

MAPPING OF MEXICAN PHARMA MARKET & IDENTIFYING TARGET CUSTOMERS, SEGMENTS

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of Master

of Business Administration (MBA)

in

Pharmaceutical Management

by

Venkata Naga Sai Sudeepti Guntupalli

Under the Supervision and Guidance of

Dr. Surya Prakash

School of Pharmaceutical Management

2023

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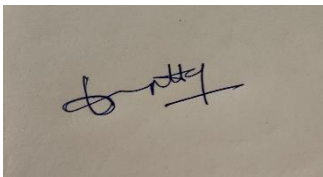
Dr. Surya Prakash

School of Pharmaceutical Management

2023

DECLARATION BY STUDENT

I hereby declare that this dissertation titled Mapping of Mexican API Market, Identify potential customers & segments is the bonafide record of my original researchwork. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished workof others has been duly acknowledged in the text.

A rectangular box containing a handwritten signature in dark ink. The signature is stylized and appears to read 'Venkata Naga Sai Sudeepti'.

Venkata Naga Sai Sudeepti

CERTIFICATE

This is to certify that Ms. Venkata Naga Sai Sudeepti Guntupalli in partial fulfillment of the requirements for the award of the degree in MBA Pharmaceutical Management from the IIHMR University, Jaipur. She has successfully completed her internship at Aurobindo Pharma Limited during March 13, 2023 – June 01, 2023.

Place: Hyderabad

Date: 01.06.2023


UNB Raju
Sr. Vice President-Corporate HR

CERTIFICATE

This is to certify that the dissertation titled Mapping of Mexican API Market, Identify potential Customers & Segments is a record of the research work undertaken by Venkata Naga Sai Sudeepti Guntupalli in partial fulfillment of the requirements for the award of the degree of MBA Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Dr. Surya Prakash
Faculty Guide
IIHMR University, Jaipur

Dr. Saurabh Kumar Banerjee
School Dean
IIHMR University, Jaipur

Mexican Active Pharmaceutical Ingredient Market Mapping & Identifying Customers for APL

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INTRODUCTION

Aurobindo Pharma Limited

Aurobindo Pharma is a public company, founded in 1986 by Mr.P.V.Ramprasad Reddy and Mr.Nithyananda Reddy along with other professionals. Aurobindo is having presence in key therapeutic segments like Cardiovascular, Anti-retroviral, Anti-diabetic, Neurosciences, Gastroenterology, Anti-biotics and others, with market in 150 countries, of over 290 products in various therapeutic segments. Core strengths include large manufacturing capabilities, efficient regulatory affairs team ensuring market compliance, technology, dedicated R&D setup for API and FD.

With over 200 commercialization of APIs APL have five of the manufacturing facilities inspected and approved by US FDA, UK MHRA, TGA Australia, ANVISA and other trusted regulatory agencies. API plants are equipped with dedicated quality control laboratories with practice of DIMAP, FEMA methodologies as a part of QMS.APL offers Penicillins, Cephalosporins, Anti-retrovirals, Anti-infectives and other non-beta lactams along with sterile and non-sterile anti-biotics. APL has applied for 200+ US DMF and about 2000+ filings in other countries with close to 500 patents in place.

Mexican Pharmaceutical Market overview

Generic APIs are expected to be in demand over the forecast period due to the consolidation in the pharma industry and various drugs going off patent.

Mexican generic pharma market will be doubled by 2029 (according to report of 2020) considering the increase in the demand. Current healthcare expenditure is 6.2% of GDP (2020)¹

India is the fifth-largest supplier of pharmaceuticals to Latin America. The country's pharma export grew 14.5 per cent to US\$ 1,196 million to Latin America in fiscal year 2020-21.²

For Mexico's economy, medical tourism is a significant industry. People are pouring into Mexico from all over the world, particularly from the America and Canada. In the past 20 years, the cost of healthcare in the US has nearly doubled. Utilizing this price phenomena, Mexico has created top-notch healthcare facilities at a low cost. On their total treatment costs, patients can save anywhere between 35% and 80%³

The value of the Mexican generic drug market will double to 6.0bn in 2029, reflecting a compound annual growth rate (CAGR) of 6.2%. In 2019, generic medicines accounted for 30.8% of the total pharmaceutical market. Forecast show that this will increase to 47.8% over the next 10years.

Mexico's relatively low-cost environment, growing domestic market and the NAFTA have made it an attractive export base. Meanwhile, the domestic market has been looking more attractive to multinational drug makers because of improved performance by market regulator COFEPRIS, which has allowed.

Epidemiology

Despite extensive efforts to improve general healthcare, the number of chronic diseases in the country will continue to increase significantly in the coming years. As chronic diseases rise in Mexico, the need for medicines will increase, increasing investment prospects for pharmaceutical companies. Non-communicable diseases characterized by a high burden, such as diabetes, cardiovascular disease, cancer, mental and behavioral disorders, account for approximately 75% of all deaths in Mexico.

Opportunities with Mexico

Recently, easing out on regulatory process is observed in terms of clinical trials, BA/BE studies performed on Mexican population where a lot of FDF companies can now register their products with COFEPRIS without any struggles. Previously the cost, time invested were higher due to performing the trials and studies on Mexican population, now they can submit the readily available drug related documents without having to perform studies on Mexicans.

Tenders for generic drugs are increasing which in turn acts as an opportunity for generic API's in Mexico.

