Final Report

On

Detail Study of Pharmaceutical and Medicine Manufacturing Industries in Nepal

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We hope this study will be useful to prepare further policy and directives related to pharmaceutics industry in context of Nepal.

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ABBREVIATION

A.D.	Anno Domini
AIDS	Acquired immunodeficiency syndrome
APPON	Associations of Pharmaceuticals Producers of Nepal
B. Tech.	Bachelor in Technology
B.E.	Bachelor in Engineering
B.S.	Bikram Sambat
CPP	Certificate of Pharmaceutical Product
DDA	Department of Drug & Administration
DOI	Department of Industry
EPA	Environmental Protection Act
EPR	Environmental Protection Rule
FGD	Focused Group Discussion
FSMS	Food Safety Management System
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
INGO	International Non-Governmental Organization
ISO	International Organization for Standardization
KII	Key Informant Interview
MBA	Master in Business Administration
NGO	Non-Governmental Organization
NPDA	Nepal Pharmaceutical Dealers Association
NPL	National Pharmaceutical Laboratory
NPR	Nepali Rupees
PGDM	Post Graduate Diploma in Mechanical
SAWTEE	South Asia Watch on Trade Economics and Environment
TB	Tuberculosis
TOR	Terms of Reference
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRS	Technical Report Service
USD	US Doller
VAT	Value Added Tax
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER I: INTRODUCTION

1.1 Background

The historical event of the development of pharmacy was started during ancient Lichchhavi ruler Amshu Berma date back to 605-620 AD when a Ayurvedic hospital was established. In 1641- 1674 AD, King Pratap Malla started ayurvedic medicine production unit in the royal place. Modern allopathic medicines were introduced in Nepal in 1816 AD after Suguali Treaty and establishment of British residency in Nepal. Allopathic medicine manufacturing was started in 1969 in private sector and a government undertaking Royal Drug Limited was established in 1972.

Government of Nepal established Department of Drug Administration (DDA) in 1979 A.D (2036/07/01 B.S.) erstwhile under Ministry of forest & soil conservation and went under Ministry of Health and population after Poush, 2041 B.S. DDA is one of the three departments under Ministry of Health & Population.

Nepal has promulgated the Drug Act 1978(2035 B.S.), to prohibit the misuse or abuse of medicines and allied pharmaceutical products as well as false or misleading information relating to efficacy and use of drugs and to regulate and control the production, marketing, distribution, export, import, storage and utilization of those drugs which are not safe for the public use, efficacious and of standard quality. To implement & fulfill the aim and objectives of Drug Act 1978 and various regulations are made under it.

In accordance with the objectives of the National Health Policy, 1991, to improve & manage by establishing co-ordination among governmental, non-governmental & private organizations involved in activities related to medicine production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow, the National Drug Policy, 1995 has been implemented. Achieving the aim & objectives of National drug policy is another important area for DDA.

Nepal has become a WTO member on April 23, 2004. Accession of Nepal to WTO has brought both opportunities and challenges to Nepalese pharmaceutical industries. World market of pharmaceutical products is now open to Nepalese industries and simultaneously Nepalese market is open to industries worldwide. In this context Nepalese pharmaceutical industries should be able to explore the opportunities and make best use of the opportunities. In addition,

Nepalese industries should also identify the external threats for them and make efforts to overcome the threats. Therefore, it has become imperative for individual Nepalese pharmaceutical industries and Pharmaceutical Industry as a whole to formulate the strategies which could lead them to their growth and how they could harness their strengths for exploiting the opportunities before stepping into WTO/TRIPS regime in 2016. Since majority of pharmaceutical industries in Nepal are SMEs, there is a necessity for a facilitating role by the government for gearing-up Nepalese industries to utilize the opportunities under WTO regime. Therefore, it is also imperative to identify the roles to be played by the government to facilitate the Nepalese pharmaceutical sector to enter WTO regime. With a view to fulfil these needs this study has been carried out.

The usage of pharmaceuticals is governed by the underlying medical science. The four primary medical sciences are as Allopathy or modern medicine has gained global popularity, Ayurveda, an ancient Indian Science, mainly uses herbal remedies, Unani, having Chinese origin, is prevalent in South East Asia, and Homeopathy, founded by a German Physician, was fairly popular in the early 19th century. World-over the pharmaceuticals industry is focused on Allopathy, the most modern medical science. Other modes of medical treatment such as Homeopathy, Ayurveda and Unani are more prevalent in their world countries.

Dramatic changes are occurring in the 21st century pharmaceutical industry. Transition creates uncertainty, with both increased risk and increased opportunity. Medicine development and time-to-market remain vital to business success in the pharmaceutical industries, but manufacturing efficiency has become equally important to future success and competitive advantage. Major business drivers include increasingly crowded therapeutic categories, powerful and increasingly global competition, weak new product portfolios, and increasing regulatory requirements that new pharmaceutical products be proven both safe and effective before they can be marketed and sold.

Today the success of a pharmaceutical company depends upon the quick market growth of a newly launched medicine to get the cash back for the development. The market success of the next generation of medicines will depend on the interest of the customers and the worldwide penetration from the very first moment.

Entire sectors are going under business trauma because of Covid-19. This fiscal year has become more of a year of survival for all enterprises. Especially service industries, tourism,

aviation and hospitality sectors have been hit hard by the outbreak. Tourism sector being one of the largest industries has been contributing 8 percent to Nepal's economy, which shall by now would not contribute for the next 6 months at least. Similarly, foreign employment, which has been contributing 26% to the nation's GDP in the form of remittance, has been impacted by the increased rate of virus pandemic.

At present situation there are 62 pharmaceutical industries manufacturing human related medicines, 8 pharmaceutical industries manufacturing medicines for animals and 73Ayurvedic medicine manufacturing industries. There are 390 foreign pharmaceutical industries which are supplying medicines through importers in Nepal. While analyzing data of domestic production and import of pharmaceutical products; it has been observed that market share of domestic production is 46%, medicine from India is 52% and other countries medicine is 2%. Specifically, vaccines, biotechnological products and modern technology related medicines; used for Anti-cancer, ART, critical care etc. are imported.

There were 359 medicines listed in National List of Essential Medicines in 2016. The medicines added in the Anti-tubercular and Antiretroviral groups are added to match with the National TB program and HIV AIDS Control Program of Government of Nepal.

1.2 Objectives

To analyze the current status of Human Allopathic Medicine (Pharmaceuticals) Manufacturing Industries with respect to demand, supply, energy consumption and challenges for sustainability.

1.3 Scope of the Study

The scope of the study has covered the following area:

- Annual Demand of medicine (allopathic) and its import/export status: category wise-injection/Tablet/Powder/Syrup
- Industry Details: (Name of industries, their detail address, production capacity and actual capacity, investment Consumption etc.)
- Capacity Utilization (including approved capacity and actual capacity)
- Energy consumption
- Number of employee engaged
- Demand Forecast

- Supply and Gap
- Capacity of Domestic Industries in terms of self Sufficiency
- Percentage basis import and availability within the country (Domestic availability vs import)
- Status and trend of import for medicine production industries.
- Availability of Raw Materials domestically for medicine manufacturing industries for upcoming years.
- Technology adopted
- Status of WHO GMP standard/ Quality aspects
- Marketing aspects
- environmental impacts
- Challenges faced by the medicine manufacturing Industries
- Financial position and area for improvement (Policy level, association level and industries level)
- Possible Suggestions

1.4 Legal Provision of Medicine Manufacturing Industry in Nepal

Under the Drug Act 2035, the following rules/regulations & codes have been implemented as supporting tools for the active enforcement of Drugs Act, 2035.

- Drug Advisory Committee & Drug Advisory Committee Formation Rules, 2037 (1970)
- Drug Registration Rules, 2038 (Second Edition 2058)
- Drugs Investigation & Inspection Rules, 2040
- Drug Standard Regulation, 2043
- Drug Donation Guidelines (For Quality Assurance of Donated Drugs)
- Drug Sales & Distribution Codes, 2071
- Good Practice Codes for Drug Production, 2072
- Medicine Registration Guidance, 2073
- National Health Policy-2071
- National Drug Policy-1995
- Nepal Health Service Act-2053
- Nepal Health Service Regulation-2055
- Narcotic Drug (Control) Act-2033

1.5 Limitations of the Study

- Six industries out of 40 selected did not provide the information and some provide partial information only. In such cases, secondary data has been used from sources like DOI, DDA and APPON.
- Questionnaire have been prepared as per TOR for study of self-reliant pharmaceutical products in tablet, capsules, powder, liquid and ointment. However, the individual industries and APPON provided information product/molecule wise. Hence study has been focused to find out self-reliant medicines.
- Import and export pharmaceutical products status could not be provided in quantity since Department of Custom has not maintained the import and export data in details including quantity and category.

CHAPTER II: LITRATURE REVIEW

2.1 History of Pharmaceutical and Medicine in Nepal

The true history of Nepali pharmaceutical market started with the establishment of Bir Hospital. At that time medicines were imported to fulfill the demand of public. Nepal Pharmaceuticals established its first allopathic plant at Godavari but it could not be successful. The penetration of private sector took place with the establishment of Chemidrug industries in 2026 B.S. (1970 AD) and following it Royal drug limited also started its operation as a government industry in 2029 B.S. (1973 AD). There was a big gap between 2029 to 2038 B.S. (1973-1982 AD). Then came a phase between 2038-2042 B.S. (1982-1985 AD) when introduction of industries like Manoj, Everest, Lomus and NPL took place. On the other hand, during this span of time there was mushrooming of saline industries which also failed. The new era for Pharma Industry came during 2050 B.S. (1994 AD) when there was rapid flourishing of pharma industry.

During this phase Drug act was formulated in 2035 B.S. (1978 AD) under which the government regulatory body DDA (Department of Drug Administration) was established 2036 B.S. (1979 AD) In 2060 B.S. (2004 AD) DDA introduced the concept of GMP (Good Manufacturing Practice) and its certification which inspired the Nepali pharmaceutical companies to produce Quality Medicine and made them able to dream to compete with the international market. Until now 20 companies have been certified and the deadline to obtain the certificate has been announced till the end of 2068 B.S. (Mid-April 2012). The recent DDA policy presented a criterion of WHO recommended certification for foreign companies to market their products in Nepal due to which several substandard Indian companies had to withdraw their market from Nepal. Apart from having an extra financial load to some companies, it has also opened door for export opportunities.

According to Drug Bulletin of Nepal published by DDA; Vol. 30, No.3; April-July 2019 up to Ashadh 2076, total 373 foreign allopathic pharmaceutical industries were registered whereas domestic were 73 in 9949 and 9166 brand medicines available respectively.

2.2 Demand of Pharmaceutical and Medicine in Nepal

The global pharmaceutical market is expected to reach nearly USD 1455-1485 billion by 2021, an increase of USD 350-380 billion from the USD 1,105 billion recorded in 2016. This growth is coming mainly from market expansion in Pharmerging countries and demographic trends in

developed countries due to an ageing population. Global brand spending is forecast to increase to USD 815 832 billion in 2021. Global generic spending is expected to increase to USD 495-505 billion by 2021.

The United States share of global spending will increase from USD 461.7 billion in 2016 to USD 645-675 billion in 2021, while the European share of spending will grow from USD 151.8 billion to USD 170-200 billion. Meanwhile, pharmerging countries will spend USD 315-345 billion in 2021 from USD 242.9 billion in 2016.

The consumption of medicines in the Nepalese market during the fiscal year 2017/18, is worth USD 0.386 billion, of which medicines worth USD 0.160 billion is manufactured by the domestic companies. Annually USD 0.226 billion is spent for import of medicines mainly by the from India (USD 0.187 billion). This way the domestic production takes care of about 41.42% of total consumption.

At present, the total pharmaceutical market of Nepal is estimated to be NPR 53 billion (approx. USD 430 million). Nepal imports NPR 28.65 billion worth of medicine from India and other countries, which is about 54.5% of the total market share, while NPR 24 billion worth of medicines are produced by domestic industries, which is 45.5% of the total market share.

If government takes effective actions based on its budget announcement meaning to make self-sufficient in essential medicines by promoting domestic industries, the domestic production can take care of 75% of total market. This would result in development of domestic industries in the road map of self-sufficiency with good promotion and protection of domestic industries.

In the initial years, the Nepali companies used to produce only normal medicines for illnesses like common cold, diarrhoea, fever, cough, a few antibiotics and tonics. But today, they have evolved from that situation and are now producing essential drugs even for cardiac, diabetic and liver patients.

Except for 10 percent of medicines, produced all kinds of medicines here in Nepal.(Business E-news dated 2016.02.29)

According to sources, while new companies are using the latest available facilities for manufacturing drugs, the old ones too are upgrading and doing everything they possibly can to maintain quality.

2.3 Details of Pharmaceutical and Medicine Manufacturing Industries

According to information provided by DDA on 2077/10/12, there are 66operating domestic allopathic pharmaceutical industries registered for manufacturing and have got permission for sales and distribution. Four other industries are registered and have got permission for sales and distribution but currently they are not operating due to technical reasons of the industries. There are 33 new industries which are registered for manufacturing but have not yet got permission for sales and distribution. (Table 3.1)

Pharmaceutical industrialists say that the size of the domestic pharmaceutical market currently stands at Rs. 46 billion and that the industry has been growing at 18-20 percent per year over the past 7-8 years. Similarly, according to them the investment in the industry has already reached around Rs 18 billion.

Despite having several constraints like power crisis and labor unrest, the domestic pharmaceutical industries have attained an encouraging growth. Manufacturers say that the sole factor behind the growth is quality and also "Some of the companies are able to compete even in the global market"

There are total 57 domestic Pharmaceutical Industries associated with APPON, out of which 4 industries in Province No. 1, 12 in Province 2, 28 in Bagmati Province, 13 in Lumbini Province. (Table 3.2)

2.4 Energy Consumption

Nepalese endured a crippling power shortage for a decade (2006-2016). In 2014 winter, Nepalese were enduring 14 hours of power outrage every day. However, NEA has officially announced elimination of Load shedding in Nepal from May, 2018. Peak load is 1,160 MW as on July 2019. Per capita energy consumption 245 kWh and expected to be 1500 kWh in next 5 years.

