaceuticals after graduation. Moreover, the industry faces difficulties due to excessive reliance on Active Pharmaceutical Ingredient (API) imports, limited product baskets, lack of Research andDevelopment(R&D)and lab testing facilities, lack of infrastructure in the API park, complexity in industrial plots payment, dearth of bioequivalence test facilities, and patentable molecules in the post-graduation era.

**Recommendation:**Bangladesh needs to accentuate self-reliance in API production, R&D, reverse engineering, and technical know-how as well as make a functional API Park, develop acurriculum to have experts in Synthesis Chemistry, and establish anaccredited bioequivalence study center to secure patentable molecules and API.



*Keywords: Pharmaceuticals& API, Product Diversification, Export Diversification, LDC Graduation, Challenges& Potential, Autoregressive Integrated Moving Average (ARIMA)*
*JEL Code:F1,F14, F140 F170, F190*




## 1. INTRODUCTION

Bangladesh is on the pathway to Graduation in 2026 and meets all three criteria in the 1st and 2nd United Nations Committee for Development Policy (CDP) triennial review in February 2021. Even after Covid-19 spreads out, Bangladesh retains its positive economic growth starkly. Graduation from LDC will pose a multifaceted pressure for market access, preference erosion, Trade-Related Aspects of Intellectual Property Rights (TRIPS) advantage erosion, value addition conditions, additional tariffs, and likely reduction of overall export in potential sectors like the pharmaceutical and leather sector, etc. Bangladesh will lose patent exemption on pharmaceutical products after 2026 and it is estimated that export income may fall 5.5 % to 7.5% in the graduation period. Moreover, exporters would face an additional 6.7% tariff which could result in an estimated export loss of $2.7 billion as estimated by UNCTAD [1].

The pharmaceuticals industry, the next multi-billion-dollar opportunity for Bangladesh, has grown significantly with a current market size of over US$ 3 billion as per the Bangladesh

Association of Pharmaceutical Industries (BAPI) [2]. The sector has been growing at an annual rate of 16.7% and is expected to exceed US$ 6 Billion by 2025 according to export data from Export Promotion Bureau (EPB) [3]. The Bangladeshi drug is dominated by the branded generic drug, accounting for almost 80% of the drug produced locally and the top ten pharmaceutical companies produce 70% of the domestic market. The article has explored the domestic pharmaceutical sector, market size, and the export-import trend while addressing LDC graduation's impact on the pharmaceutical industry. The sudden outbreak of COVID-19 directly hit the healthcare and pharmaceutical sectors of Bangladesh, as sourcing Active Pharmaceutical Ingredients (API) from China and other countries was hampered due to disruption in the supply chain.

The study addresses the challenges and prospects of the pharmaceutical sector, export, and market diversification features, especially challenges due to the implication of the TRIPS agreement after graduation.The study further explores the worldwide import of pharmaceutical products HS code-wise to identify the export potential of pharmaceutical products.As a result of the high quality and cost-effectiveness of Bangladeshi pharmaceuticalproducts, there is usually huge demand for the products in the global market but dependence on Chinese and Indian API reflects the necessity for strengthening backward linkage in API production in Bangladesh. Here, the potential area of market diversification is explored with the International Trade Centre's (ITC) export potential map. Moreover, the export forecast for the pharmaceutical sector is prepared with the ARIMA model in the study.

Along with this, the author has conducted 20 Key Informant Interviews (KIIs) among the representatives of the Business Chamber and Association of Pharmaceutical and API Industries, Bangladesh Small and Cottage Industries Corporation (BSCIC), National Board of Revenue (NBR), industry owner, companies and researchers as well as public and private sectors representatives of the industry for extracting the concerns of stakeholders.The stakeholders have identified that over-dependence on API import, challenges related to API production, lack of Research and Development (R&D) lab test, lack of uncertainty in gas connection in API park, lack of bioequivalence test facility, and having less patentable molecules create challenges for the sector.

## 2. LITERATURE REVIEW

Asadujjaman, Hassan & Ratin [4] addressed that after the formulation of the National Drug Policy 1982, the industry became able to meet the major portion of local demand. Alam [5] urged that the industry meets 98% of the domestic demand and contributes around 1.8% to the Gross Domestic Product (GDP).Faisal MA [6] cited in the Eastern Bank Limited(EBL) report that the domestic manufacturers produce almost all types of medicine, including high-tech products like insulin, hormones, anti-cancer products, etc. and most of them have production facilities for tablets, capsules, liquid dry suspensions, injections, ointments, creams, nasal sprays, granules, etc.Specialized delivery products like a dry-powder inhaler and prefilled syringe/ lyophilized injection are the most citable products.Bangladesh Investment Development Authority (BIDA) [7] explored that the domestic pharmaceutical sector is expanding rapidly, some companies have been certified by different international regulatory bodies like US-FDA, UK-MHRA, Australia-TGA, EMA, Health Canada, TFDA, Taiwan, ANVISA, Brazil EU, etc. for quality products manufacturing.

Currently, the Bangladeshi pharmaceutical industry can source only 10% of the total API requirement domestically[i] and the estimated market size of the APIs is around US$730 million. Migrant Resource Centre (MRC) [8] report estimated that demand for APIs will reach around US$1,409 million in 2025.There are 26 API producers in the country, producing

around 40 API molecules according to the author's interview withrepresentative from BAPI and pharmaceutical industry. Thoughthe domestic demand for APIs is growing, local production remains low in the place of demand, leading to significant API imports. BIDA estimated that Bangladesh imported approximately US$ 600 million of API into the country in FY 2018-19.As a result,150 pharmaceutical companies are successfully operating their business in the domestic market while the domestic pharmaceutical market amounted to US 3195 million in 2021 whichwas incremental since 2017as per BAPI data.