Gaining approval from COFEPRIS (regulatory body of Mexico) to market drugs in Mexico may be hard work, but having a product approved by the Mexican regulator can also mean gaining access to the markets of other Latin American countries.

Mexico's geriatric population is increasing, hence growing aging population and increase in incidence of chronic diseases is driving the demand of API Market. In upcoming years growing consumer demand for affordable medications will continue to be country's increased rate of generic drug consumption.

Medical tourism – North Americans patients travel to Mexico for their medical needs primarily to save a huge amount over what they pay in their respective countries

SCOPE OF STUDY

Mapping Mexico pharmaceutical market as a potential market to expansion of API Business

Mexico is the second largest pharmaceutical market in LAC and is in top 15 rank globally with a lot of potential opportunities to explore. The generic pharma industry in Mexico is huge along with which they are dependent on outsourcing of majority of its API from foreign countries. The need for less expensive alternatives is driven by the rise of Obesity, Diabetes, and other chronic conditions which are costly to treat and require daily intake of medication intake from the patient. As a result, need for the generic API will only increase in the future. Considering the strengths of Aurobindo pharma in production capacity of different segments of generic API, APL_u can leverage the opportunities to expand its wings into Mexico.

Identification of prospective customers for Aurobindo's products based on the portfolio compatibility

Mexico has many generic drug manufacturers, and potential customers have been identified for APL to further expand its business into Mexico. With a population of over 130 million and a growing middle class, the demand for pharmaceuticals in Mexico has been increasing steadily over the years. The country is also home to several pharmaceutical manufacturers, which have been expanding their operations to meet the growing demand. Mexico is also host to several manufacturing companies based out of Mexico who manufacture required products to distribute in the market.

RESEARCH METHODOLOGY

Primary objective is to map the Mexican Pharmaceutical Market and identify the areas where Aurobindo can explore for opportunities, identifying specific therapeutic segments where in Aurobindo is strong at and identifying targets for each of the segment for expansion of business. Mexican Pharmaceutical Market is largely unexplored market for Aurobindo. So, for identifying the key areas to venture data points and insights were taken from various proprietary and publicly available databases. For more specific approach, websites of individual companies were also identified. Data is gathered from proprietary data bases like IMS, Info drive from which observations required were made.

Based on the data compiled and curated as per requirement, targeting was done for the companies based on the company's product portfolio and sales values.

In this report focus is on the top 20 pharmaceutical companies that contribute to the Generic pharmaceutical market. For each company shortlisted, the respective top therapeutic segments and products which can be offered are identified.

Mexico's pharmaceutical environment and scope of the market are understood. Mexican pharmaceutical companies with high revenue are identified where top therapeutic segments are selected and top products having the value of more than \$50,000 USD are taken into consideration and the products which can be offered to customers are obtained.

MEXICAN API MARKET OVERVIEW

Strengths:

- The region's second-largest market for medicines after Brazil.
- With regulatory standards that are superior to those of most of its southern neighbours, it is one of Latin America's most developed markets.
- Strong commercial ties with the US, Canada, and the EU.
- Mexico is very highly developed and competitive pharmaceutical manufacturing region with about 200 organizations and has higher presence of global corporations.

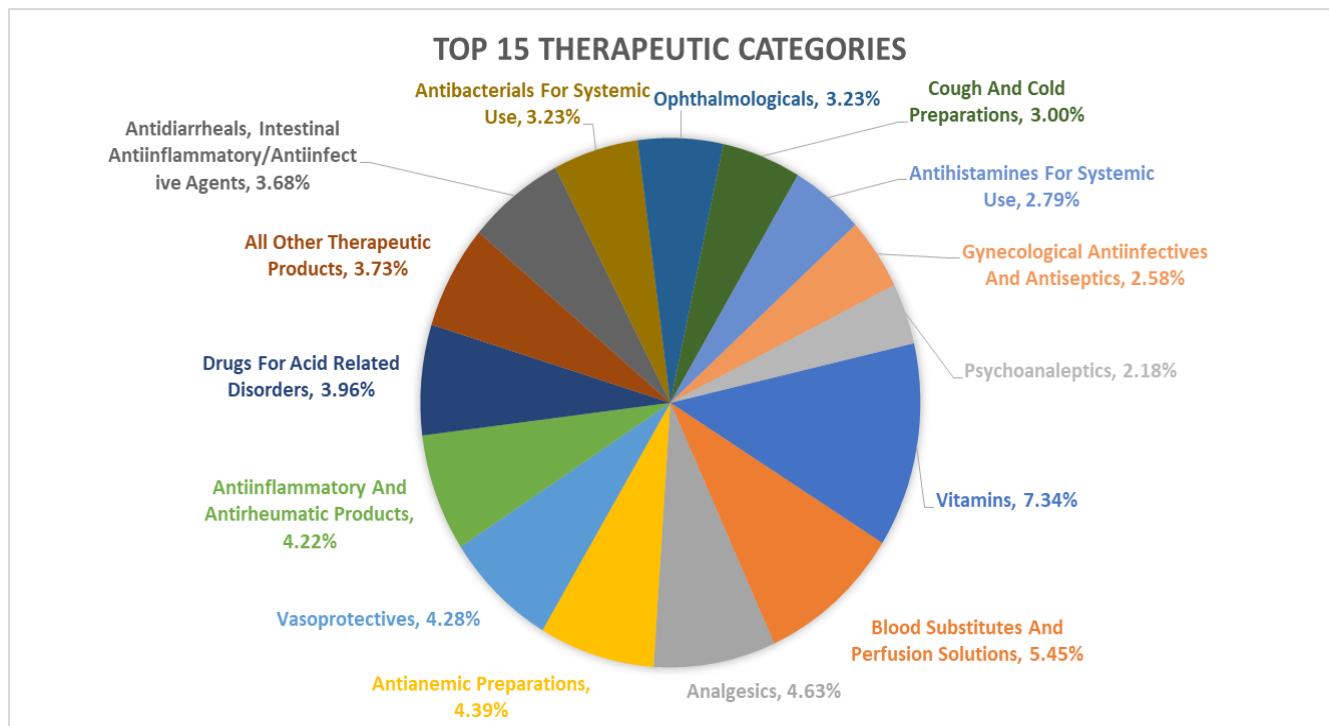
Weakness:

- Law enforcement is patchy and overshadowed by other significant problems, such as cartel-related violence, especially when it comes to the enforcement of counterfeit drugs.
- Private security is a well-known overhead expense for manufacturers operating in Mexico, and red zones, or illicit marketplaces, are well-known to the authorities.

Opportunities:

- Medical tourism is increasing in Mexico which is becoming a major business where people across US, Canada are travelling to Mexico for medical treatments.
- Easing out of regulatory procedures to fasten the drug approval process is seen as major opportunity

Top Therapeutic Segments of Mexico



Trends in pharmaceutical market (M&A)

One example of M&A that has recently taken place in the Mexican pharmaceutical market is the acquisition of Perrigo's pharmaceutical operations in Mexico and the rest of Latin America by Advent International in 2021. This has helped Advent International expand its previous investments in the region and continue its previous regional strategy of the pharmaceutical sector. Perrigo, the world's largest supplier of over the counter (OTC) personal care products, adheres to the highest standards of product quality and safety.

Major Players – Generic

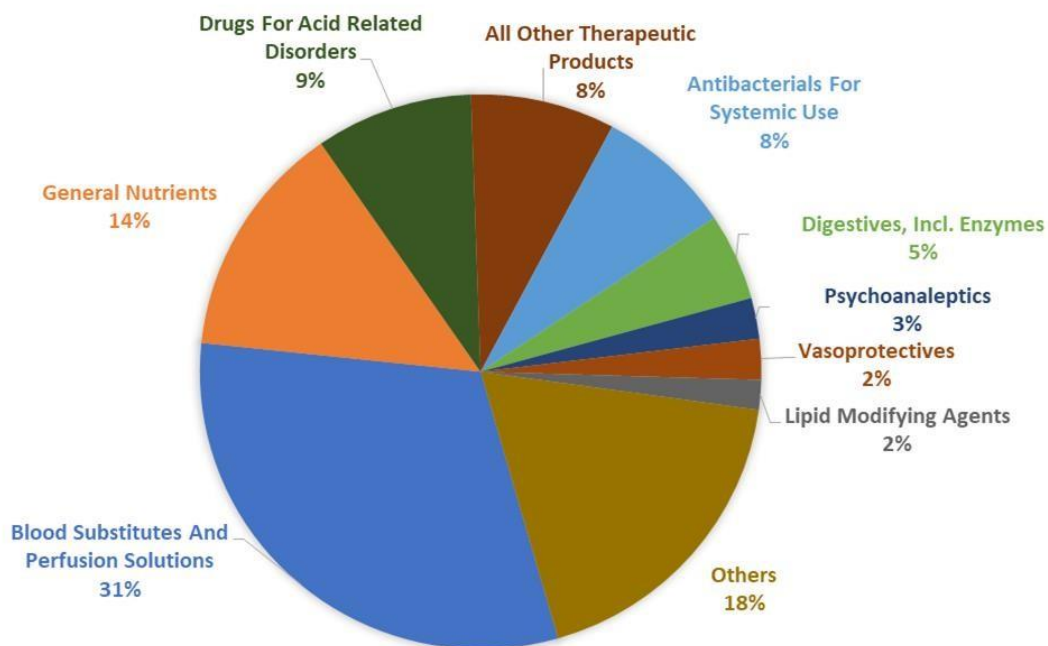
Top Therapeutic Segments of Generic Companies

PiSA

PiSA Pharmaceutical Company was founded in 1945 in Guadalajara, Mexico, and has grown to become one of the largest pharmaceutical companies in the country. It has 77 years of history of serving in public and private segments in Mexico, United States, Caribbean and Latin America.

Nephrology, Infectology and Anesthesiology and other medical specialties are among many areas of health that are treated by PiSA, which specializes in production, marketing, distribution of drug and medical equipment's. PiSA's API segment is a vital part of its operations, representing its expertise in developing and producing active pharmaceutical ingredients.

PiSA manufactures a wide range of APIs, catering to various therapeutic categories such as cardiovascular, central nervous system, respiratory, gastrointestinal, and more.