According to Energy Data Sheet by Water and Energy Commission Secretariat (WECS), June 2014, 7.89% energy was consumed by Industry Sectors but according to Nepal Energy Sector Assessment, Strategy and Road Map, ADB, 2017; only 5.8% energy is consumed by the industry sector.

According to estimations of the NEA energy demand will grow in the next 17 years with an average annual rate of 8.34 %. The current demand of 4430 GWh annually is expected to double until 2018 and exceed 17,400 GWh by 2027. Along with the growing demand it is

projected that system peak load will increase with similar annual growth rates, reaching 3679 MW in 2027.

Energy consumption by Pharmaceutical industries is lower than other manufacturing industry like Cement Industry, Rolling Mills etc. However, there is lack of details study in the energy consumption by pharmaceutical industry. This study will make a clear figure on the energy sector.

2.5 Capacity Utilization of Pharmaceutical and Medicine Manufacturing Industries

Capacity utilization of pharmaceutical industries is noticed to vary from 25% to 80% depending upon the scale and product range. Industries of large scale with relatively larger range and form of products have 60% and above. The poor capacity utilization in pharmaceutical sector is said to be due to less product range and form, and also installation of plant and machineries of higher capacity than required due to lack of knowledge and information at the time of establishment.

The industry has made a lot of progress, especially over the past one decade. But it is yet to utilize its full potential because of several reasons.

The entry of private sector pharmaceutical producers after the 1990s changed the face of the domestic drug market which was once overwhelmingly dominated by foreign products.

According to E-news published on New Business Age dated 2016.02.29, growth of the pharmaceutical industry has been seen, even at times when many other manufacturing industries seem to be performing badly, investors seem to be confident and willing to invest in pharmaceutical production. At least one new industry joining the fold every year and this is a healthy sign for the industry. The quality and zeal of manufacturers to move with global trends have helped them to attain an impressive growth.

Even at the current growth rate, the domestic manufacturers will capture at least 80 percent of the domestic market share by 2025.

2.6 Import Status of Medicine

Although Nepal's domestic medicine market is still dominated by foreign products, particularly Indian products, domestic manufacturers are increasing their market share. According to a study carried out by South Asia Watch on Trade Economics and Environment (SAWTEE), the share of domestic companies in the country's pharmaceutical market was only about 30 percent

in 2005. Today, according to industry insiders, domestic companies have an impressive share of 45 percent.

According to industrialists, there is a possibility of exporting medicines from the country if the government supports the industry. Some domestic companies have already started exporting medicines, Lomus Pharmaceuticals is taking the lead in exports. Besides Lomus, four other domestic drug-makers—Nepal Pharmaceuticals Laboratory (NPL), Deurali-Janata Pharmaceuticals, Elder Pharmaceuticals and National Health Care Nepal—have received the Certificate of Pharmaceutical Product (CPP), one of the prerequisites for obtaining the export licence from the DDA. (Business Age E-news, dated 2016.02.29)

Despite having immense potential for exports, the sector is yet to achieve its full potential. Lack of government initiative to promote the sector has played a major spoilsport. They don't have a sound economic and social environment for industrial operations. The pharmaceutical industry can achieve much more than what it has so far, urging the government to do more to promote domestic companies rather than increasing dependency on imported products. (Business Age E-news, dated 2016.02.29).

At present, the total pharmaceutical market of Nepal is estimated to be NPR 53 billion (approx. USD 430 million). Nepal imports NPR 28.65 billion worth of medicine from India and other countries, which is about 54.5% of the total market share, while NPR 24 billion worth of medicines are produced by domestic industries, which is 45.5% of the total market share. Presently 59 industries are in operation and 26 industries are in pipeline.

Nepal imports 70-75% of raw materials from India while 25-30% from China. India imports around 80% of the intermediate products from China to manufacture raw materials.

According to data published by Custom office; the import of pharmaceutical products including Allopathic, Ayurvedic, Veterinary etc. for last five years are NRs. 28.18, 30.11, 27.27, 24.13 and 26.58 Billion Rupees respectively.

2.7 Production of Raw material in Nepal

According to Vivek Man Baidya, Executive Director of Vijaydeep Laboratories, Nepal imports 70-75% of raw materials from India while 25-30% from China. India imports around 80% of the intermediate products from China to manufacture raw materials. Therefore, Nepal is dependent heavily on India and India is dependent on China. Production of the raw materials and intermediate products have reduced sharply in China, as a result, the cost has gone up 2-3 folds. Most of the domestic industries are either shut down or running at 20% capacity during the study done industry wise. The industry is facing problem to import raw materials from India due to the increasing trend of epidemics while China, on the other hand, is not responding.

According to 15th Five Year Plan (2018-19 to 2023-24), investment facilitation and support for infrastructure development will be provided to promote industries based on domestic raw materials including medicines. Support and assistance will be provided towards the development of infrastructure and promotion of industries based on domestic raw materials including medicine. In order to reduce trade deficit, there is an immediate need for export promotion and import management by identifying, developing, and increasing production. Additionally, the country needs to attain self-reliance in basic needs goods, including agriculture, fuel, and medicine.

2.8 Technology adaption by Pharmaceutical and Medicine Manufacturing Industries in Nepal

The technologies used to manufacture pharmaceutical products in Nepalese industries differ from semi-automatic to automatic depending upon the form of pharmaceutical product. – Tablets, capsules, liquid, ointment, dry syrup, powder, injectable etc. The machineries used to manufacture pharmaceutical product are mostly from India. But instruments and equipment for quality control and quality assurance are mostly from third countries like Singapore, Japan, Germany, etc. All the industries have incorporated quality control in its production process, but only a few have system for quality assurance. With a view to enhance technology and quality of the sector, two industries have come forward and developed linkages with academia. Only one industry has technical collaboration with Bangladesh Company.

2.9 Challenge faced by Pharmaceutical and Medicine Manufacturing Industries

There exists a number of issues and challenges that Nepalese pharmaceutical sector is facing. According to the study "the Nepalese Pharmaceutical Industry in the context of Nepal's newly acquired WTO Membership" on 2005, the major issues and challenges are as follows (11):

2.9.1 High Dependence on Imports

The Nepalese pharmaceutical market is highly dependent on the imports, because about 69.7 per cent of the market (Rs. 8649 million) is catered through imports. Such high dependence on the imports is very critical for any pharmaceutical market. Although the issue of higher price is not a concern in the market due to a large number of companies in the generic market at present, but it would definitely be a major issue in a patent recognized import driven market. Therefore, Nepal needs to move towards a self-dependent vibrant domestic pharmaceutical market. Likewise, all ingredients like bulk drugs and active pharmaceutical ingredients for Nepalese pharmaceutical sector are required to be imported from outside making the sector totally dependent on imports.

2.9.2 Low Tariff Barriers for Import of Drugs

Only 5% customs duty is levied on the imported drugs, whereas domestic industry has to pay up to 17 per cent in the form of duty including Value Added Tax on imports of packaging and others auxiliary inputs. These increase the cost of production affecting the competitiveness of Nepalese industries. (Note: Recently government removed VAT through Financial Ordinance on 14 Jan, 2006)

2.9.3 Constraint to Export

The neighboring markets for the Nepalese pharmaceutical industry are China, India, Pakistan and Bangladesh, but most of these markets are more or less self-sufficient with the well-developed domestic pharmaceutical industries. Export potential in other countries is limited due to less access of market and regulatory information, higher transport costs and high registration costs in export markets. For example, with the enactment of a regulation enforced since April 2003, Nepali drug companies have to pay US $ 1,500 as a registration fee at Central Drug Lab of India prior to exporting drugs to Indian market, while Indian companies have to pay just Rs 50,000 to DDA, Nepal for exporting their medicines to Nepal. Along with the high registration charge, the amended Act has also imposed different new fees including factory inspection charge amounting to US $ 5,000 and quality examination fee of US $ 1,000 to each new brand of the foreign drug exported to India. While the Indian companies are taking the advantage of the low drug registration fees in Nepal, Nepalese companies have to pay exorbitant fees in India reducing their competitiveness in Indian market. The Indian process for importing medicines from Nepal is long and cumbersome causing difficulty in export. As Nepal is a land locked country, export from Nepal needs to overcome many hurdles in course of transit and transfer of products. Currently, the only option

Nepalese industries have is routing through either India (Kolkatta port) or Bangladesh (Chittagong Port) to export medicines is by air transport. Moreover, infrastructures in those ports are relatively very poor and bureaucratic processes are cumbersome affecting the shelf-life of medicines as well as cost of exports from Nepal.

2.9.4 Proliferation of Brands

Nepalese pharmaceutical market has high proliferation of brands and in fact it is one of the markets having high per capita of brands. It is not due to the foreign companies alone, as domestic companies too have good number of brands in the market. With the increasing number of brands, the marketing and sales budget of the companies are increased drastically affecting their competitiveness. This is because the companies have to establish high recall of their brands in the market through planned marketing and heavy sales promotion. The only differentiation in a generic market where in the technological superiority lasts for a short time, is through heavy marketing and sales promotions with good distribution system. Even it would be difficult for the prescribing doctors to choose from the available brands in the market. In such a situation, there are higher chances of low customized medicine prescriptions, as the doctor can concentrate on the few brands at any given time in order to identify their responses.

2.9.5 Unregistered Drugs in Market

There are some substandard drugs available in the Nepalese market. Substandard drugs which are either diluted or don't meet the standards prescribed in the country's pharmacopoeia. The US Food and Drug Administration estimates that about 10 per cent of all drugs around the world are counterfeit and 60 per cent of them are found in developing countries. The World Health Organization estimates that 35 per cent of the fake drugs produced in the world come from India, where about 20 per cent of all drugs sold are either fake or substandard. Sale of unregistered drugs is prevalent in Tarai regions due to open border with India. The monitoring and regulation systems aren't vigilant enough to meet this danger and are compounded by lax enforcement of prescription rules. Antibiotics are readily available across the counter in Nepal.

2.9.6 Low Research and Development

Nepalese pharmaceutical industry has a market of around Rs 2500 million. Since there are 39 industries in total, each industry has market of an average of Rs. 64 million. Of the total, most are of small and medium scales and only a few are of large scale enterprises. With such low average revenue and majorities of being of small and medium scale, most of the industries are not able to spend on research & development

activities, not even into the reverse engineering of the molecule production. A low investment in R&D due to lack of incentives has hindered the industry from becoming self-sufficient, be it in bulk drugs or formulations. Industries have to pay 20 per cent custom duty in import of instruments to be used in R&D. Pharmaceutical sector spending significant amount in R & D is noticed to be more dynamic and vibrant, which could be seen in the case of Bangladesh.

2.9.7 Poor Healthcare Infrastructure

Even compared with the ones of neighboring countries, healthcare infrastructure of Nepal is not a developed one and only people living in urban areas are able to use the available infrastructure. About 85 per cent of the rural population lacks even basic healthcare facilities. There is acute shortage of medical doctors. The total number of allopathic doctors is about 4000 and majority of them are staying in the capital and other major cities. The public and doctor ratio is approximately 6000:1. Health workers in rural health care, who serve most of the population, are isolated from specialist support and up to date information. Nepal's average life expectancy varies greatly from 74 years in Kathmandu to 37 years in rural areas, and maternal mortality is among the highest in the region. Infectious diseases, maternal and prenatal disorders, and nutritional deficiencies account for more than 2/3rds of the diseases in Nepal. One out of 11 children dies before they reach age of five. Most of these children die within their first year. Although children under the age of 5 represent only 16 per cent of the population, they contribute approximately half of the total burden of disease in the country. The poorly-resourced clinics are the only means of hope for healthcare in large areas of rural Nepal. The poor healthcare infrastructure is affecting in making people aware of modern medicine and slowing the growth of consumption of pharmaceutical products in the country.

2.9.8 Security Concerns Impeding Healthcare

Apart from the difficult terrains, insurgency and political instability are inhibiting the pharmaceutical industry in proper distribution of the drugs in several parts of the country. The most affected are the western, mid-western and far-west development regions. The mountainous and hilly regions of central and eastern development region are also affected except the Kathmandu Valley and other urban areas. Frequent bandhs (general strikes/closures) and blockades for days are preventing the smooth distribution

of drugs. Many health institutions are unable to operate to its capacity due to security concerns.

Major challenges since the outbreak begun have been collection of payments from the local market, sharp reduction in sales due to lockdown, restrictions in the transportation of the medicines to other places, and availability of raw materials.

To gear up the activity for better survival position of the industry, government and banking sector's role is crucial. Policy for collection from market party needs to be secured as goods that were sold in credit earlier needs to be paid by now.

2.10 Financial position of Manufacturing Industries in Nepal

As per Industrial Policy, 2010, the fixed capital up to 50 million rupees is categorize as small industry, capital of 50 to 150 million rupees is medium scale and above 150 million rupees is large scale industries. The policy has been revised and changed the fixed capital investment for small, medium and large scale. According to industrial enterprises act 2016, the fixed capital up to 100 million rupees is categorize as small industry, capital of 100 to 250 million rupees is medium scale and above 250 million rupees is large scale industries.

According to the financial position mentioned during the company registration and industry registration, most of the rolling mills are large scale having above 250 million rupees fixed capitals.

According to National Drug Policy 1995, the domestic pharmaceuticals industries will be accorded a status among national priority sectors. In order to achieve self-reliance in the production of essential drugs the entrepreneurs will be encouraged to promote and establish pharmaceutical industries both in public and private sectors. The aim is to be able to produce 80% of the essential drug formulations in the coming 10 years. Production of active ingredients, excipient and packaging materials will be encouraged. While purchasing drugs for the public sector, first priority will be given to domestic products in accordance with the financial regulations. The government will provide facilities in the importation of machineries, equipment, raw materials, excipients and packing materials required for the domestic pharmaceutical production. Private sectors will also be encouraged to set up quality control laboratories for drugs to be used within the country

2.11 GMP Certification

After establishment of the DDA, every effort has been made to regulate the pharmaceutical industry to operate with effective implementation of Good Manufacturing Practices (GMP). To ensure production of quality, safe and efficacious medicines a competitive price, a detailed understanding of the implementation of GMP norms in the pharmaceutical industry would be essential. During 2004 with stringent regulatory norms, then DDA took a strong decision to initiate World Health Organization recommended Good Manufacturing Practices (WHO GMP) certification to pharmaceutical companies of Nepal.