### 2.1 GlobalPharmaceutical Product Market

The pharmaceutical industry has grown significantly worldwide over the period and the global pharmaceutical market valued at 1.48 trillion dollars in 2022. This represents a marginal increase from the 2021 market valuation of US$ 1.42 trillion (Statista) [9]. Statista's market outlook for 2022 has also explored that the commercial "blockbuster" drug can generate more than US$1 billion in a year. It implies that a single product can play a major role, as a small number of drugs drive a certain segment of the market.Statista further provisionedthat the largest market segment of pharmaceutical products is Oncology Drugs amounting to US$ 188.90 billion in 2022. Here, from ITC trade data, the top 15 imported products at a six-digit level in the world are shown and Bangladeshi exported products which are green colored fall under HS Code: 300190, HS: 300220, HS: 300230, HS: 300290, HS: 300390, HS: 300190, HS: 300590 and HS Code: 300230 (ITC) [10]. It shows that the Bangladeshi pharmaceutical sector needs to ensure minimum value addition conditions with domestic API invention and chemical synthesis so that it can grasp a large portion of the market.

***Table 1: Top 15 World Import of Pharmaceutical Products at Six-digit Level***

| Product HS code | Product label | Imported value in US$ Million 2021 |
|---|---|---|
| 300490 | "Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes | 359528.17 |
| 300215 | Immunological products, put up in measured doses or in forms or packings for retail sale (excl. | 149165.61 |
| 300220 | Vaccines for human medicine | 125857.78 |
| 300439 | "Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in | 40587.92 |
| 300212 | Antisera and other blood fractions | 32499.67 |
| 300214 | Immunological products, mixed, not put up in measured doses or in forms or packings for retail | 22750.27 |
| 300420 | "Medicaments containing antibiotics, put up in measured doses ""incl. those in the form of **...** | 16147.37 |
| 300290 | Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses | 12195.45 |
| 300431 | "Medicaments containing insulin but not antibiotics, put up in measured doses ""incl. those | 10301.84 |
| 300432 | "Medicaments containing corticosteroid hormones, their derivatives or structural analogues **...** | 10103.05 |
| 300390 | Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic | 6575.16 |
| 300190 | Dried glands and other organs for organo-therapeutic uses, whether or not powdered; heparin | 5313.23 |
| 300590 | Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated | 5027.82 |
| 300230 | Vaccines for veterinary medicine | 4910.47 |

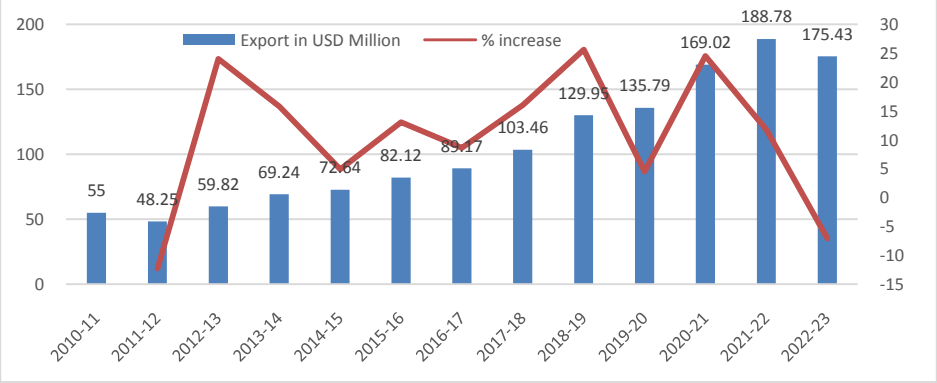
| Product HS code | Product label | Imported value in US$ Million 2021 |
|---|---|---|
| 300610 | Sterile surgical catgut, similar sterile suture materials, incl. sterile absorbable surgical ... | 4894.76 |

***Source:*** *ITC Trade Data 2021 & EPB Data*

## 2.2 Export & Import Trend of Pharmaceutical Sector

The contribution of the pharmaceutical sector to GDP is on the rise and it has become one of the largest potential sectors in Bangladesh to earn foreign currency and contribute to the national exchequer. After focusing on the domestic market for many years, Bangladeshi pharmaceutical companies have entered the global market in recent years. It is explored that around 1,200 products have been accredited for import by the authorities at the importing countries and are being exported to more than 150 countries including,the USA, UK, Canada, Australia, Germany, EU, etc. as cited in the Asadujjaman, Hassan & Ratin study.According to EPB, export is growing fast as the current export earning is US$175.43 Million in FY 2022-23.

***Figure 1:*** ***Export Trend of Bangladesh Pharmaceutical sector in US$ Million***




*Source: EPB 2022-23*

From the given data, it is shown that the market of pharmaceutical export is concentrated on the HS Code: 300490 (Other medicaments of mixed or unmixed products, for retail sale, nes) which amounts to US$110.84 million in FY 2020-21 and US$ 124.40 million in FY2021-22. It is around 66% of the total export of pharmaceutical products. The trend over the past decade shows an incremental export growth of pharmaceutical products.