PISA - THERAPEUTIC CATEGORY CATEGORIES

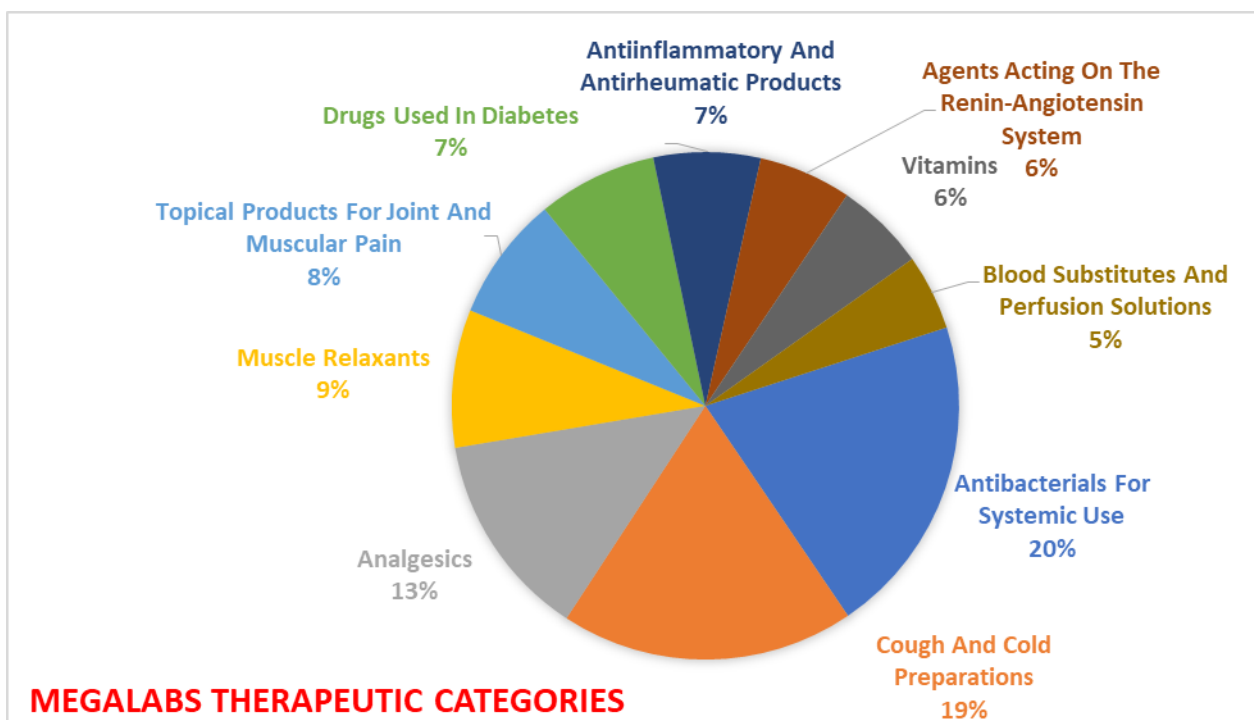
- ✓ PiSA's major therapeutic segment as per the sales revenue is Blood substituents and perfusion solutions that cater large volume parenterals and injectable solutions. Other segments catering to PiSA are General Nutrients, Antacids, Antibacterials and CVS products
- ✓ Drugs for Acid Related Disorders account for 9% of their revenue and is the second biggest segment. This segment is one of the key segments of focus for APL
- ✓ Antibacterials for systemic use account for 8% of their sale. APL expansive business in this category makes this segment a key area to focus for alternative and new development opportunities

- ✓ CNS drugs majorly Psychoanaleptics account for 2 % of the revenue. APL is catering to 20 API in this segment
- ✓ Analgesics, anti-diabetics, **Anti-inflammatory** segments contribute to minor segment of PiSA's market in Mexico. APL has a good presence in all these segments and is a good segment to explore with PiSA

Megalabs

Megalabs is a Mexican pharmaceutical company, with presence over 20 countries and are pioneers in introduction and marketing of multivitamins in 1960's. In addition to its strong presence in the domestic market, Megalabs has expanded its operations to several countries across Latin America, including Argentina, Brazil, Colombia, Ecuador, Peru, and Venezuela.

The international expansion has enabled the company to reach a wider population and contribute to healthcare accessibility in these regions. They have line of products focused on Gyneco-Uro, Gastroenterology, Paediatrics, Dermatology, Anti-acne, Musculoskeletal, Ophthalmology, and General Medicine etc.