With the announcement of making a voluntary application to DDA to obtain WHO GMP certification, out of 7 applicants, five companies namely Nepal Pharmaceutical Laboratories Private Limited, National Health Care Private Limited, Quest Pharmaceuticals Private Limited, Deurali Janta Pharmaceuticals Private Limited and Omnica Laboratories Private Limited were awarded with WHO GMP on 27.08.2004 as first five companies to get the certificate on same day. Then on successive years more and more companies got the WHO GMP certification.

Recently DDA has developed a "Good practice codes for drug production, 2072" based mainly on WHO good manufacturing practices; main principles for pharmaceutical products, Forty-fifth report, WHO Technical Report Series 961, 2011. The code is promulgated on 17.08.2016 based on the Nepal government ministerial level decision dated 15.04.2015 by replacing drug manufacturing code 2041 for effective use of rule 11 of medicine registration regulation 2038. This code, so called National GMP code is made mandatory to be followed by all concern with effective form 17.08.2017 after one year of promulgation. However, the WHO GMP certification is made voluntary to be obtained only for those, which are planning to go to export market.

As of 21.11.2018, 14 out of 54 running pharmaceutical companies are holding valid National GMP certificate and 18 out of 54 running companies are holding WHO GMP certificate. Among them only 10 companies are holding both the certificates, 8 companies are holding only WHO GMP certificate and 4 companies are holding only National GMP certificate. Some companies are waiting to get the certificate after audit form DDA auditors, some are in the process of audit and some are getting ready for making an application for audit to obtain the certificate.

The Good practice codes for drug production, 2072, so called National GMP code is the Nepalese version of WHO GMP certification guideline based mainly on WHO TRS 961, 2011.

So both the National GMP and WHO GMP certifications are based on same guideline and basic principles. There is no significant difference between the two-certification principles. At the moment DDA is conducting separate audit to award National GMP and WHO GMP certifications based on same guiding principle. The audit process followed for both certifications are identical. As both the certifications are based on same guideline and principles, it would be very much wise to consider both certifications are equivalent to each other. Any company that is awarded with one can be considered automatically eligible to get the other without further audit. This would avoid duplication of work for audit and delays in conducting audits for the certification in the present scenario of busy schedule of regulatory executives. This would also have avoided violations on mandatory clause of effective implementation of the promulgated Good practice codes for drug production, 2072 in stipulated time schedule.

Most of these companies as urged by DDA, have already acquired GMP Certificate and are also ISO 9001, ISO 14001 certified by few companies.

According to study report by APPON on June 2019, there are 37 Industries have already certified with WHO Recommended GMP and 20 other are in pipeline.

CHAPTER III: METHODOLOGY

3.1 Conceptualization

Depending upon the scope of study, both qualitative and quantitative data have been collected. The quantitative data were mostly available through secondary sources, the specific quantitative data as well as qualitative data were obtained from direct interviews, focus group discussions (FGD) and key informant interviews (KII). Therefore, a mixed research method has been adopted. The questions asked were both open- or closed-ended according to the scope of the study. Semi-structured method was preceded by observation, informal and unstructured interviewing in order to allow the researchers to develop a keen understanding of the topic of interest necessary for developing relevant and meaningful semi-structured questions. The aim of this research was to explore more unknown thoughts and ideas from the respondent and semi-structure method was supposed to be the best for such type of study.

3.2 Sample Universe

The scope of the study was to analyze the present situation, identify gap between supply and demand, and analyze trends of Medicine manufacturing industries in Nepal. For that reason, every Pharmaceutical manufacturing industry were sample universe of this research purpose. The industry was categorized into the following two categories:

- Pharmaceutical Manufacturing Industry listed in DDA (Operating).
- Pharmaceutical Manufacturing Industry associated in APPON.

There were 103 allopathic Pharmaceutical Manufacturing Industries which has got license from DDA till 2077/10/12 in five Provinces out of which 66 were running. For the study purpose, the running Pharmaceutical Manufacturing Industries listed in the DDA were the sample universe, since it was the mandatory registration in DDA for manufacturing, sales & marketing. Of those 66 industries listed in DD, almost industries are medium and large scale. The tables 3.1 provides the exact list of these industries.

Table 3. 1 List of Registered Pharmaceutical Industries in DDA (Running Allopathic Pharmaceuticals as on dated Jan 2021)

S.N.	Name of Industry	Province	District
1.	Amtech Med Pvt. Ltd.	1	Morang
2.	Alive Pharmaceutical Pvt. Ltd.	1	Sunsari
3.	Manoj Pharmaceutical Works	1	Sunsari
4.	Shiv Pharmaceutical Laboratories	1	Sunsari
5.	Alliance Pharmaceuticals Pvt. Ltd.	2	Bara
6.	Apex Pharmaceuticals Pvt. Ltd.	2	Bara
7.	Arya Pharmalab Pvt. Ltd.	2	Bara
8.	Everest Parenterals Pvt. Ltd.	2	Bara
9.	Genetica Laboratory Pvt. Ltd.	2	Bara
10.	National Healthcare Pvt. Ltd.	2	Bara
11.	Prime Pharmaceuticals Pvt. Ltd.	2	Bara
12.	Quest Pharmaceuticals Pvt. Ltd.	2	Bara
13.	Samar Pharma Company Pvt. Ltd.	2	Bara
14.	Supreme Health Care Pvt. Ltd.	2	Bara
15.	GD Pharmaceutical Pvt. Ltd.	2	Parsa
16.	Magnus Pharma Pvt. Ltd.	2	Parsa
17.	Maruti Pharma Pvt. Ltd.	2	Parsa
18.	Nepal Pharmaceuticals Laboratory Pvt. Ltd.	2	Parsa
19.	Arrow Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
20.	CTL Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
21.	Everest Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
22.	Hukam Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
23.	JJ Laboratories Pvt. Ltd.	Bagmati	Bhaktapur
24.	MDH Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
25.	Meera Biotech Pvt. Ltd.	Bagmati	Bhaktapur
26.	Ohm Pharmaceuticals Laboratories Pvt. Ltd.	Bagmati	Bhaktapur
27.	Omnica Laboratories Pvt. Ltd.	Bagmati	Bhaktapur
28.	QBD Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
29.	Qmed Formulation Pvt. Ltd.	Bagmati	Bhaktapur
30.	Simca Laboratories Pvt. Ltd.	Bagmati	Bhaktapur

S.N.	Name of Industry	Province	District
31.	CTL Pharmaceuticals Pvt. Ltd. (Unit-2)	Bagmati	Chitwan
32.	Divine Health Care Pvt. Ltd.	Bagmati	Chitwan
33.	Innovative Pharma Lab Pvt. Ltd.	Bagmati	Chitwan
34.	Kasturi Pharmaceuticals Pvt. Ltd.	Bagmati	Chitwan
35.	Keva Pharmaceuticals Pvt. Ltd.	Bagmati	Chitwan
36.	Livecare Pharmaceuticals Pvt. Ltd.	Bagmati	Chitwan
37.	Royal Pharmaceuticals Pvt. Ltd.	Bagmati	Chitwan
38.	Nova Genetica Pvt. Ltd.	Bagmati	Dhading
39.	Taurus Pharma Pvt. Ltd.	Bagmati	Dhading
40.	Chemidrug Industries Pvt. Ltd.	Bagmati	Kathmandu
41.	DeuraliJanta Pharmaceuticals Pvt. Ltd.	Bagmati	Kathmandu
42.	Lomus Pharmaceuticals Pvt. Ltd.	Bagmati	Kathmandu
43.	Mark Formulations Pvt. Ltd.	Bagmati	Kathmandu
44.	Nepal Aushadhi Limited	Bagmati	Kathmandu
45.	Nepal CRS Company	Bagmati	Kathmandu
46.	Pharmaco Industries Pvt. Ltd.	Bagmati	Kathmandu
47.	S R Drug Laboratories Pvt. Ltd.	Bagmati	Kathmandu
48.	Curex Pharmaceuticals Pvt. Ltd.	Bagmati	Kavre
49.	Hester Biosciences Nepal Pvt. Ltd.	Bagmati	Kavre
50.	Aadee Remedies Pvt. Ltd.	Bagmati	Lalitpur
51.	Florid Laboratories Pvt. Ltd.	Bagmati	Lalitpur
52.	Numarks Pharmaceuticals Pvt. Ltd.	Bagmati	Lalitpur
53.	Rhododendron Biotech Pvt. Ltd.	Bagmati	Lalitpur
54.	Vega Pharmaceuticals Pvt. Ltd.	Bagmati	Lalitpur
55.	Vijayadeep Laboratories Limited	Bagmati	Lalitpur
56.	Sumy Pharmaceuticals Pvt. Ltd.	Gandaki	Nawalpur
57.	Time Pharmaceuticals Pvt. Ltd.	Gandaki	Nawalpur
58.	Panas Pharmaceuticals Pvt. Ltd.	Lumbini	Nepalgunj
59.	Apple International Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
60.	Asian Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
61.	Biogain Remedies Pvt. Ltd.	Lumbini	Rupandehi

S.N.	Name of Industry	Province	District
62.	Corel Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
63.	Grace Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
64.	Nepal Remedies Pvt. Ltd.	Lumbini	Rupandehi
65.	Siddhartha Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
66.	Universal Formulations Pvt. Ltd.	Lumbini	Rupandehi

Table 3. 2 List of Industries Associated with APPON

S.N.	Institution	Providence	District
1	Alive Pharmaceuticals Pvt. Ltd.	1	Sunsari
2	Amtech Med Pvt. Ltd	1	Morang
3	Manoj Pharmaceutical Works	1	Dharan
4	Shiva Pharmaceutical Lab	1	Dharan
5	Arya Pharma Lab. Pvt. Ltd.	2	Bara
6	Alliance Pharmaceuticals Pvt. Ltd	2	Bara
7	Apex Pharmaceuticals Pvt. Ltd.	2	Bara
8	Genetica Laboratory Pvt. Ltd.	2	Bara
9	National Healthcare Pvt. Ltd	2	Bara
10	Quest Pharmaceuticals Pvt. Ltd.	2	Bara
11	Samar Pharmaceutical Pvt. Ltd.	2	Bara
12	Nepal Pharmaceutical Laboratory Pvt. Ltd.*	2	Parsa
13	DENIUM Laboratories Pvt. Ltd.	2	Parsa
14	G.D. Pharmaceuticals Pvt. Ltd.	2	Parsa
15	Maruti Pharma Pvt. Ltd	2	Parsa
16	Supreme Health Care Pvt. Ltd.	2	Bara
17	Chemidrug Industries Pvt. Ltd.	Bagmati	Kathmandu
18	DeuraliJanta Pharma P. Ltd.	Bagmati	Kathmandu
19	Lomus Pharmaceuticals Pvt. Ltd	Bagmati	Kathmandu
20	Mark Formulation Pvt. Ltd	Bagmati	Kathmandu
21	Pharmaco Industries Pvt. Ltd.	Bagmati	Kathmandu
22	SR Drugs Laboratories Pvt. Ltd.	Bagmati	Kathmandu
23	Aadee Remedies Pvt. Ltd	Bagmati	Lalitpur
24	Florid Laboratories Pvt. Ltd	Bagmati	Lalitpur
25	Rhododendron Biotech Pvt. Ltd	Bagmati	Lalitpur
26	Vijayadeep Laboratories Ltd.	Bagmati	Lalitpur
27	Vega pharmaceuticals Pvt. Ltd.	Bagmati	Lalitpur

28	Hukam Pharmaceuticals Pvt. Ltd	Bagmati	Bhaktapur
29	CTL Pharmaceuticals Pvt. Ltd. *	Bagmati	Bhaktapur
30	Everest Pharmaceuticals Pvt. Ltd.	Bagmati	Bhaktapur
31	MDH Pharmaceuticals Lab. Pvt. Ltd	Bagmati	Bhaktapur
32	Nova Genetica Pharmaceuticals Pvt. Ltd	Bagmati	Dhading
33	Omnica Laboratories Pvt. Ltd.	Bagmati	Bhaktapur
34	Ohm Pharmaceuticals Lab Pvt. Ltd.	Bagmati	Bhaktapur
35	Tizig Pharma Pvt. Ltd.	Bagmati	Banepa
36	Simca Laboratories. Pvt. Ltd.	Bagmati	Bhaktapur
37	Taurus Pharma Pvt. Ltd	Bagmati	Dhading
38	Innovative Pharmaceuticals Pvt. Ltd,	Bagmati	Chitwan
39	Kasturi Pharmaceuticals Pvt. Ltd	Bagmati	Chitwan
40	Livecare Pharmaceuticals Pvt. Ltd.	Bagmati	Chitwan
41	Keva Pharmaceuticals Pvt. Ltd	Bagmati	Chitwan
42	Royal Pharmaceuticals Pvt. Ltd.	Bagmati	Chitwan
43	CurexPharmaceuticals Pvt. Ltd.	Bagmati	Kavre
44	Divine Healthcare Pvt. Ltd.	Bagmati	Chitwan
45	Asian Pharmaceuticals Pvt. Ltd. *	Lumbini	Rupandehi
46	Live Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
47	Nepal Remedies Pvt. Ltd.	Lumbini	Rupandehi
48	Universal Formulations Pvt. Ltd.	Lumbini	Rupandehi
49	Siddhartha Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
50	Apple International Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
51	Biogain Remedies Pvt. Ltd.	Lumbini	Rupandehi
52	Grace Pharmaceuticals Pvt. Ltd	Lumbini	Rupandehi
53	Panas Pharmaceuticals P. Ltd	Lumbini	Nepalgunj
54	Sumy Pharmaceuticals Pvt. Ltd	Gandaki	Nawalpur

55	Time Pharmaceuticals Pvt. Ltd	Gandaki	Nawalpur
56	Royal Sasa Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi
57	Corel Pharmaceuticals Pvt. Ltd.	Lumbini	Rupandehi

* Manufacture both human and veterinary allopathic Medicines.

3.3 Sample Method

The research scope was focused on the DDA listed allopathic (Human) operating Pharmaceutical manufacturing industries. The registered industries found on Five provinces, as listed below. From the list of operating industries, 60 percent industries from each province were selected for study.