***Table 2:HS Code WiseTop 10 Pharmaceutical*** ***Products Export in US$ million***

| HS Code | Product Description | FY2021-22 |
|---|---|---|
| 300320 | Medicaments of other antibiotics, not for retail sale | 21.377 |
| 300390 | Other medicaments with >2 constituents, not for retail sale, nes | 9.878 |
| 300410 | Medicaments of penicillins or streptomycins for retail sale | 7.774 |
| 300420 | Medicaments of other antibiotics, for retail sale | 6.454 |
| **300439** | Medicaments of other hormones, for retail sale, nes | 13.493 |
| 300450 | Other medicaments of vitamins or other products of 29.36 for retail sale | 1.210 |
| 300490 | Other medicaments of mixed or unmixed products, for retail sale, nes | 124.403 |
| 300650 | First-aid boxes and kits | 0.258 |

| HS Code | Product Description | FY2021-22 |
|---|---|---|
| 300660 | Chemical contraceptive preparations based on hormones or spermicides | 1.840 |
| 300670 | Gel preparations designed to be used in human or veterinary medicine. | 0.834 |

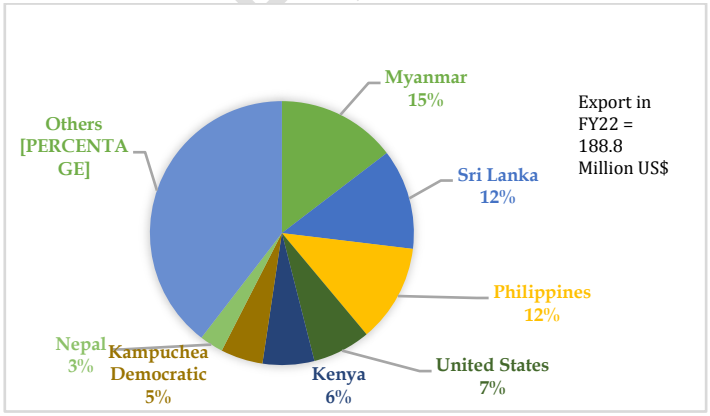
*Source: EPB Export data FY 2021, FY 2022*

Rahman [11] identified that Bangladesh is highly dependent on imports of API, even though 90%ii of API are recently imported from different countries. The over-dependence of Bangladesh on Chinese, Indian API, and other sourcing countries reflects the necessity for strengthening backward linkage in API production in Bangladesh. MRC report explored that approximately 40% of the raw materials came from China, 30% came from India, and the rest came from other countries like Korea and Germany till 2017.But in FY 2021-22, Bangladesh sourced 34% of its API from China and 32% of its API from India (Bangladesh Bank) [12].Meanwhile, in analyzing the 2-digit level HS Code of API products or organic chemicals, it was found that Bangladesh imported major API ingredients under HS Code 29 in FY 2021-22 amounted to US$1247.62 millionaccording to Bangladesh Bank Data.

### 2.3Pharmaceutical Export Market

Bangladesh can export to any country if the medicine is not under patent and has the export opportunity to another LDC or non-WTO country that has not implemented product patent protection (UN CDP) [13]. Bangladeshi pharmaceutical companies may export their products into markets that are regulated, such as those in the United States, Germany, Europe, and Developed Countries if their product is registered in those developed countries. It can be challenging for SMEs to register their product with drug regulators in such nations. Similarly, Bangladeshi firms can export into moderately regulated markets like Tanzania and Malaysia, which have moderate levels of regulation. Even though certain nations do not necessarily demand rigorous certification, a firm might get a competitive edge by becoming certified in a regulated market because it denotes quality. The majority of Bangladeshi medicines are sold to countries with markets that are not entirely regulated, including Bhutan, Pakistan, Sri Lanka, Nepal, Vietnam, and Myanmar. Exports from Bangladesh were on the rise but in 2022-23, the export in Sri Lanka, Myanmar, and Pakistan is decreasing as per an interview with an industry insider and stakeholder of BAPI.

**Figure 2: Top export destinations of pharma products from Bangladesh in FY2021-22**

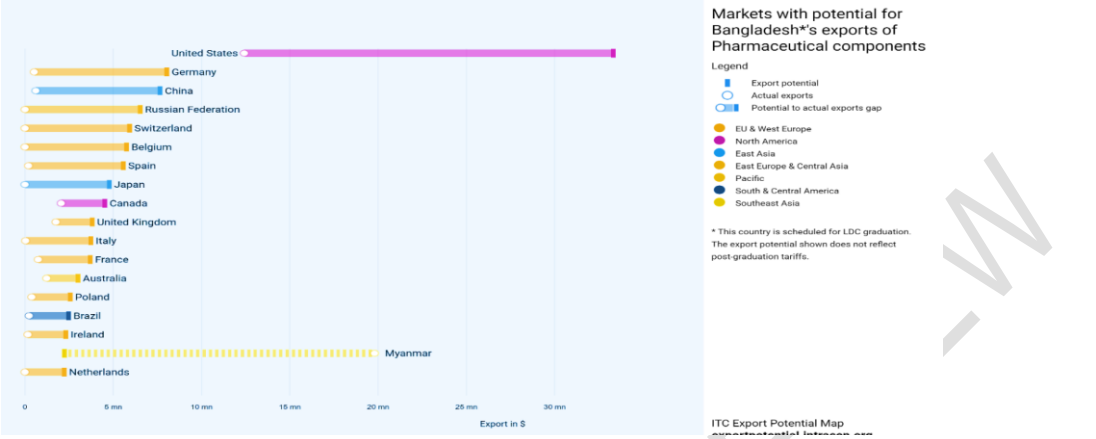



*Source: EPB Fiscal Year 2022*

Except for those countries cited in Figure 2,Bangladesh has the potential to export into the market of Russia, Switzerland, Belgium, Spain, Japan, Canada, the United Kingdom, Saudi

Arabia, France, Italy, Australia Poland, Brazil, United Arab Emirates, Myanmar, Netherlands, and Mexico.The markets with the greatest potential for Bangladesh's exports of pharmaceutical components are the United States, Germany and China.