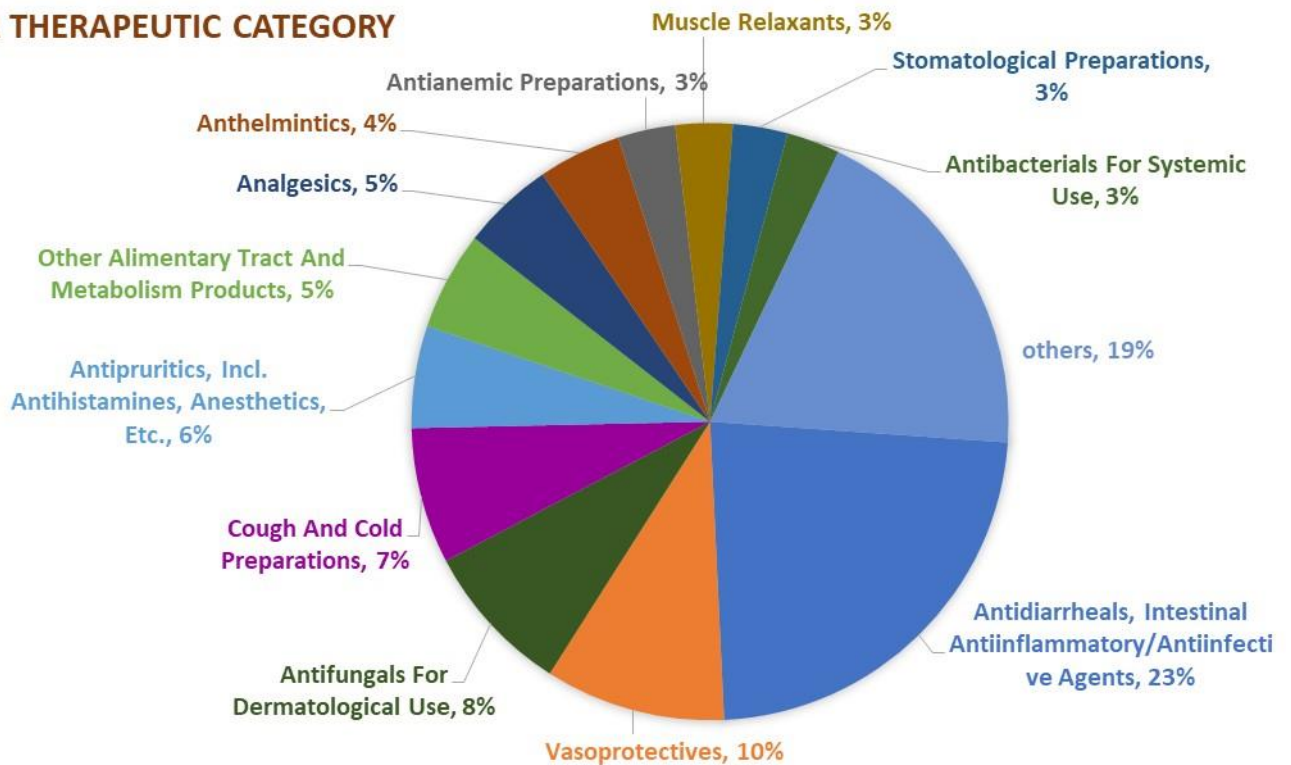


- ✓ Antibiotics for systemic use account for the largest therapeutic segment of 20% where APL has the huge expansion of products in this category for offering
- ✓ Cold and cough preparations account for 19% of the sale value, this segment being the second largest can be seen as the major key area to focus
- ✓ Analgesics account for 13% of the sale for Megalabs in which APL has a strong presence hence can be seen as a good opportunity to focus
- ✓ Other categories like Muscle Relaxants, Topical products for joint and muscular pain ,Drugs Used in Diabetes etc contribute to a smaller section compared to the remaining segments
- ✓ APL is offering most of the products that Megalabs is involved and can be a good target for alternative source opportunities. APL portfolio also includes several new products in these segments and are good offerings for new developments

Sanfer

Sanfer is one of the leading companies in the Mexican pharmaceutical market with international presence, always concerned about participating in the strengthening of the health of the population. They have innovative pharmaceutical products with therapeutic characteristics that offer an effective treatment alternative to their prescribers and consumers.