Table 3. 3 List of Industries province wise and selection for study

S. N.	Province	No. of Operating Industries	% Concentration	60% as sample
1	Province-1	4	6.06	2
2	Province-2	14	21.21	8
3	Bagmati	37	56.06	22
4	Lumbini	9	13.63	6
5	Gandaki	2	3.03	2
Total		**66**	100	40

Out of total 66 industries, 40 (60% from each province of existing industries) are selected from the sample universe as shown in table 3.4

Figure 3. 1 Number of Industries Province Wise

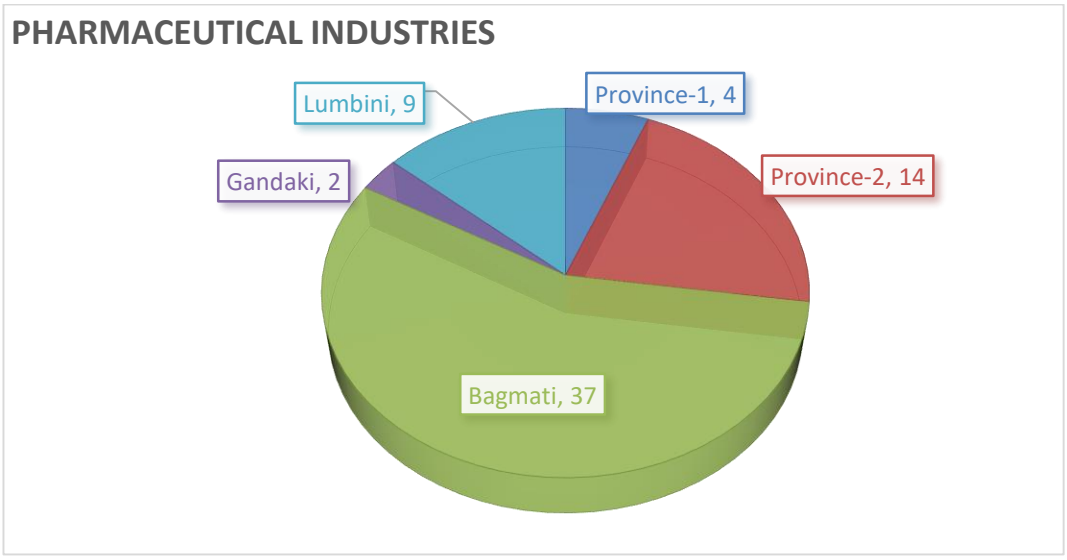


Table 3. 4 List of Selected Industries for Study

S. N.	Name of Industry	Province	Address	Contact Person	Contact No.	E-Mail
1.	Amtech Med Pvt. Ltd.	1	Katahari Morang	Mr. Manish Agrawal Mr. Pramod Shrestha	9852020028 9841265417, 021-524173	antechmedicine@yahoo.com amtechmed55@yahoo.com
2.	Manoj Pharmaceutical Works	1	Dharan Sunsari	Mr. Manoj Agrawal Mr. Narayan Agrawal	9852045097 9851032865, 025-524146	manoj.drn@gmail.com narayan16apr@gmail.com
3.	Alliance Pharmaceuticals Pvt. Ltd.	2	Pipara Bara	Mr. Sunil Pradhan	9851048208 053-521055	alliancesimara@gmail.com
4.	Arya Pharmalab. Pvt. Ltd.	2	Chattapipara, Bara	Mr. Sauarav Sanghai	9806843942 051-532178	Sauravsanghai@gmail.com rohitagl@yahoo.com
5.	Genetica Laboratory Pvt. Ltd.	2	Motisar Bara	Mr. Suresh Agrawal Mr. P. S. Thakuri	9855020145 9745011787 051-621758	geneticamktg@gmail.com gntclab@gmail.com
6.	National Healthcare Pvt. Ltd.	2	Nitanpur Bara	Mr. Jagdish Roongata Mr. R. Mahato	9855022169 9851041371, 051-580236	ed@nationalhealthcare.com.np dm@ nationalhealthcare.com.np
7.	Quest Pharmaceuticals Pvt. Ltd.	2	Chattapipara, Bara	Mr. Umeshlal Shrestha Mr. Prithvi Raj Mr. Bhandari	9851127550 9855022272 9851022800 051-580172	umeshlshrestha@gmail.com quest.ktm@quest.com.np
8.	Maruti Pharma Pvt. Ltd.	2	Parsa	Mr. Prabhat Roongata Mr. Sudarshan Bista	9801020825 9801062259 051-418233	prabhatroongta@marutipharma.com sudaeshanbista@marutipharma.com

9.	Arrow Pharmaceuticals Pvt. Ltd.	3	Bhaktapur	Mr. Mahesh Bhatta	01-5142116 01-4372108	info@arrowpharmaceuticals.com meheshbhatta72@gmail.com omnipankaj@gmail.com
10.	Ctl Pharmaceuticals Pvt. Ltd.	3	Sallaghari Bhaktapur	Mr. Bijendra Pokhrel Mr.Dipendra Pradha	9851061039 985106347601-429941	ctl@infoclub.com.np
11.	Everest Pharmaceuticals Pvt. Ltd.	3	Byasi Bhaktapur	Mr. Umanga Rana Sariya	9802026450 01-6614877	eplnrs@gmail.com info@everest-hcg.com
12.	Hukam Pharmaceuticals Pvt. Ltd.	3	Thimi Bhaktapur	Mr. Vijay Kumar Dugar Sarad Khanal Mr.Ramesh Dawadi	9851020342 9851081140, 986628871	hppl@dugargroup.biz
13.	MDH Pharmaceuticals Pvt. Ltd.	3	Jhaukhel Bhaktapur	Mr. Deepak Prasad Dahal Mr. Gopal Prasad Upadhya	9851024461 9851019747 01-4425335	Upadhy1gopal@gmail.com lamsalkrishna@gmail.com dahalgh@gmail.com
14.	Ohm Pharmaceuticals Laboratories Pvt. Ltd.	3	Thathali Bhaktapur	Mr. Sudarshan Khayaguli Mr. Sumit Chandra Shrestha	9851025200 9841293999 01-6915193	skhayaguli@hotmail.com sumit.ch.shrestha@gmail.com
15.	Simca Laboratories Pvt. Ltd.	3	Bhaktapur	Mr. Prabhu R. Vaidya Mr. Ashok Sharma	9851033032 9851043557 01-6631259	yatichem@mos.com.np simca@mos.com.np simcalab@gmail.com
16.	Innovative Pharma Lab Pvt. Ltd.	3	Jugedi Chitwan	Mr. Biplab Adhikari Mr.Pradip Luitel	9851051059 9801228203	biplabadhikari@gmail.com innovativepharmalab@gmail.com
17.	Keva Pharmaceuticals Pvt. Ltd.	3	Ratnanagar ,Chitwan	Mr. Rajendra Dulal Mr. K.P. Chattaut	9851004000 9851010701, 9801090701	rajendra@keva.com.np

18.	Royal Pharmaceuticals Pvt. Ltd.	3	Bharatpur Chitwan	Mr. Pawan Kumar Sah Mr. PremThapa	056-571005 9855084501, 01-596005	royalpharmainfo@gmail.com
19.	Deurali Janta Pharmaceuticals Pvt. Ltd.	3	Dhapasi Kathmandu	Mr. Hari Bhakta Sharma Mr.Nilraj Acharya	9851021281 9802088084 01-4371061 F	info@deuralijanta.com
20.	Lomus Pharmaceuticals Pvt. Ltd.	3	GairidharaKathmandu	Mr. Pradeep Jung Pandey Mr. Prajwal Jung Pandey	9851023955 9851039755, 01-4436396	lomus@ntc.net.np info@lomus.com.np
21.	S R Drug Laboratories Pvt. Ltd.	3	Satungal Kathmandu	Mr. Sanjay Kumar Agrawal	9851049054 01-4312945	sanjay@srdrug.net ska579@gmail.com
22.	Pharmaco Industries Pvt. Ltd.	3	Ramkot Kathmandu	Mr. SanuKaji Shrestha	9851042920 01-4037838	pharmaco42@gmail.com
23.	Chemidrug Industries Pvt. Ltd.	3	Thankot Kathmandu	Mr. Kiran Shakha UttamDwa	9801020098 9851067010 9801067010, 01-4111921	chimi_drug@yahoo.com dwa.uttam@gmail.com
24.	Curex Pharmaceuticals Pvt. Ltd.	3	Banepa Kavre	Mr. Pawan Mittal Mr. Sushil Mittal	9851021091 011-661855	
25.	Florid Laboratories Pvt. Ltd.	3	DhapakhelLalitpur	Mr. Vijay Raj Shakya Mr. Umesh K. Devkota	9851071982 9851003884 01-5570866	vrsnpj45@gmail.com florid@mail.com.np
26.	Vega Pharmaceuticals Pvt. Ltd.	3	Bumati Lalitpur	Mr. R. C. Bhandari Mr. Narnath Adhikari	9801196722 9801196721 01-6923276	vlab@vijayadeep.com.np narnath.adhikari@vega.com.np
27.	Vijayadeep Laboratories Limited	3	Hari Siddhi Lalitpur	Mr. P. M. Vaidya	9851025000 01-5551188	Vijayadeep53@gmail.com

28.	Sumy Pharmaceuticals Pvt. Ltd.	4	Mukundapur Nawalpur	Mr. Jay Rana Mr. Bijaya Shrestha	9803963162 9801398227 078-545316	Purchase.sumy@gmail.com Sumypharma.np@gmail.com
29.	Time Pharmaceuticals Pvt. Ltd.	4	Mukundapur Nawalpur	Mr. G. N. B. Chhetri Mr. Asnish Bhandari	9855055300 9851035912 9802650505 056-620391	mayanarayan2004@yahoo.com sudershan.time@gmail.com info@timepharma.com
30.	Asian Pharmaceuticals Pvt. Ltd.	5	Padsari Rupandehi	Mr. Hutananda Khanal	9857020763 071-429152	hutanandakhanal@hotmail.com
31.	Biogain Remedies Pvt. Ltd.	5	Pathardada Rupandehi	Mr. Prakash Gyawali Mr. Abisekg ghimire	9857036903 9857011634	biogain@gmail.com suraj.bhatarai@gmail.com
32.	Grace Pharmaceuticals Pvt. Ltd.	5	Beldada Rupandehi	Mr. Suraj Bhattrai	9857034106 071-545599	gracepharmabtc@gmail.com
33.	Siddhartha Pharmaceuticals Pvt. Ltd.	5	Madhawaliya Rupandehi	Mr. Giri Raj Pathak Mkt. Director	9811458699 9801104901	Siddharthapharmaceuticals24@gmail.com info@siddharthapharma.com
34.	Universal Formulations Pvt. Ltd.	5	Chilhiya Rupandehi	Mr. Damodar Pokhrel	9851061935 071-620419	dpokhrel2020@gmail.com ufpl.purchase@gmail.com

3.4 Tools

The tools used for study purpose are as follows:

- Questionnaire survey
- Stakeholders' Discussion (Direct interviews and KII)
- Statistics and Data Analysis (pie chart, bar chart, histogram)
- Trends analysis

3.5 Methods

The methods used for the data collection are:

- Interview to focused persons
- Observation of Industries
- Discussions and review of documents and data
- Data collection through structured questionnaire from concerned stakeholders

3.6 Sources of Information

The major sources of data used in the report are:

Primary Sources

- Pharmaceutical and Medicine Manufacturing Industries
- Department of Drug Administration (DDA)
- Associations of Pharmaceuticals Producers of Nepal (APPON)
- Department of Industry (DOI)
- Federation of Nepalese Chamber of Commerce& Industries
- Confederation of Nepalese Industries
- Department of custom
- Experts of Pharmaceutical and Medicine

Secondary Sources

- Publications of different Government agencies, semi government and private sectors
- Document analysis and review of past journals and articles related to subject
- The papers, seminar papers, approach papers produced by consultants and experts
- Other published Statistical Data

3.7 Activities

The following activities have been done for the completion of the assigned project within the given time period:

- Desk review
- Accessing and coordinating with different stakeholders (policy makers, officials from Ministry of Industry, representative of Pharmaceutical and Medicine manufacturing industry, officials from selected line ministries and experts)
- Field Visit of the selected industries and their head office
- Review of relevant past journals and articles on Pharmaceutical and Medicine.

CHAPTER IV: RESULT AND DISCUSSION

4.1 Introduction

4.1.1 Industry Details

There are 103 medicines and drugs manufacturing industries registered in DDA, Nepal till dated 2077/10/12 (DDA). Out of which, 66 industries are in operation where they have got license both for manufacturing and marketing, 33 industries are under process of getting license for marketing purpose and 4 industries are not in operation due to technical reason although they have got licenses.

Province wise, out of 66 industries, there are 4 (6.06%) industries in province-1, 14 (21.21%) in Province-2, 37 (56.06%) in Bagmati Province, 2 (3.03%) in Gandaki Province and 9 (13.63% in Lumbini Province. There are no pharmaceutical industries in the Province 6 and Karnali Province.

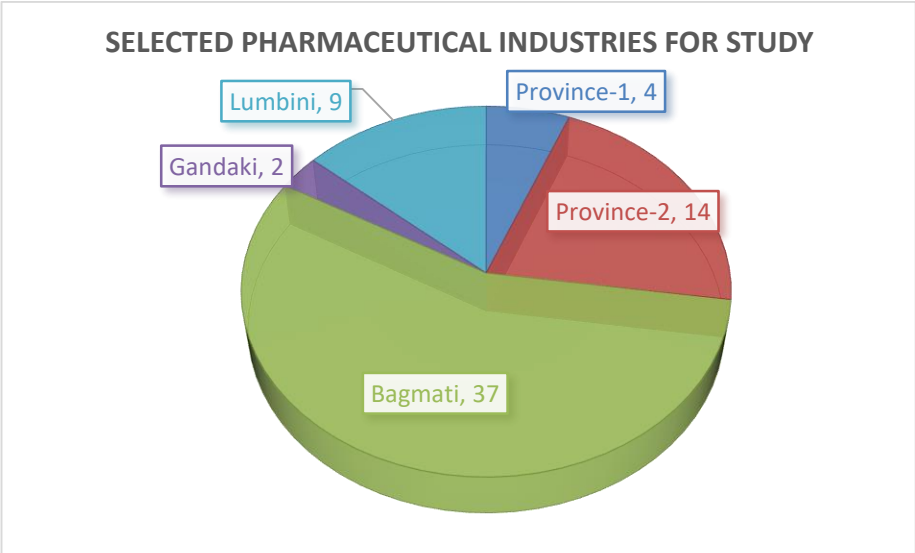
Forty industries were selected randomly for the study purpose. They were 2 from Province-1, 8 from Province-2, 23 from Bagmati, 2 from Gandaki and 5 from Lumbini Province.