***Figure 3: Export Potential Gap for top 20 Countries for Pharmaceutical Sector***




The graphs show the largest absolute difference between potential and actual exports in value terms. It also explores that Bangladesh has thepotential for additional exports worth $21 million in the USA market. Accordingly, in Germany and China, there are 8-10 million export potential for Bangladesh while in the whole of Europe, as shown in Figure 4, Bangladesh has an export potential of about US$ 50 million. Similarly, in Myanmar, Bangladesh has the potential to export an extra US$15 million, which indicates diversification of the market needs to be enhanced, as there is huge export potential for pharmaceutical products.

## 2.4 Challenges of Pharmaceutical Sector after Graduation

Bangladesh would lose patent exemption on pharmaceutical products after 2026 and after graduation according to Ministerial Conference (MC-12), the graduated countries have the probability to enjoy the benefit of TRIPS waiver till 2033 in patent right but it is not certain, as the conference has adopted the decision below:

> "An eligible member may apply the provisions of this Decision until 5 years from the date of this decision. The general council may extend such a period taking into consideration the exceptional circumstances of the Covid-19 pandemic"[iii]

As a result, numerous non-generic medication varieties will no longer be manufactured. Domestic manufacturers may be required to pay royalties on patents to continue the production process and failing to do so could result in patent infringement.The primary concern for Bangladesh is that the country's pharmaceutical industries are falling behind in terms of research and innovation, particularly in API manufacture and reverse engineering of medicine.

Bangladesh benefits from cheaper labor costs, but it is in a disadvantageous situation due to incremental cost factors ofActivePharmaceutical Ingredients (APIs). Moreover, the production of APIs is being curtailed by multinational corporations (MNCs), which are also looking for new, less expensive API suppliers or developing nations, where they may complete the entire manufacturing processof medicine. The health markets in Europe and the US are cost-constrained, and inventive companies have limited product pipelines. As a

result, generic firms expand more rapidly compared to non-generic firms (Kathuria & Malouche) [14].

EBL report stated that about 80% of the medications sold in Bangladesh are generic, and 20% are patented.Since Bangladesh's API capacity is negligible, businesses import 90% of their APIs. Sheel [15] informed that some Bangladeshi businesses have invested in high-quality raw materials, production techniques, and technical know-how to meet the growing demand for APIs, but the domestic markets lack regulatory framework means that inferior products receive more consumer attention than superior ones. Bumpas, Kostermans, and Nair [16] explored that due to insufficient regulation, consumers are not unable to distinguish between low-quality products and high-quality ones and cannot make quality product purchases when companies with small investment in quality are still selling drugs alongside those with significant investment in quality.

### *2.4.1 LDC Specific Challenges*

Tazin[17] urged that Bangladesh be allowed to produce patented generic pharmaceutical items to sell domestically and export to markets all over the world due tothe flexibility available for LDC under theWTO TRIPS agreement. The World Trade Organization granted developing and underdeveloped countries the freedom to create generic pharmaceuticals in 2001 under TRIPS without requiring them to obtain licenses or pay the patent holders for a set period.Later it was extended to 2026 for graduated LDC and Bangladesh. Bangladesh is allowed to produce any patented medicines without taking prior permission from innovator companies who own patents the non-generic medicine.To compete in the global market, Bangladesh will need to rely on conventional business strategies that provide the highest quality product at the lowest price, which may be challenging due to over-dependence on imported API and Molecules.

Bangladeshi pharmaceutical firms operate in a protected domestic market and moves to open the economy after graduation will most likely lead to cost & quality increment.The LDC-related flexibilities facilitate Bangladeshi investors to export drugs at a lower cost to countries where the medicine is not under patent conditions or producers do not pay royalties and do not incur the R&D costs borne by innovating firms in patent-protected markets.The South Centre urged, after graduation, as a result of the reinstatement of patents, “the lack of competition could lead to a significant increase in the price of medicines, particularly for therapeutic areas concerning non-communicable diseases which will be among the major contributors to the disease burden of Bangladesh” [18]. Along with less competition, production costs would increase as local producers would have to pay royalties and other costs for complying with intellectual property rights. The South Centre also identifies that Bangladesh may also be forced to remove import restrictions, opening the local industry up to competition from large-scale producers with nations like China and India after graduation. Meanwhile, the South Centre also explores that stronger patent protection, greater competition from imports, and fewer restrictions on the participation of multinational players in the domestic market could lead to a weakening of local producers, which in turn would have economic, employment, and public health implications including higher prices.