SANFER THERAPEUTIC CATEGORY

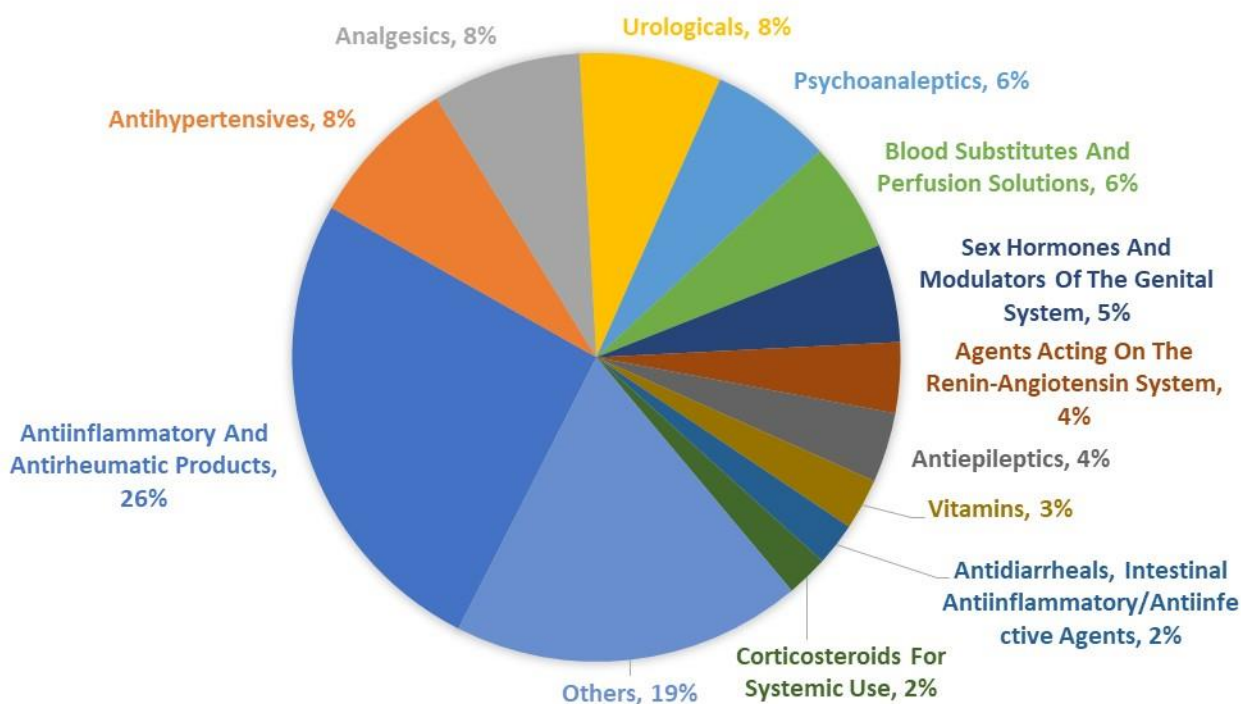


- ✓ Antidiarrheal, Intestinal Anti-inflammatory/Anti-infective agents account for 23% for Sanfer which is the largest segment of the organization in terms of revenue
- ✓ Antifungals for Dermatological use account for 10% of the sale where APL has a strong presence of product offerings, being the second largest segment, this is seen as a key area to focus for APL
- ✓ Cough and Cold preparations, Analgesics, Antibacterials for Systemic use account for 7%, 5%, 3% and other segments contribute to a smaller representation for Sanfer

Adium

Having a presence over 17 countries, Adium is a leading pharmaceutical company which develops, manufactures and market high quality product throughout Latin America. Their purpose is to serve doctors and patients, access to new effective treatments to improve quality of lives. They are involved in Cardiology, diabetes, Pain Management, Rare diseases, Gastroenterology, Gynaecology, Haematology, Immunology, Neurology, Obesity, Oncology, Urology etc.

ADIUM THERAPEUTIC CATEGORIES

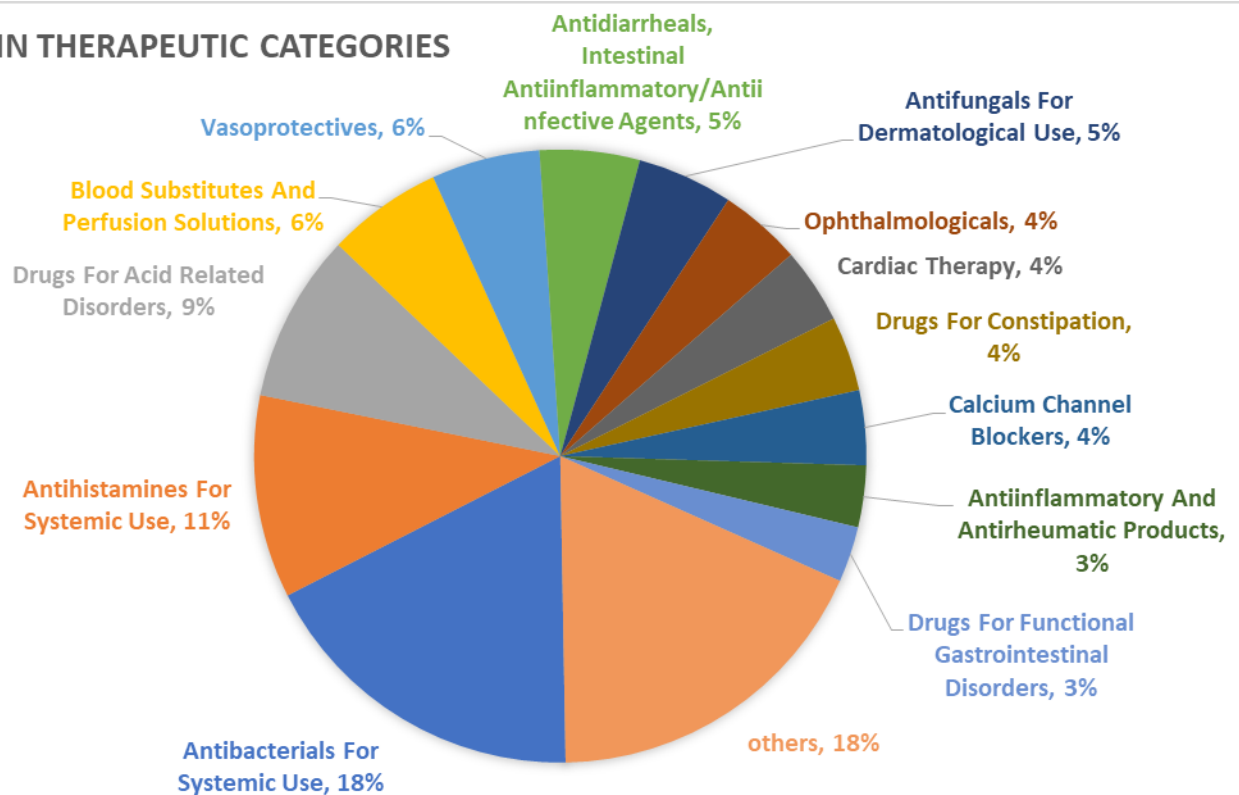


- ✓ In Adium, Anti-inflammatory and anti-rheumatic products account for 26% of the revenue making it the largest segment to focus considering the occupied portion of sale
- ✓ Anti-hypertensives account for 8% of the therapeutic category where APL has a strong presence in product offerings of 24 products
- ✓ Urologicals account for 8% of the revenue, Psychoanaleptics, Agents Acting on The Renin-Angiotensin, Antiepileptics account for 14% in total and all other segments contribute to smaller segments to target

Senosiain

Senosiain was founded in 1928, a leading Mexican pharmaceutical company dedicated in manufacture and marketing of quality pharmaceutical products expanding its business in Latin American countries.