Table 4. 1 List of Selected Pharmaceutical Industries for Study

S. N.	Province	Sample Size
1	Province-1	2
2	Province-2	8
3	Bagmati	22
4	Lumbini	6
5	Gandaki	2
Total		40

(Note: Out of 40 selected industries (as above table 4.1), only 34 industries' data were included in this report because 6 industries (Two from Province-2, three from Bagmati Province and one from Lumbini Province) did not provide information.)

Figure 4. 1 Selected Pharmaceutical Industries for the Study



4.1.2 Size and Investment of the Selected Industry

All the selected industries are private limited and almost are large scale (90%) industries having total capital more than Nepalese Rupees 25 crore. Few medium scale industries (10%) are also planned for increasing their investment. The average source of investment of these industries are 100% internal and 56% from Loan and 44% from equity.

4.2 Production

4.2.1 Types of Products

Almost all the selected industries are producing medicines and drug in the form of Tablets, capsules, Liquid (Syrup/Suspension), Powder (Dry Syrup), Ointment/cream and eye/ear drops.

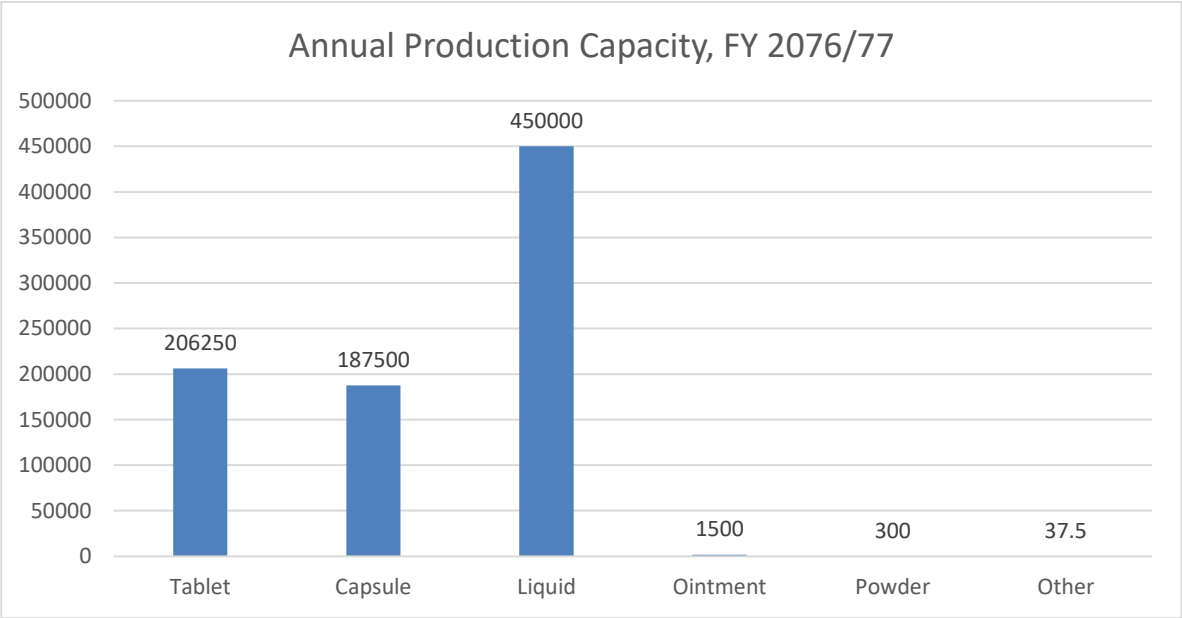
4.2.2 Annual Production Capacity

Table 4. 2 Annual Production Capacity of Pharmaceutical Industries in 2076/77

S.N.	Products Group	No. of Company	Average Batch Size	Batch/ Year	Total Unit per Year (00,000)
1	Tablet	66	2500000	125	206250
2	Capsule	60	2500000	125	187500
3	Liquid	45	5000000	200	450000
4	Ointment	40	15000	250	1500
5	Powder	20	15000	100	300
6	Other (Eye/Ear)	5	15000	50	37.5

Source: Field Survey, 2021

Figure 4. 2 Annual Production Capacity in FY 2076/77



Annual capacity of tablets production from 66 industries is 2.06 billion, for capsules production from 60 industries is 1.87 billion, for liquid from 45 industries is 4.5 billion, for ointment from 40 industries is 0.15 billion, for powder from 20 industries (Dry syrup) is 0.03 billion and other (Eye/Ear drop) from 5 industries is 0.0037 billion units.

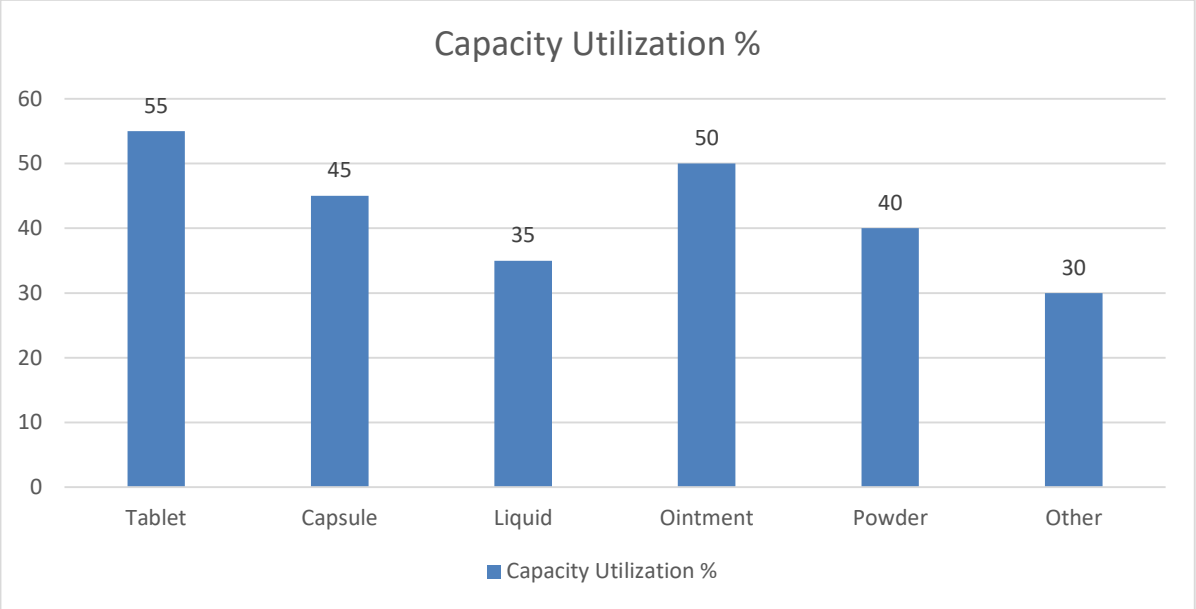
4.2.3 Capacity Utilization

Table 4. 3 Capacity Utilization of Medicines & Drugs Manufacturing Industries

S.N.	Products Group	Capacity Utilization for the Fiscal Year 2076/77 (%)
1	Tablet	55
2	Capsule	45
3	Liquid	35
4	Ointment	50
5	Powder	40
6	Other (Eye/Ear)	30

Source: Field Survey, 2021

Figure 4. 3 Capacity Utilization



Capacity utilization of Nepalese running pharmaceutical industries for Tablet manufacturing is 55%, for capsules is 45%, for Liquid is 35%, for Ointment is 50%, for Powder is 40% and for Other (Eye/Ear) is 30%.

4.3 Human Resource

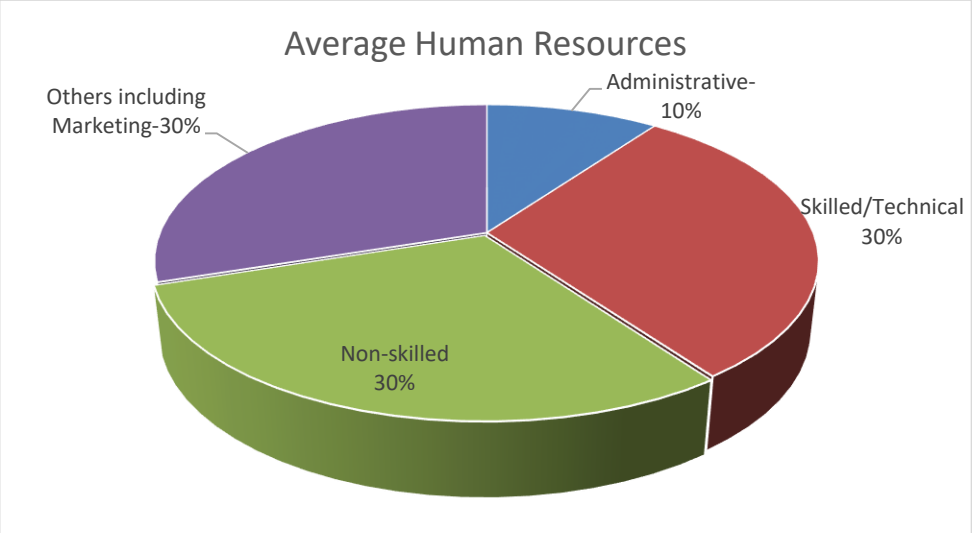
4.3.1 Type and Number of Human Resource

Table 4. 4 Human Resources in Medicines & Drugs Manufacturing Industries

S.N.	Products Group	Average Man Power %
1	Administrative	10
2	Skilled & Technical	30
3	Non-skilled	30
4	Others including Marketing	30

Source: Field Survey, 2021

Figure 4. 4 Average Human Resources



In average, administrative staffs are 10%, while skilled/technical staffs are 30%, non-skilled are 30% and others including marketing are 30%. Direct employment of Pharmaceutical industries is about 20 thousand. The technical and skilled manpower available are almost local (Nepali) and are employed as permanent basis.

4.4 Electricity Consumption

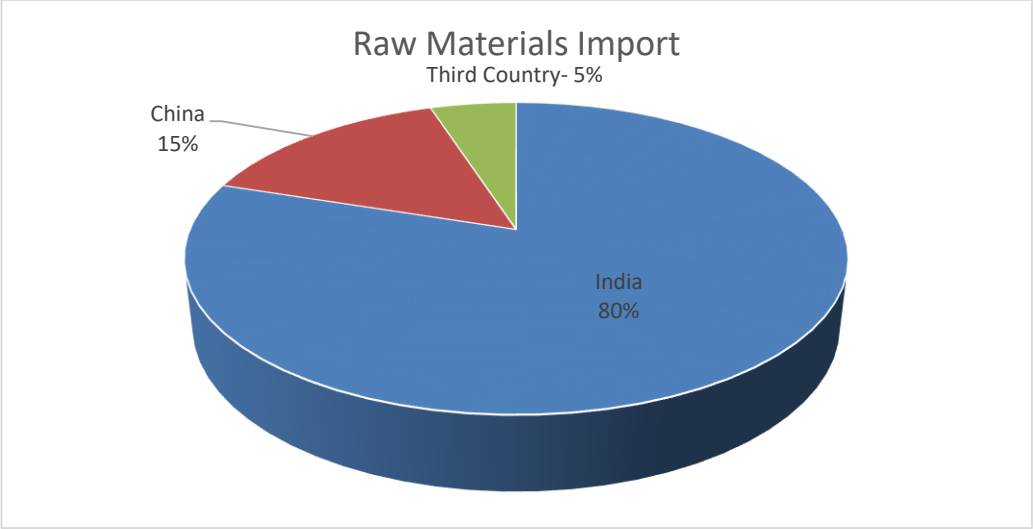
Electricity demand supplied by NEA is sufficient for current situation. Those industries having DG of smaller capacity, uses for other purpose than operation of plant. Total electricity demand is about 10 MW which is being supplied sufficiently. About 2 MW electricity were consumed from other sources like solar and DG.

4.5 Raw Materials

Raw materials are imported mostly from India (80%). Some industries import raw materials are also from China (15%). Raw materials are sometimes purchased from Australia, Thailand, Singapore, Spain, South Korea, Bangladesh but in very little amount (5%). Total raw materials import value on 2076/77 was 9 billion rupees whereas packaging materials was of 2.5 billion rupees.

Primary and secondary packaging materials (Bottle & cap, Blisters pack, Duplex, Labels) are totally purchased from India but tertiary packaging materials like C. B. Boxes are purchased mostly from local /domestic industries.

Figure 4. 5 Raw Materials Import



4.6 Technology

Most of the medicines & drugs manufacturing industries have semi-auto production process, and most machineries are from India. Packing technology are mostly automated for all the products groups. Capsules manufacturing process are generally automatic in most of the industries.

4.7 GMP Certification

Out of 66 operating industries, 36 industries are GMP certified from WHO and/or National Guidelines (DDA) and 10 are in process of getting GMP, however 20 industries have not crossed two years of operations to apply for GMP. 10 industries are certified with other management system like ISO 9001 and ISO 14001.