Along with these, there are various challenging factors, dragging the pharmaceutical sector behind compared to the expected growth.Addressing these problems, Sultana [19] underscored that a bioequivalence study center is necessary for the registration of an

exportable product in both moderately and well-regulated markets. Bangladeshi pharmaceutical firms need to make significant investments to meet international manufacturing standards as per the explanation of Hasan and Essar [20]. In addition, they have underscored that the extra expense of importing API under COVID-19 places an additional strain on pharmaceutical companies trying to make medicines for the local market.

Bumpas, Kostermans, and Nair further stressed that Bangladesh companies have a lack of capacity for warehouse maintenance of pharmaceutical products. Internationalstandards dictate that warehouses must maintain the environmental standards stated on the product insert. Similarly, the lack of cold chain facilities in airports for export creates complexities in pharmaceutical product exports from Bangladesh.

## 2.5Potential of Pharmaceutical Sector

The TRIPS agreement has turned Bangladesh into a center for affordable and high-quality generic medicines and contract manufacturing, with exports to potentially more than 100 countries across the world as per BAPI data. Even, more than ten leading Bangladeshi pharmaceutical companies are exporting generics to international markets. A number of these firms are also evolving as contenders to high-ranked Indian companies in certain areas. Muktadir [21] urged that pharmaceutical firms in the country are modernizing their factories and receiving certifications from the USA, Australia, Canada, and the EU.The rapid rise of non-communicable diseases (NCDs) like cardiovascular diseases, cancer, chronic respiratory disease, and diabetes in theBangladeshi population has led to a growing demand for drugs used for NCDs' treatment according to theEBL report.

Since 2015, there has been a rapid increase in demand for APIs from the local drug formulation industry according to the BIDA report. It is estimated that demand for APIs will exceed US$ 1,400 million by 2025, providing API producers with promises of stable market access as per theMRCreport. By 2025, the global API market is anticipated to reach US$ 319.07 billion. The scheduled patent expiry of blockbuster pharmaceuticals, the rise in healthcare costs, and government policies favoring generic drugs will all contribute significantly to the market expansion of APIs for generics. Additionally, China, one of the main producers of APIs, is relocating its production location due to worries about costs and sustainability. Additionally, some API companies may think about broadening their supply-chain based in light of the COVID-19 pandemic's disruption to the supply chain.

Given the facilities and support provided by the government to the pharmaceutical sector, this sector is maturing over time and leading pharmaceutical companies have increasingly focused on expanding their business in highly regulated markets, including the USA, UK, Canada, Australia, Germany, EU, etc. They are now exporting medicine to highly regulated countries, including the USA, UK, Canada, Australia, Germany, Europe, etc. Regarding this issue,Islam, Rahman, & Al-Mahmood [22]urged several smaller companies to enterhighly regulated overseas markets as the industry can establish itself as a rigorous export-oriented industry.Bumpas, Kostermans, and Nair further urged that pharmaceutical labor costs are approximately 30%[iv] less in Bangladesh thanin India. At present, Pharmaceutical white-collar workforce cost is less than that of other countries, implying the comparative advantage of the sector that that of competing countries. Contract manufacturing for a product that will

be exported to a market under regulation is a new area of opportunity for expanding export in the world market.

## 3. METHODOLOGYOF THE STUDY

The study applied a Qualitative Approach and a 'SWOT' analysis was also deployed to identify major sectoral strengths, opportunities, weaknesses, and threats. The study uses qualitative tools to evaluate the area of market and product diversification ofthe pharmaceutical industry and finally usesthe Autoregressive Integrated Moving Average (ARIMA) model to forecast what will be the export figure after 2032 and what interventions need to be taken to reach the expected level of growth.

As a result of the high quality and cost-effectiveness of Bangladesh pharmaceutical products,there isusually a huge demand for the products in the global market. We could have exported more but the export process is complex and time-consuming. Over the past two years, 1200 pharmaceutical items acquired export registration and are now being shipped to more than 150 nations, including the USA, UK, Canada, Australia, Germany, and the EU, etc.according to BAPI data. Here, using ARIMA Model the study determines the trend of future valuefollowing the model developed by Mohini, Prasad, Nguyen-Huy and Deo [24]. The AR model equation is:

$$y_t = c + a_1 y_{t-1} + \cdots\cdots\cdots\cdots\cdots + a_p y_{t-p} + u_t \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots (1)$$

$y_t$is the observed time series and $a_1$, $a_p$ are the AR parameters, c is a constant, p is the order of the AR, and $u_t$ is the white noise i.e. sequence of random numbers. Similarly, the MA model is represented as:

$$y_t = \mu + u_{t+} m_1 u_{t-1} + \cdots\cdots\cdots\cdots\cdots + m_q u_{t-q} \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots (2)$$

Where $m, \ldots\ldots\ldots, m_p$ are the MA parameters, q is the order of MA, $u_t$, $u_{t-1}$, $\ldots\ldots\ldots\ldots u_{t-q}$are the (error) terms, and μ is the expectation of $y_t$ . By integrating these two models with the same training data, the ARIMA model becomes:

$$y_t = c + a_1 y_{t-1} + \cdots\cdots + a_p y_t - p + u_t + m_1 u_{t-1} + \cdots\cdots + m_q u_{t-q} \cdots\cdots\cdots (3)$$

Where p and q are the autoregressive and moving average terms, respectively. Each component in ARIMA functions as a parameter with a standard notation. For ARIMA models, a standard notation would be ARIMA with p, d, and q, where integer values substitute for the parameters to indicate the type of ARIMA model used. The parameters can be defined as:

p: the number of lag observations in the model; also known as the lag order.
d: the number of times that the raw observations are differenced; also known as the degree of differencing.
q: the size of the moving average window; also known as the order of the moving average.