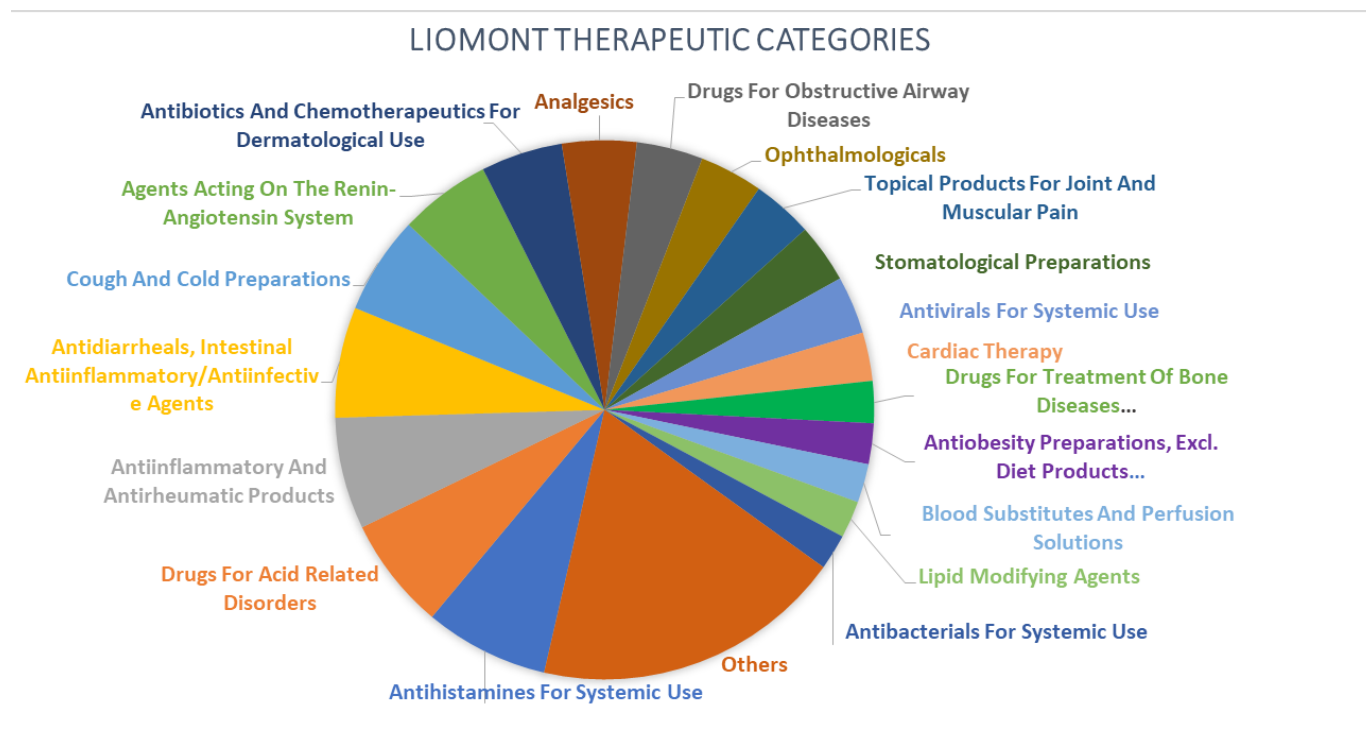
SENOSIAIN THERAPEUTIC CATEGORIES



- ✓ Antibacterials for systemic use account for 18% making it the largest segment contributing to sale of Senosiain, APL has a strong presence in Antibiotics with products to offer about 50 and make this as a key area to focus to capture
- ✓ Antihistamines for systemic use account for 11% of the sale, it is the second largest segment to focus for APL, drugs for acid related disorders, Anti-diarrheals, Intestinal Anti-inflammatory/Anti-infective Agents together account for 17% and other segments account for smaller representation
- ✓ APL is offering most of the products that Senosiain is involved and can be a good target for alternative source opportunities. APL portfolio also includes several new products in these segments and are good offerings for new developments

Laboratorios Liomont

Liomont Laboratories was founded in 1949, whose business include manufacturing of medicinal products for human and veterinary use. Liomont is generic pharmaceutical company which producing pharmaceutical and biological drugs.