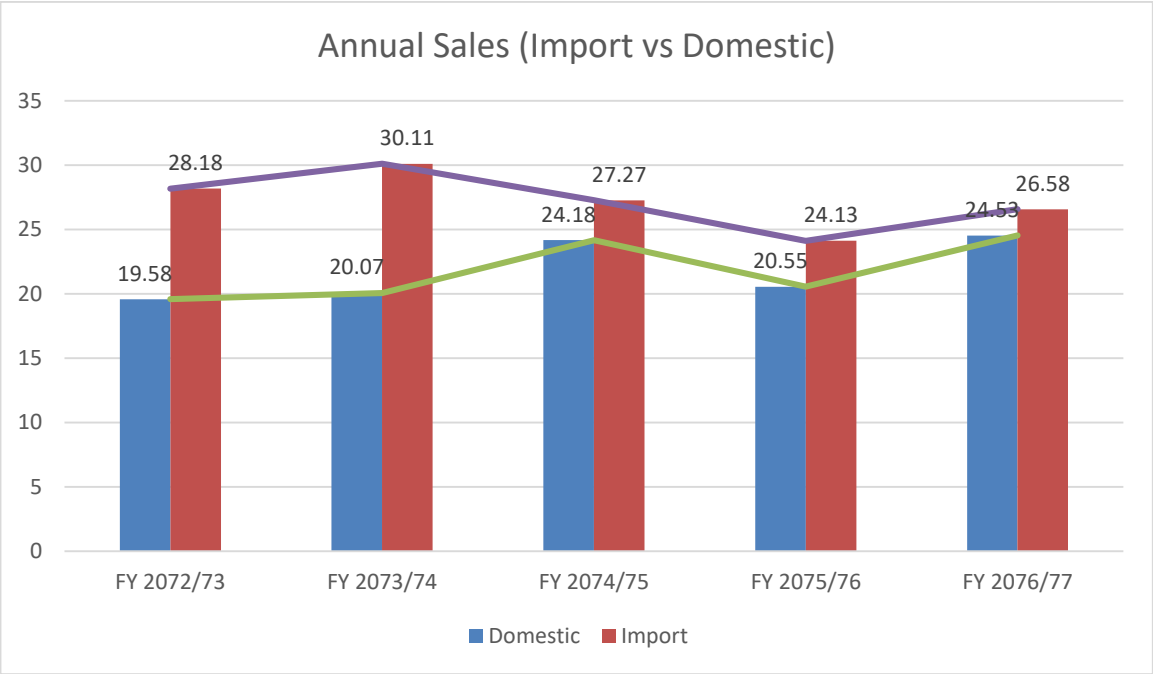
4.8 Annual Sales

Table 4. 5 Annual Sales of Medicines & Drugs in Last Five Years

S.N.	Products Group	Fiscal Year (Billion Rupees)				
		2072/73	2073/74	2074/75	2075/76	2076/77
1	Import	28.18	30.11	27.27	24.13	26.58
2	Domestic Sales	19.58	20.07	24.18	20.55	24.53
Total		**47.76**	**50.18**	**51.45**	**44.68**	**51.11**

Source: Field Survey, 2021

Figure 4. 6 Annual Sales (Import vs Domestic Sales)



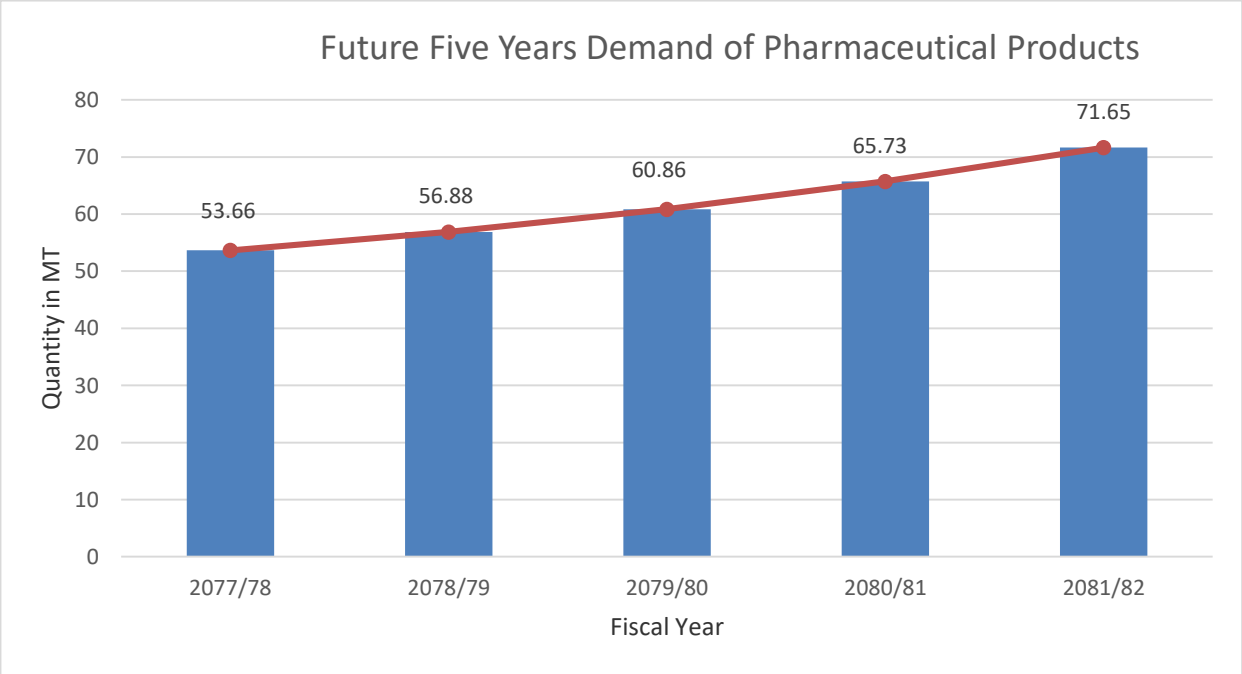
Annual sales in the year 2072/73 was 47.76 billion rupees in total, out of which domestic sales was 19.58 billion rupees (41%). Annual sales in the year 2073/74 was 50.18 billion rupees in total, out of which domestic sales was 20.07 billion rupees (40%). Similarly, in the year 2074/75, the sales were 51.45 billion rupees in total, out of which domestic sales was 24.18 billion rupees (47%). In the year 2075/76, it was 44.68 billion rupees, out of which domestic sales was 20.55 billion rupees (46%) and in the year 2076/77, the total sales were 51.11 billion rupees, whereas domestic sales were 24.53 billion rupees (48%).

Table 4. 6 Future Five Years Demand of Pharmaceutical Products

S.N.	Fiscal Year	Value in Billion Rupees
1.	2077/78	53.66
2.	2078/79	56.88
3.	2079/80	60.86
4.	2080/81	65.73
5.	2081/82	71.65

Source: APPON, 2021

Figure 4. 7 Future Five Years Demand of Pharmaceutical Products



According to the survey feedback collected from APPON, five years future demand of pharmaceutical products is shown in the above figure. Annual demand of pharmaceutical products will be increased by 5% to 9% from 2077/78 to 2081/82 and average annual increment will be 7%.

4.9 Financial Status

Total investment of 66 running pharmaceutical industries is more than 35 billion rupees whereas fixed capital is 65% and working capital is 35%.

4.10 Export & Import

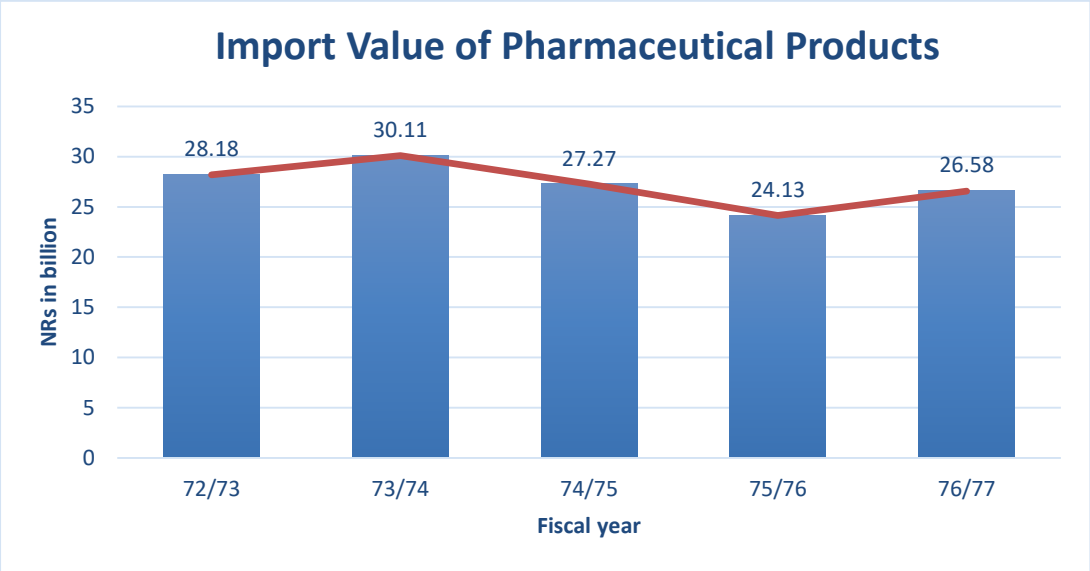
According to data published by Custom office; the import of pharmaceutical products for last five years as follows.

Table 4. 7 Import Status of Pharmaceutical Products

Fiscal Year	Import Value in Billion Rupees
2072/73	28.18
2073/74	30.11
2074/75	27.27
2075/76	24.13
2076/77	26.58

Source: Department of Custom

Figure 4. 8 Import Value of Pharmaceutical Products



According to Department of Custom, the import value of pharmaceutical products of last five years shows that it was highest in the fiscal year 2073/74 i.e. 30.11 billion rupees and lowest in the year 2075/76 i.e. 24.13 billion rupees.

Few industries are exporting pharmaceutical products to foreign countries but in vary trace amount. There is no data provided by the selected individual industry, APPON and Custom Office in quantity.

4.11 Environment Related

Almost all pharmaceutical industries have conducted Initial Environmental Examination as per provision of EPA and EPR in Nepal after 1997. In order to minimize the environmental impact from the industries, some pharmaceutical industries have installed Solar PV system for lighting purpose. It is mandatory to install effluent treatment plant in pharmaceutical industries in order to manage wastes. Hence all the industries have installed ETP of different capacities as per their production capacity. The recalled/Non-conforming/returned medicines are disposed through ETP.

4.12 Annual Demand & Supply

Table 4. 8 Annual Consumption (Demand & Supply) of Self-Reliant Medicines in the FY 2075/76

S. N.	Name of the Product /Molecule	Dosage Form	Demand & Supply			% National Market Consumption
			Total Consumption	Total Import	National Industry	
1.	Aceclofenac	Tablets/ Syrup Capsules/	33900000	8900000	25000000	73.7
2.	Alprazolam	Tablets	6750000	1750000	5000000	74.1
3.	Amlodipine	Tablets	140000000	45000000	95000000	67.9
4.	Amoxycillin	Capsule/ Tablet / Suspension	36500000	11650000	24850000	68.1
5.	Amoxycillin and clavuanic acid	Capsule/ Tablet / Suspension	3528235	1226845	2301390	65.2
6.	Antacid containing Aluminium, Magnesium salts	Tablet/ Suspension	5500000	1078200	4421800	80.4
7.	Anticold tablet (PCM Combination)	Tablet/ Capsule/ Syrup	15000000	3175000	11825000	78.8
8.	Atrovastatin	Tablets (5, 10, 20 mg tablets)	15700000	6000000	9700000	61.8
9.	Azithromycin	Capsule/ Tablet/ Suspension	50000000	13930000	36070000	72.1
10.	Cefexime	Oral dosage form (Tablets/ Suspension)	3035000	950000	2085000	68.7
11.	Cefodoxime	Tablet/ Capsules/ Syrup	15000000	6050000	8950000	59.7
12.	Cetrizine	Tablet/ Suspension	41600000	17500000	24100000	57.9
13.	Cough preparation containing approved combination	Tablet/ Capsule/ Syrup	5000000	1050000	3950000	79.0
14.	Diclofenac	Capsule/Tablet	23700000	3750000	19950000	84.2
15.	Diclofenac and dielthalamine	Capsule/Tablet	45000000	13900000	31100000	69.1
16.	Diclofenac potassium /Sodium	Capsule/Tablet	23700000	8750000	14950000	63.1
17.	Dicyclomine HCL	Tablet/ Syrup/ Capsules/	39500000	7250000	32250000	81.6
18.	Drotaverine	Tablets (40 mg and 80 mg)	2091500	350000	1741500	83.3
19.	Enzyme preparation containing	Tablet/ Capsules/ Syrup	7500000	1535000	5965000	79.5

S. N.	Name of the Product /Molecule	Dosage Form	Demand & Supply			% National Market Consumption
			Total Consumption	Total Import	National Industry	
	approved combination					
20.	Escitalopram	Capsule/Tablet	3012805	676800	2336005	77.5
21.	Fexofenadine	Tablet/ Syrup/ Capsules/	17500000	3028000	14472000	82.7
22.	Fluconazole	Tablet/ Capsules	3500000	725000	2775000	79.3
23.	Gabapentine	Tablet, Capsules	2500000	1089000	1411000	56.4
24.	Gention Voilet	Solution	0	0	0	0.0
25.	Hyoscine Butybromide	Tablet	5500000	750000	4750000	86.4
26.	Indomethacin (immediate release)	Capsule	1800000	100000	1700000	94.4
27.	Itopride	Tablet/ Capsules	5000000	1189000	3811000	76.2
28.	Itraconazole	Tablet/ Capsules	13250000	2518000	10732000	81.0
29.	Levocetrizine	Tablet/ Suspension	45600000	15000000	30600000	67.1
30.	Losartan Potassium	Tablets (25, 50 mg tablets)	55000000	20000000	35000000	63.6
31.	Mefenemic Acid	Tablet, Capsules	2250000	639000	1611000	71.6
32.	Metformin	Tablets	81583333	20000000	61583333	75.5
33.	Metformin and combination sitagliptin	Tablets	20500000	5500000	15000000	73.2
34.	Metformin and combination with Glimepiride	Tablets	16500000	1500000	15000000	90.9
35.	Metronidazole	Capsule/ Tablet/ Suspension	50,000,000	7500000	42500000	85.0
36.	Metronidazole + Diloxanide furoate	Capsule/ Tablet/ Suspension	15750000	2538250	13211750	83.9
37.	Multivitamins combination products	Tablet/ Capsule/ Syrup	50,000,000	10850000	39150000	78.3
38.	Nimesulide	Tablet	36800000	6000000	30800000	83.7
39.	Omeprazole	Capsule/tablet	6750000	1750000	5000000	74.1
40.	Oral rehydration salts containing approved composition	Sachet (powder for solution)	46500000	14500000	32000000	68.8

S. N.	Name of the Product /Molecule	Dosage Form	Demand & Supply			% National Market Consumption
			Total Consumption	Total Import	National Industry	
41.	Ornidazole	Tablet/ Capsules/ Syrup	3100000	763000	2337000	75.4
42.	Pantoprazole	Capsule/Tablet	87200000	27500000	59700000	68.5
43.	Paracetamol	Tablets/ Capsules/ Suspension	106158750	30000000	76158750	71.7
44.	Paracetamol + Chlorozoxazone	Tablets	6000000	250000	5750000	95.8
45.	Paracetamol +Ibuprofen combination	Tablet/ Suspension	70000000	21500000	48500000	69.3
46.	Pregabalin	Tablet/ Capsules	24250000	5600000	18650000	76.9
47.	Rabeprazole	Capsule/Tablet	36500000	7500000	29000000	79.5
48.	Ranitidine	Capsule/Tablet	27500000	8750000	18750000	68.2
49.	Rosuvastatin	Tablet/ Capsules	16750000	5875000	10875000	64.9
50.	Sitagliptin	Tablets	41000000	11500000	29500000	72.0
51.	Spironolactone and combination with Frusemide	Tablets	425525	162500	263025	61.8
52.	Telmisarton	Tablet/ Capsules	6000000	2250000	3750000	62.5
53.	Tinidazole	Tablet	4750000	1500000	3250000	68.4
54.	Tizanidine	Tablets	1500000	150000	1350000	90.0
55.	Semisolid Preparation	Tube/ Semi solid	6800000	2340000	4460000	65.6
	Total		1,430,235,148	395288595	1034946553	72.88

Source: APPON, 2020

The above table shows that 55 products/molecules are towards self-reliant in Nepal. The average market consumption of 55 by national industries is 72.88%. The highest market consumption of Nepalese industry is in Indomethacin Capsules i.e. 94.4% and lowest in Gabapentine Tablet / Capsules is 56.4%.