From fiscal year 2010-11 to 2021-22, EPB export data are used to forecast the normal growth of the sector till 2031-32. Four ARIMA models at different values of p, d, and q are estimated using theSPSS Packages26.0 to forecast the export growth of thepharmaceutical

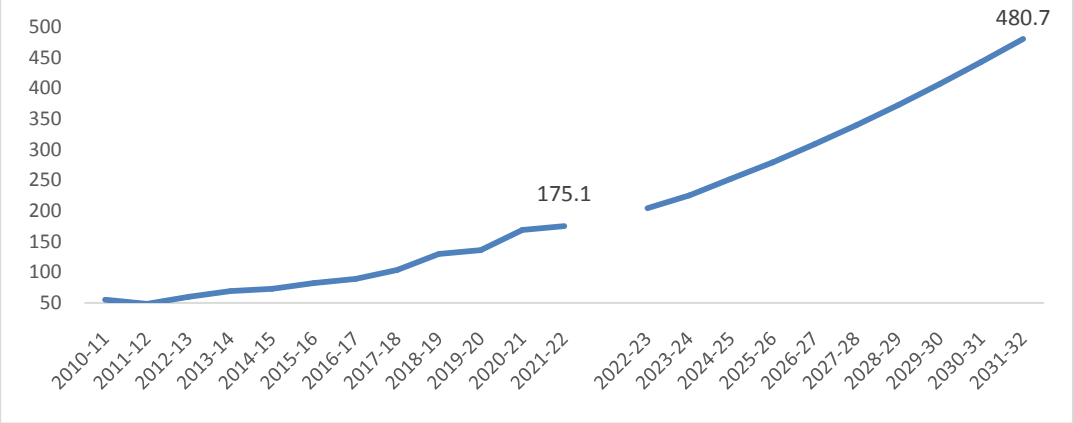
industry. From this comparison, the ARIMA(1,1,1) model is the best-fit model followingARIMA models at different values:

Table 3: Different Tested ARIMA Model

| Model | Stationary R-squared | R-squared | RMSE | MAPE | MaxAPE | MAE | MaxAE | BIC |
|---|---|---|---|---|---|---|---|---|
| ARIMA(0,1,1) | **.672** | .979 | 6.980 | 5.716 | 20.181 | 5.168 | 10.732 | **4.540** |
| ARIMA (0,0,0) | .929 | **.929** | 12.237 | 10.127 | 36.648 | 9.008 | 20.156 | 5.423 |
| ARIMA (1,1,1) | .718 | .982 | **6.916** | **5.306** | 20.459 | **4.436** | **9.871** | 4.740 |
| ARIMA (1,1,0) | **.664** | .979 | 7.068 | 6.067 | **19.324** | 5.124 | 11.215 | 4.565 |

It is expected that in FY2032, the export ofthe pharmaceutical sector will reach around US$480.7 million if the current export trend continues without any intervention. However, there is a possible negative impact on the current export growth as Bangladesh has to pay Intellectual Property (IP)payments for non-generic medicine and higher prices due to having no developed indigenous molecules. Moreover, the majority market share of exports from Bangladesh is concentrated in Developing countries and LDCs which donot follow the intellectual right properly.

***Figure 4:Pharmaceutical Sector Export Projection in US$ Million from FY2022-23 to 2031-32***




Source: Author Own calculation based on EPB Export Data from 2010-11 to 2021-22 and projected data from FY2022-23 to FY2031-32 is sourced by author own's calculation.

## 4. RESULTS

It was found in HS code analysis, that Bangladesh's earnings from HS Code: 300490 (Other medicaments of mixed or unmixed products, for retail sale) from the single pharmaceutical product amount to US$ 67% of the total export. It explores, that Bangladesh lags in product diversification while the majority of its market share is concentrated in Sri Lanka, Nepal, Myanmar, Kenya, and Khempuchia. Similarly, the recent economic crisis amid the Ukraine and Russia war has lessened the pharmaceutical exports to those countries in FY 2021-22.

The pharmaceutical industry has grown significantly in the last five years. So does, its export growthis forecasted to be US$480.7 million by 2032 if the normal growth rate continues against the challenges of LDC graduation. Due to IP rights and API molecules-related

issues, the cost of production after graduation and hence, the export cannot reach the expected level. The domestic demand for drugs is on the rise due to incremental GNI per Capita, population growth, changing disease profiles, lifestyle changes, and rapid urbanization.

Given the concern, the onus of the private sector is to invest more in R&D and reverse engineering for API to reap the demand of the domestic market while the responsibilities of the public sector are to expedite the trade facilitation as well as address the LDC graduation challenges. In addition to these, the operational API park along with infrastructure facilities can act as a turning point for this purpose, but activating all the utility facilities in the least possible time becomes a murky task. The sector needs to ensure as many as innovations and known molecules in the public domain as possible before graduation, to avoid implications of enforcement of the patent regime. Given the above, establishing more research institutions capable of undertaking R&D activities and setting up institutions like NIPER and CDRI in India (e.g., Bangladesh Institute of Pharmaceutical Education, Research and Development – BIPERD) get priority. Accordingly, the capacity of Contract Research Organizations CROs needs to be enhanced to conduct clinical trials for biosimilar and biotech products and prepare trained professionals to undertake CROs for BE studies. These ramifications will continue to help the growth of the pharmaceutical industry. Fromthe stakeholder interview and literature review, the following SWOTStrengthsand Weaknesses along with Opportunities and Threats are found:

***Table 4:* SWOT Analysis of Pharmaceutical Sector**

| **Strengths** | **Weakness** |
|---|---|
| a) Lower white collar workforce costs<br>b) Manufacturing Facilities for earlier import-dependent drugs<br>c) Quality medicine at affordable price<br>d) Many companies have international accreditation<br>e) Export led improvement for quality control | a) More than 90% APIs are imported<br>b) Insufficient investment in API, R&D, reverse engineering and technical know-how<br>c) API park yet to be functional.<br>d) Lack of skilled labour and technical workforce for API<br>e) NBR reluctance to provide tax break as per National API Policy<br>f) Lack of Synthesis Chemistry expertise<br>g) Lack of know how about handling patent<br>h) Unavailability of accredited bioequivalence study center or Contract Research Organization (CRO)<br>i) Don't have any patentable molecules and API |
| **Opportunities** | **Threats** |
| a) Huge scope in world pharmaceutical market<br>b) Tax Waiver, Export subsidies and cash incentive up to graduation<br>c) Patent waivers for patented pharmaceutical products until | a) Ending WTO TRIPS agreement waiver after graduation<br>b) Lack of protection option for domestic industry in IP and Patent act<br>c) Incremental production price due to patent right orientation |

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| graduation<br>d) Protected domestic market & domestic demand<br>e) Export Potential in the global API market | d) Globalization led extremely competitive international market<br>e) Complex Biosimilar product registration guideline<br>f) Cannot export to the market where patent is granted<br>g) Lack of Cold chain facilities in airport for export |

It was also found that exporting pharmaceutical products from Bangladesh is adifficult task because a company needs to adhere to each country's unique product rules, registration procedures, language requirements, cultural preferences, national packaging standards, and industry protection systems. Exporters also need to make a sizeable commitment in terms of money, time, and paperwork to register the product in the target country to start the registration procedure for entering the market. Here, supporting services from the commercial counselor of the Bangladeshi embassy in different countries can facilitate the export of pharmaceutical companies.

## 5. DISCUSSION

Addressing the Rule of Origin in different trade agreements, the South Center urged that there is a condition for concessionary value addition, and Bangladesh does not comply with the value addition condition while exporting pharmaceutical products in a developed and regulated market. Following graduation, Bangladesh must meet criteria requiring a minimum of 40%–50% value addition before exporting any pharmaceutical product to overseas markets, and therefore domestic self-sufficiency in API production is required.

Stakeholders asserted that Bangladesh needs to accentuate self-reliance in API production, R&D, reverse engineering, and technical know-how as well as make a functional API Park, develop a curriculum to have experts in Synthesis Chemistry, and establish anaccredited bioequivalence study center or Contract Research Organization (CRO) to secure patentable molecules and API.

Stakeholders have opined that a pharmaceutical company must obtain registration from the country's drug or food administration body of the potential export destination country to export pharmaceutical products to international markets. From a KII with an official of the leading pharmaceutical industry, the author comes to know that the procedure for registering a product in a foreign country is so complex, that businesses frequently establish offices there to sell their products. Here, the company must pay for the official costs as well as the logistical support of the office. Often small companies do not register their products on those markets which costs much to maintain their expenses, and they find less profitability. Some hidden charges have to be paid by Bangladeshi companies to register pharmaceutical products in LDC’s countries.

Stakeholdersunderscored that Bangladesh currently has few resources available for bioequivalence research.A company must conduct its bioequivalence test in a foreign nation at a significant testing expense of US$ 50,000–100,000(Kathuria & Malouche). BAPI and pharmaceutical exporters first felt the necessity of having a bioequivalence test facility in Bangladesh and they proposed to set up a modern bioequivalence test center for the promotion of pharmaceutical export but no step has been taken till now, hampering overall

export. Alternatively, the stakeholder in the interview urged that pharmaceutical manufacturersagree withthe government that the International Center for Diarrhoeal Diseases and Research in Bangladesh (ICDDRB) or Bangladesh Council for Scientific and Industrial Research (BCSIR) can start a bioequivalence test at a reasonable cost.

Stakeholders have further stressed thatonly there are practical difficulties associated with basic chemical import authorization for API since an entrepreneur must obtain authorization from seven to eight organizations in Bangladesh to import the product from foreign sources according to a representative interview from BAPI. For instance, a company must apply for permission from the Bangladesh National Authority for Chemical Weapons Convention, Department of Explosives, Department of Narcotics Control, Ministry of Industry, Ministry of Commerce, Directorate General of Drug Administration, etc. A respondent of KII revealed in an interview, “renowned pharmaceutical company requires 11 months, and another requires 9 months to get permission to import basic chemicals. The stakeholders of API industries have suggested preparing a one-stop service to facilitate the sourcing process of basic chemicals from different countries.

An industry stakeholder further addressed that Bangladeshi pharmaceuticals export is concentrated in a few products, implying the necessity for diversification. Hence, regulatory bodies and DGDA can suggest extra incentives for new product export and market diversification. He also suggested that the product registration process may be facilitated by additional assistance from the commercial counselor of the Bangladesh embassy in a foreign country as it can evaporate the cost of doing business as urged by a stakeholder. He further urged that Bangladesh should therefore utilize the pertinent research exemption provided by Section 38 of the National Patent Act of 2022.