4.13 Challenges Faced by Medicine and Drugs Manufacturing Industries

4.13.1 Internal Challenge

- Availability of technical/ skilled manpower.
- Manpower stability.
- Heavy investment and high bank interest rate.
- Employee demand.
- Team work, lack of integrity and unwilling to perform task.
- Forceful donation by local villagers, political parties.

4.13.2 External Challenge

4.13.2.1 Government policy, rules and regulations

- Import policy for self-sustained medicines.
- Import of raw and packing materials.
- Prohibit and impose tariff in foreign products.
- Product development facilitation.
- Marketing license policy (Copied from European Country).
- Lengthy process for license of manufacturing.
- Intervened by DDA regarding technology and infrastructure as compare with other similar industry.
- There is no price controlling system.
- There is no export policy for local medicines.
- No support to cater the interest of local pharmaceutical industry.
- No strict monitoring of unethical pharma practice.
- Tariff of raw materials for packaging materials high (13%) but finished packaging materials is low (1%). Due to this reason costs of packaging materials are cheaper than local suppliers.

4.13.2.2 Technology

- Huge investment for technology change from semi-auto to fully automatic and cannot afford by all.
- Facilitate technological transfer and high tech equipment.
- WHO GMP guidelines are not properly justify each process and premises.
- New industry uses latest technology.
- Almost are semi-automatic and they consume high man power.
- Depend on other country for raw materials and machineries, so that it will take long process to get materials and maintain huge inventory.

4.13.2.3 Market

- Unhealthy and unethical marketing practices.
- Credit facilities system (90 days).
- Non-registered medicine in the border area.
- Retailer focus only for medicines of high bonus company.
- Difficult to compete with multinational company.

4.13.2.4 Consumer

- Training require to consumer.
- Low educated on the side of medicine & health
- Price and quality awareness.
- Patients only use medicine as per Doctor's prescription.
- Medical store sell medicines of high commission only, not focus on local medicine.

4.13.2.5 Others

- Fluctuation of foreign exchange rate
- Transportation of raw materials and medicines
- High cost due to import of raw materials from India.
- Recall of medicine to all (Nepali/Indian and other company)
- There is challenge to compete with Large industry on few specific brands.

4.14 Expectations from Government Bodies

4.14.1 Company Registration Office

- Timely online update facility
- Decentralization system

4.14.2 Department of Industry (DOI)

- Regulation to facilitate primary/secondary industry
- Ease on product addition, trademark registration.

4.14.3 Department of Drugs Administration (DDA)

- Manufacturing and marketing licensing process should be fast and transparent.
- Fastness and promptness in work.
- Protection to national industry.
- Promote Nepali industries.
- Recruit industry professionals.

4.14.4 Inland Revenue Department (IRD)

- Facilitate taxation.

4.14.5 Custom Office

- Fast server on their application software.
- Availability of manpower to be increased (Less counter for depositing money).

- Excise duty to be removed.

4.14.6 Nepal Electricity Authority (NEA)

- Smooth and quality power supply/no voltage fluctuation.
- Tariff should be same for dedicated and normal line.
- Reduce the price of power and rebate.
- Uninterrupted power supply/ free from load shedding.
- Power should be supplied as demanded.

4.15 Suggestions/Area for Improvements

- Employee should be there in DDA and Custom office for prompt service.
- Priority to Nepali company by Nepal Government.
- Medicines import discourage by high custom charge.
- Government should facilitate on raw materials and machine purchase.
- Help to speed up the process of product and marketing license.
- DDA must support to all domestic industries in terms of technical guidance.
- Pricing policy is not applicable to quality medicines.
- Discouraging policy on import medicines.
- Promote Nepalese industries for export in different countries.

CHAPTER V: CONCLUSION AND RECOMMENDATIONS

5.1 Findings and Conclusion

- There are 103 allopathic pharmaceutical industries registered in DDA, out of which only 66 industries are in operation. Four industries have stopped their production due to technical reason. (Manoj Chemical Works, Denium Laboratories Pvt. Ltd., Lomus Parenteral and Formulations Pvt. Ltd. and Unique Pharmaceuticals Pvt. Ltd.) Remaining 33 industries though registered have not yet received license for sales and marketing.
- Annual capacity of tablets production from 66 industries is 2.06 billion, for capsules production from 60 industries is 1.87 billion, for liquid from 45 industries is 4.5 billion, for ointment from 40 industries is 0.15 billion, for powder from 20 industries (Dry syrup) is 0.03 billion and other (Eye/Ear drop) from 5 industries is 0.0037 billion units.
- Capacity utilization of Nepalese running pharmaceutical industries for Tablet manufacturing is 55%, for capsules is 45%, for Liquid is 35%, for Ointment is 50%, for Powder is 40% and for Other (Eye/Ear) is 30%.
- The five-years future demand of pharmaceutical products will be increased by 5% to 9% from 2077/78 to 2081/82 and average annual increment will be 7%.
- The total demand electricity is about 10 MW, out of which NEA has supplied 8 MW and 2 MW energy is supplied from other sources like Diesel and Solar.
- The direct employment generated from Pharmaceutical Industries is about 20 thousand. The percent composition of administrative, technical /skilled, non-skilled and others are 10, 30, 30 and 30 respectively.
- Total investment in Pharmaceutical Industries is about 35 billion of 66 running industries.
- The raw materials i.e. active and excipient imported from India is 80%, from china is 15% and from other countries is 5%.
- About 90% (59) Industries are large scale and 10% are Medium scale. All industries have internal investment.
- Market distribution system of pharmaceutical products are through Dealer (Stockiest) and few from tender also.
- Most of the Pharmaceutical Industries have semi-auto production process and machineries are purchased mostly from India. Filling equipment are automatic.

- Out of 66 operating industries, 36 industries are GMP certified from WHO and/or National Guidelines (DDA) and 10 are in process of getting GMP,
- Only 10 industries are certified with management system like ISO 9001 and ISO 14001.
- The import value of pharmaceutical products in last five years was highest in the fiscal year 2073/74 i.e. 30.11 billion rupees and lowest in the year 2075/76 i.e. 24.13 billion rupees.
- According to APPON, import status and capacity utilization of the running industries, 55 products/molecules are towards self-reliant in Nepal. The average market consumption of 55 products by national industries is 72.88%.

5.2 Recommendations/Way Forward

- Government should promote medicines towards self-reliant by discouraging import on such products for the sustainable development of the national industries.
- Since market share of existing Pharmaceutical industries is lower than import, stakeholders should now promote for domestic sales and export of national products whereas possible.
- The DDA should provide prompt service for license, registration and testing of medicines to promote Nepalese products.
- DDA should provide market license timely so that the product recall may be minimized and liabilities of industries may be minimized.
- Tariff or custom duty for packaging raw materials need to be lower than the tariff of finished packaging products. So that domestic industries can supply required packaging products.
- Nepal government should facilitate for raw materials and latest technology procurement, so that the cost of production can be reduced and finished goods can be available at competitive price.
- APPON, industries and related stakeholders with the help of government should aware consumers, retailers and doctors on quality of domestic pharmaceutical products.
- Government should monitor and control for un-authorized medicines especially in border side.
- Data should be updated in MIS of DOI related to capacity increment, investment of industries, name of industries etc.

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CHAPTER V: ANNEXES

ANNEX A: Team Composition

S.N	Name of Expert	Position in Team	Education	Experiences	Remarks
1.	Arun Dongol	Team Leader	B.E. Electrical and electronic	15 Years	ISO 9001:2015 certified Auditor
2	Hari Prasad Subedi	Team Member	B. Tech (Food)	10 Years	FSMS and ISO 9001:2015 certified Auditor
3	Laxmi Prasad Gupta	Team Member	PGDM (MBA)	20 Years	ISO 9001:2015 Certified Auditor

ANNEX B: List of Pharmaceutical Industries Registered in DDA

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
(उद्योग शाखा)

फोन नं.: ४७८०२२७, ४७८०४३२
फ्याक्स नं.: ९७७-१-४७८०५७२
पोष्ट बक्स नं. १००३८
ई-मेल: druginfo@dda.gov.np
inspection@dda.gov.np
मदन भण्डारी पथ, बिजुलीबजार
काठमाडौं, नेपाल

पत्र संख्या ०७७/७८
चलानी नं. ८८३८

मितिः २०७७/१०/१२

श्री उद्योग विभाग
योजना, अनुमगन, तथा औद्योगिक तथ्यांक शाखा
काठमाडौं ।

विषयः जानकारी सम्बन्धमा ।।

उपरोक्त बिषयमा च.न.७७२३, मिति २०७७/१०/०६ को पत्रको सम्बन्धमा व्यहोरा अवगत भयो। सो सम्बन्धमा यस विभागको **DAMS** रेकर्ड अनुसार यस विभागमा दर्ता भएका एल्लोपेथिक औषधि उत्पादक उद्योगहरुको सुची सि.न. १ देखि सि.न. १०४ सम्म रहेको लिस्ट पाना-३ यसै पत्र संग संलग्न गरि जानकारीको लागि पठाईएको व्यहोरा निर्देशानुसार अनुरोध छ।

२०७७/१०/१२
किरण सुन्दर वज्राचार्य
(फार्मेसी अधिकृत)
फार्मेसी अधिकृत (आठौं)

Manufacturer > Registration > Approved

विभागमा दर्ता भएका एल्लोपेथिक औषधि उत्पादक उद्योगहरुको सुची

SN	Certificate No	Manufacturer Name	Remarks
1	1730117104404	Everest Pharmaceuticals Pvt Ltd	Product Available in market
2	1730120064500	Universal Formulations Pvt Ltd	Product Available in market
3	1730120092003	Nepal Pharmaceuticals Laboratory PVt Ltd	Product Available in market
4	1730121034035	Arya Pharmalab Pvt Ltd	Product Available in market
5	1730121040137	Vega Pharmaceuticals Pvt Ltd	Product Available in market
6	1730121042140	Hukam Pharmaceuticals Pvt Ltd	Product Available in market
7	1730121045153	Apple international Pharmaceuticals Pvt Ltd	Product Available in market
8	1730121071119	Sumy Pharnaceuticals Pvt Ltd	Product Available in market s
9	1730121103720	AMTECH MED PVT LTD	Product Available in market
10	1730121104623	Magnus Pharma Pvt Ltd	Product Available in market
11	1730122045028	CTL Pharmaceuticals Pvt Ltd	Product Available in market
12	1730122053545	Siddhartha Pharmaceuticals Pvt Ltd	Product Available in market
13	1730122054013	Vijayadeep Laboratories Limited	Product Available in market
14	1730123083116	Asian Pharmaceuticals Pvt Ltd	Product Available in market
15	1730124025635	NATIONAL HEALTHCARE PVT LTD	Product Available in market
16	1730124095252	OHM Pharmaceuticals Laboratories Pvt Ltd	Product Available in market
17	1730126014201	PHARMACO INDUSTRIES PVT LTD	Product Available in market
18	1730126042556	Simca Laboratories Pvt Ltd	Product Available in market
19	1730128081010	Florid Laboratories pvt ltd	Product Available in market s
20	1730130073324	Aadee Remedies Pvt Ltd	Product Available in market
21	1730130082724	Genetica Laboratory Pvt Ltd	Product Available in market
22	1730131095137	MANOJ PHARMACEUTICAL WORKS	Product Available in market
23	1730131102521	MANOJ CHEMICAL WORKS	**
24	1730131104428	SHIV PHARMACEUTICAL LABORATORIES	Product Available in market
25	1730202041632	Qmed Formulation P Ltd	Product Available in market
26	1730203002958	Time Pharmaceuticals Pvt Ltd	Product Available in market
27	1730203030742	Alive Pharmaceutical Pvt Ltd	Product Available in market
28	1730203051323	JJ Laboratories Pvt Ltd	Product Available in market
29	1730203100705	OMNICA LABORATORIES PVT LTD	Product Available in market
30	1730204094951	Panas Pharmaceuticals Pvt Ltd	Product Available in market
31	1730205103248	Quest Pharmaceuticals Private Limited	Product Available in market
32	1730206081812	Maruti Pharma Private Limited	Product Available in market
33	1730207041746	Samar Pharma Company Pvt Ltd	Product Available in market
34	1730207054607	LOMUS PHARMACEUTICALS PVT LTD	Product Available in market
35	1730210081043	Apex Pharmaceuticals Pvt Ltd	Product Available in market
36	1730211072103	Livecare Pharmaceuticals Pvt Ltd	Product Available in market
37	1730213060215	DEURALI JANTA PHARMACEUTICALS PVT LTD	Product Available in market