Stakeholders further addressed only because of imported dependent raw materials, the cost of production becomes higher than that of India and China. Hence, Bangladesh cannot compete with the Indian and Chinese companies to offer export prices, and setting the API park in motion is a very urgent issue.

Stakeholders underscored that onlydue to the claims and urges of BAPI and pharmaceutical business entrepreneurs, the government of Bangladesh has taken the initiative to establish an API park near Dhaka. A long time has already passed since we decided to establishing an API park but the park has yet to become effectively operational.

Stakeholdersinformed that domestic API companies are not getting tax breaks because of NBR's reluctance to facilitate tax breaks proposed in National API Policy 2018. According to API policy 2018, NBR is recommended to extend the tax break until 2032 under specific circumstances to make raw material suppliers eager and continue to invest 1% of their yearly revenue in R&D to maintain their eligibility for the tax exemption. Moreover, it is proposed in the National API policy that “if a company produces minimum three APIs or laboratory reagents in a year, they will get a 22.5% cut in corporate tax, meaning that they will pay 7.5% in tax” only remain in black and white in government gazette (SANEM)[23].

**5.1Challenges Related to API Park**

In the author's interview, the business and association representatives of the pharmaceutical sector identified that fully in-operational API parks became the major concern for the API industry in Bangladesh. They listed the following problems and requested to address these issues at the least possible time:

- Though theinternal gas connection and distribution line are prepared in the API industrial park, the gas connection is not linked with the main line. The industry people have contributed financiallyto establishing the Central Effluent Treatment Plant(CETP) in the industrial park but it cannot become fully operational due to lack of gas supply.

- Bangladesh Small and Cottage Industries Corporation (BSCIC) accepted in a stakeholder meeting that itwould removethe 12.5% service charge and include a 5% overhead cost for every plot[v]. Till now, BSCIC has not issued any gazette or circular regarding this issue, and hence a plot owner cannot pay the payment of theplot because of uncertainty in determining the plot price.

- In the industrial park,BSCIS has established 1st class infrastructure for central fire extinguishing servicewith an auto-controlledfire hydrant system and fighting management but no workforce is being employed till now to manage the system. Without an active central fire extinguishing service, firms cannot operate its function.

- In the park, there areseveral high-voltage electricity pillars and polls in the distributed individual industrial plot,creating uneven risk. Besides, there are many places in the park downgraded to the normal level of the road because of inefficient filling of ground with sand in the industrial plot. As a result, around 4-8 feet of plot land are gone down from the normal level of land. Moreover, the boundary walls of the park need to be elevated because after filling the sand in the plot, many boundary walls become low and can easily be crossed.

## 6. CONCLUSION

Amid LDC graduation, Bangladesh will face several problems related to patent rights and payment, value addition conditions, and incremental product costs for non-generic pharmaceutical products. Meanwhile, market access in different export potential countries becomes stringent if the quality of products and investment in API and R&D is not ensured. Even in the domestic market, the price of pharmaceutical products will increase due to rising production costs for patent payment. Given the context,the government has to play a significant role in the rapidly growing pharmaceutical industry, providing policy support for easier drug approval, production, marketing, and registration in the potential export destination. The fully operational API Park with all other utilities will act as a turning point for this purpose. Bangladesh needs to expand its capacities in API & molecule production, R&D, and bio-equivalence testing capacities to promote the industry. Similarly, addressing the lack of patentable molecules in the domestic industry, Bangladesh must ensure discoveries and well-known molecules are placed in the public domain before graduation to avoid the negative effects of implementing the patent regime. Moreover, Bangladesh needs to raise the capacity of Contract Research Organizations (CROs) to facilitate clinical trials for biosimilar and biotech products and take concrete measures to strengthen capacities, particularly in IP law and patent law, chemical synthesis, patent examination, synthesis

chemistry expertise, lab technicians, and accreditation specialists. Accordingly, Bangladesh needs to make available qualified CROs for the Bioequivalence (BE) test & study center and prepare trained professionals to undertake CROs for BE studies. The cited ramifications along with the public and private sector initiatives to establish research institutions capable of undertaking R&D activities and set up institutions like NIPER and CDRI in India, simplified regulatory requirements for new investments or FDI in the API sector for firms, striving toward higher levels of quality improvement and working with the global industry through joint venture can expand the export opportunity of Bangladesh.

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**Definitions, Acronyms, Abbreviations**

| | |
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| ARIMA | Autoregressive Integrated Moving Average |
| Australia-TGA | Australian Therapeutic Goods Administration TGA |
| BCSIR | Bangladesh Council for Scientific and Industrial Research |
| CETP | Central effluent treatment plant |
| CIT | Corporate Income Tax |
| EMA | European Medicines Agency |
| ICDDRB | International Center for Diarrhoeal Diseases and Research in Bangladesh |
| MRC | Migrant Resource Centre |
| NBR | National Board of Revenue |
| NBR | National Board of Revenue |
| NCDs | Non-communicable Diseases |
| TFDA | Taiwan Food and Drug Administration |
| UK-MHRA | United Kingdom Medicines and Healthcare products Regulatory Agency |
| UNDESA | United Nations Department of Economic and Social Affairs |
| US-FDA | U.S. Food and Drug Administration |