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38	1730213064729	Mark Formulations Private Limited	Product Available in market
39	1730218064903	Curex Pharmaceuticals Pvt Ltd	Product Available in market
40	1730221033430	Chemidrug Industries Pvt Ltd	Product Available in market
41	1730221060018	Nova Genetica Private Limited	Product Available in market
42	1730224065458	S R DRUG LABORATORIES PVT LTD	Product Available in market
43	1730225095647	Alliance Pharmaceuticals Private Limited	Product Available in market
44	1730226112241	QbD Pharmaceuticals Pvt Ltd	Product Available in market
45	1730231052603	Keva Pharmaceuticals Pvt Ltd	Product Available in market
46	1730305072317	NUMARKS PHARMACEUTICALS P LTD	Product Available in market
47	1730320113438	Taurus Pharma Pvt Ltd	Product Available in market
48	1730331040659	DENIUM LABORATORIES PVT LTD	**
49	1730403081855	Lomus Parenterals and Formulation Pvt Ltd	**
50	1730424094253	Biogain Remedies Private Limited	Product Available in market
51	1730510075208	Kasturi Pharmaceuticals Pvt Ltd	Product Available in market
52	1730513070248	Hester Biosciences Nepal Pvt ltd	Product Available in market
53	1730630071158	Innovative pharma lab private limited	Product Available in market
54	1730707062304	MEERA BIOTECH PRIVATE LIMITED	Product Available in market
55	1730723083321	Nepal Remedies Pvt Ltd	Product Available in market
56	1730814085031	UNIQUE PHARMACEUTICALS PRIVATE LIMITED	**
57	1730920082950	GD Pharmaceutical Pvt Ltd	Product Available in market
58	1731112130408	Royal Pharmaceuticals Pvt Ltd	Product Available in market
59	1731203105022	Rhododendron Biotech Private Limited	Product Available in market
60	1731224074752	M.D.H. Pharmaceuticals Pvt.Ltd	Product Available in market
61	1731227081819	Lyka pharmaceuticals Private Limited	*
62	1740124063912	Wave Pharmaceuticals Pvt Ltd	*
63	1740131062041	Supreme Health Care Pvt Ltd	Product Available in market
64	1740204053013	Nepal CRS Company	Product Available in market
65	1740219080822	Atom Pharmaceuticals Pvt Ltd	*ls
66	1740224110015	Nepal Aushadhi Limited	Product Available in market
67	1740410032203	Accord Pharmaceuticals Pvt Ltd	*
68	1740419072933	ABHICOM PHARMACEUTICALS PVT LTD	*
69	1740423120307	Divine Health Care Pvt Ltd	Product Available in market s
70	1740432050057	Rajdevi Pharmaceuticals Private Limited	*
71	1740527033040	Gurans Pharmaceutical Pvt Ltd	*
72	1740608112115	Lucius Pharmaceuticals Pvt Ltd	*
73	1740713051557	Pokhara Pharmaceuticals Pvt ltd	*
74	1740801162734	Elixir Life Science Private Limited	*
75	1740808074838	Medrik Pharmaceuticals Pvt Ltd	*
76	1740912125839	CITIZEN PHARMACEUTICALS PVT LTD	*
77	1741123102501	TIZIG PHARMA PVT LTD	*
78	1741229152202	Corel Pharmaceuticals	Product Available in market ls

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79	1750110000541	KANTIPUR PHARMACEUTICALS LAB PVT LTD	*
80	1750206102911	Prime Pharmaceuticals Pvt Ltd	Product Available in market
81	1750213075918	Royal Sasa Nepal Pharmaceuticlas	*
82	1750410070045	CTL Pharmaceuticals Pvt. Ltd. ,Chitwan Unit	Product Available in market
83	1750504075458	Grace Pharmaceuticals Pvt Ltd	Product Available in market
84	1750724021214	Harvard Pharmaceuticals Private Limited	*
85	1750812054726	Global Pharmaceuticals Pvt Ltd	*
86	1750910081721	Everest Parenterals Pvt Ltd	Product Available in market
87	1750918085500	Big B formulation pvt ltd	*
89	1751018052141	Arrow Pharmaceuticals Pvt Ltd	Product Available in market
90	1751105150018	IDEAL PHARMACEUTICALS COMPANY PRIVATE LIMITED	*
91	1751107045018	Derren Pharmaceuticals Private Limited	*
92	1751210074233	Nippon Pharmaceuticals Pvt Ltd	*
93	1751220081547	Life Solutions Pvt Ltd	*
94	1760112043858	Jio Phramaceuticals Pvt Ltd	*
95	1760125044843	Nepal Mars Remedies Private Limited	*
96	1760213061639	Mesa Pharmaceutical Pvt Ltd	*
97	1760229094046	Sopan Pharmaceuticals Limited	*
98	1760231092055	Kalika Pharmaceuticals Pvt Ltd	*
99	1760308091403	PHARMONICS LIFE SCIENCES PVT LTD	*
100	1760327071557	SHIVAM PHARMACEUTICAL PVT LTD	*
101	1760628110644	EMVOLIO LIFE SCIENCES PVT LTD	*
102	1761028112606	Zydin Biotech Pvt Ltd	*
103	1761102072457	MAX PHARMA PVT LTD	*
104	1770130053119	Evans Life Sciences Pvt Ltd	*

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(*) विभागमा दर्ता भई उत्पादन कार्य सुरू गर्ने क्रममा रहेका बजार बिक्रीवितरण अनुमति नपाएका ।

(**) बिभागमा दर्ता रही बजार बिक्रीवितरण पाईसकेको तर हाल उद्योगको प्राबिधिक कारणले गर्दा उत्पादन बजारमा नरहेको ।

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ANNEX- C: Photographs During Field Visit for Data Collection

Meeting with Chairperson and General Secretary of APPON

Meeting and data collection with Chairperson of Asian Pharmaceuticals

Data collection at Biogain Remidies Pvt. Ltd.

Data collection at Universal Pharmaceuticals Pvt. Ltd.

Data collection at Time Pharmaceuticals Pvt. Ltd.

Data collection at Siddhartha Pharmaceuticals Pvt. Ltd.

Data collection at Keva Pharmaceuticals Pvt. Ltd.

ANNEX D-1: Questionnaire for Study of Medicine Manufacturing in Nepal (for Industry)

(This questionnaire are prepared only for study purpose and collected information shall be kept confidential, the study has been conducted on behalf of department of industry and the program is also sponsored by DOI)

Please fill up or tick (√) mark in the relevant answer.

Section 1: Introduction

1.1 **Name of Organization**

:……..……..…

1.2 Address

Particular	**Registered Office**	**Factory**
Province		
District		
Metro/Sub Metro Politian city/ municipality/Rural municipality		
Ward No		
Place		
Telephone No		
E Mail		
Year of establishment		

1.3 Legal Registration

a) Proprietor b) Partnership c) Private Limited d) Public Limited

1.4 Type of Organization.

a) Small b) Medium c) Large

1.5 Authorized person (Top Management)

a) Chairman/MD/Director ..... Contact

No:……

b) CEO/GM/FM .....Contact

No:……

1.6 How do you identify and traceable your products ……

……..……..…

Section 2: Investment

2.1 Capital

a) Fixed Rs. ..... b) Working Rs. ..... c) Total Rs. .....

2.2. Source of Investment

a) 100% Equity b) .....% Loan & .....% Equity c) 100% Foreign Investment

d).....% Internal ..... % Foreign Investment

2.3. Type of Investment

a) 100% Internal b) 100% Foreign c) Internal …… % Foreign .....%

Section 3: Production & Import

3.1: Type of Products

a) Tablet b) Capsule c) Liquid d) ointment e) Others……

3.2: Production Capacity (in Quantity)

Particular	**Tablet**	**Capsule**	**Liquid**	**Ointment**	**Powder**	**Others**
Approved Production Capacity						
Actual Production Capacity						
Existing Running Capacity						
Capacity Utilization (%)						

3.3: Production (in Quantity)

Fiscal Year	**Tablet**	**Capsule**	**Liquid**	**Ointment**	**Powder**	**Others**
F/Y 2072/73						
F/T 2073/74						
FY 2074/075						
FY 2075/076						
F/Y 2076/077						

3.4: Import

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2072/73						
F/T 2073/74						
FY 2074/075						
FY 2075/076						
F/Y 2076/077						

Section 4: Human Resource

4.1 Type & Number of Human resource

Particular	Administrative	Technical/Skilled	Non Skilled	Other	Total
Permanent					
Contract Basic					
Daily Wages					
Total					

Section 5: Electricity Consumption

5.1 Demand Electricity…….....KVA

5.2 Supplied Electricity by NEA…….....KVA

5.3 Annual Electricity Consumption ……..Units

5.4 Source of Energy Consumption (Kw/Year)

a) NEA..... b) Diesel..... c) Turbine……d) Other.....

5.5 Do NEA provide sufficient electricity to factory?

a) Yes b) No c) If no other source of energy in %.....

5.6 Do you have applied any mechanism to minimize energy consumption?

a) Yes b) No c) If yes what is method……

Section 6: Raw Material

6.1 Use of raw material (annual)

Year	Active Raw Material (API)				Auxiliary Raw Material			
	Local	India	China	Others	Local	India	China	Others
F/Y 2072/73								
F/T 2073/74								
FY 2074/075								
FY 2075/076								
F/Y 2076/077								

Section 7: Technology Adopted

7.1 Import of machinery and country

a) ……

b) ……

c) ……

7.2 Used Technology

Activity	Technology Used		
Grinding	Auto	Manual	Other
Mixing	Auto	Manual	Other
Filling	Auto	Manual	Other
Sealing	Auto	Manual	Other
Packing	Auto	Manual	Other
Storage/Handling	Auto	Manual	Other

Section 8: Quality Related

8.1 Do you have GMP certifications

a) Yes b) No

8.2 Do you have any product certifications?

a) Yes b) No c) if yes mention…….…….

8.3 Do you have any other System certifications?

a) Yes b) No c) if yes mention…….……..…

Section 9: Market Management

9.1 Main Market .....

9.2 Annual Sales.

a) Distributors .....% b) Wholesalers.....% c) Tender…….%

d) MR……..% e) Others……

9.3 Sales and Export

9.3.1 Sales

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2072/73						
F/T 2073/74						
FY 2074/075						
FY 2075/076						
F/Y2076/077						

9.3.2 Export

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2072/73						
F/T 2073/74						
FY 2074/075						
FY 2075/076						
F/Y2076/077						

Section 11: Financial Status

11.1 Profit/Loss in last Five Years

Fiscal Year	Profit (in Amount)	Profit in % (As per sales)
F/Y 2072/73		
F/T 2073/74		
FY 2074/075		
FY 2075/076		
F/Y 2076/077		

Section 12: Environment Related

12.1 Do you have Conducted IEE/EIA?

a) IEE b) EIA c)

Others……

12.2 What method do you follow to minimize environmental Impact by Factory?

a) .....

b) .....

c) .....

12.3 Do you have faced any environmental Complaint?

a) Yes b) No c) If yes from where

.....

Section 13: Relation and coordination with Government

13.1 Are Government policies helpful to develop the Industries?

a) Fully helpful b) Partially Helpful c) Not Helpful

13.2 What do you expect from following Government Bodies? (Suggestion for Government Bodies).

a) Company Registration Office……

b) Department of Industry…….……

c) DDA…….……

d) IRD……..…

e) Custom office……

f) NEA……

g) Others if any……..…

Section 14: Challenges Faced by Industry

14.1 Internal challenges

a) .....

b) .....

c) .....

14.2 Governmental (Policy and rules/ regulations)

a) .....

b) .....

c) .....

14.3 Technology Changes

1) .....

2) .....

3) .....

14.4 Establishment of large Plant/ Industries.

1).....

2) .....

3) .....

14.5 Import

a) .....

b) .....

c) .....

14.6 Consumer Awareness

a) .....

b) .....

c) .....

Section 15: Any Suggestion

a) .....

b) .....

c) .....

d) ……

e) ……

f) ……

Authorized Representative: …… Signature:-…….

Designation: …….., Date: ……..……. Seal:

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ANNEX D-2: Questionnaire for Study of Medicine Manufacturing in Nepal (for Association)

(This questionnaire are prepared only for study purpose and collected information shall be kept confidential, the study has been conducted on behalf of department of industry and the program is also sponsored by DOI)

Please fill up or tick (√) mark in the relevant answer

1. **Total Pharmaceutical (allopathic) Industries Operation in Nepal……**

2. **Consumption of Allopathic Drugs**

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2072/73						
F/Y 2073/74						
F/Y 2074/75						
FY 2075/76						
F/Y 2076/77						

3. **Fulfillment of Demand of allopathic medicine**

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
Nepal (%)						
India (%)						
Others (%)						

4. **Import of allopathic medicine (Quantity)**

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2072/73						
F/Y 2073/74						
F/Y 2074/75						
FY 2075/76						
F/Y 2076/77						

5. **Import of allopathic medicine (in Amount)**

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2072/73						
F/Y 2073/74						
F/Y 2074/75						

FY 2075/76						
F/Y 2076/77						

6. Future Demand (Increase rate of consumption of allopathic medicine)

Fiscal Year	Tablet	Capsule	Liquid	Ointment	Powder	Others
F/Y 2077/78						
F/Y 2078/79						
F/Y 2079/80						
FY 2080/81						
F/Y 2081/82						

7. Is Medicine Exported?

a) Yes b) No

If yes where and how much annually/Type .....

……

8. Why Pharmaceuticals Industries are going to be increased?

1) .....

2) .....

9. Are all established Industries Sustain?

a) Yes (give reason)……

b) No (give reason).....

10. What action should be taken from Government to substitute the import of medicine to make self-reliant?

a) .....

2) .....

3) .....

11. What action should be taken from Association/Industry to substitute the import of medicine to make self-reliant?

a) .....

2) .....

3) .....

12. Is it possible to export of medicine? What are the facilities Nepal Government should provide to export?

1) .....
2) .....
3) .....

13. What are the challenge faced by Nepalese pharmaceuticals industries?

1) .....
2) .....
3) ……

14. Price between Nepalese and imported medicine?

a) Same b) Different c) if Different (how much).....

15. What improvement should be made to develop and sustain the allopathic Medicine Manufacturing Industries?

15.1 From Government Level/Policy level

a) .....
b) .....
c) .....

15.2 From Association Level

a) .....
b) .....
c) .....

15.3 From Industry Level

a) .....
b) .....
c) .....

16. Is there any possibility of Raw material availability for future in Nepal ?

a) Yes b) No

If Yes mention……

17. Any Suggestion

a).....

b).....

c).....

d) ……..……..

e) ……..……..

f) ……

Authorized Representative: …… Signature:-…….

Designation: ……..., Date: ……..……. Seal:

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