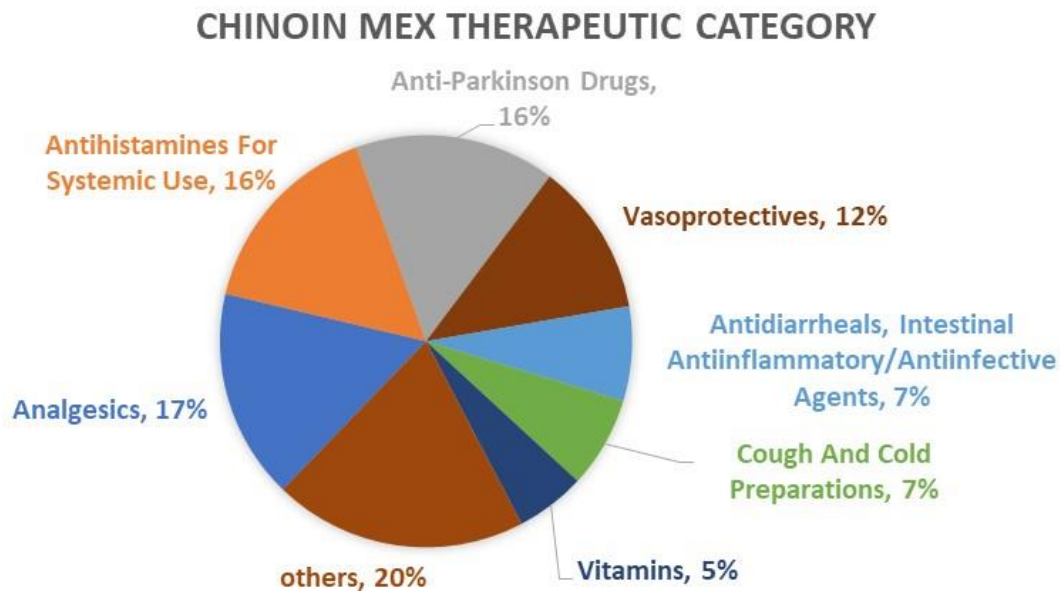


It is present in various therapeutic segments like - Drugs for Acid Related Disorders, Agents Acting on The Renin-Angiotensin System, Analgesics, Ophthalmological, and Topical Products for Joint and Muscular Pain, Drugs for Treatment of Bone Diseases, Drugs for Obstructive Airway Diseases, Lipid Modifying Agents, etc

- ✓ Antihistamines for Systemic use 7% of the revenue making it the largest segment contributing to sale of Liomont, APL can offer the products which Liomont manufactures as a good target of secondary source
- ✓ Drugs for Acid related disorders also account for 7% where APL has a strong presence in product offerings in this segment, hence can be seen as a major key area to focus
- ✓ Anti-inflammatory and anti-rheumatic products, anti-diarrheals, Intestinal anti-inflammatory/anti-infective agents also contribute to 7% each segment, hence APL has many major potential areas to focus for Liomont
- ✓ Other therapeutic segments contribute to smaller representation of Liomont's market in Mexico. APL has several new products in these segments and are good offerings for new developments with Liomont

Grupo Chinoín (Mex)

Chinoín was started in 1912, it manufactures drugs for respiratory diseases, gastrointestinal medicines, pain relaxers, corticosteroids, and gynaecological products. They also produce high quality veterinary products. They have become permanent suppliers of medicines for the National Health System in Mexico through their quality of products and more than 90 years of experience.



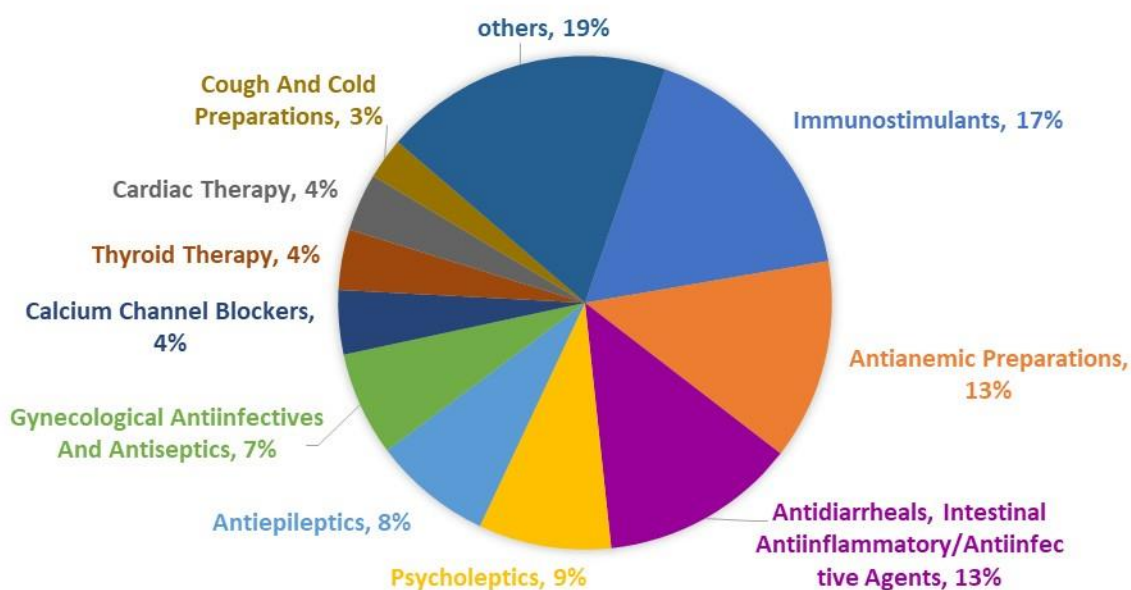
- ✓ Analgesics account for 17% of the revenue generated segment of Chinoín in which APL has a good opportunity to focus
- ✓ Antihistamines for systemic use contribute to 16% of the sale making it the second largest key category to focus for APL
- ✓ Anti-Parkinson Drugs also account for 16% of the sale making it also a largest key area to focus for APL. APL has a good position in this market hence can make a good offering to the customer
- ✓ Anti-diarrheals, Intestinal Anti-inflammatory/Anti-infective Agents and other segments contribute to smaller markets of Liomont's market in Mexico

Bagó

Originated in 1934, Grupo BAGÓ is one of the largest and most important private business organizations of Argentine origin in Latin America and has a strong global expansion, it has 3 distribution companies strategically located in Latin America, equipped with state-of-the-art technology: Disprofarma (Argentina), Novofarma (Chile) and Intercom (Paraguay).

Their products are present in over 50 countries, having 11 pharmaceutical production facilities worldwide, 148 patents developed in 28 countries under their own research and over 480 products comprising 46 therapeutic lines

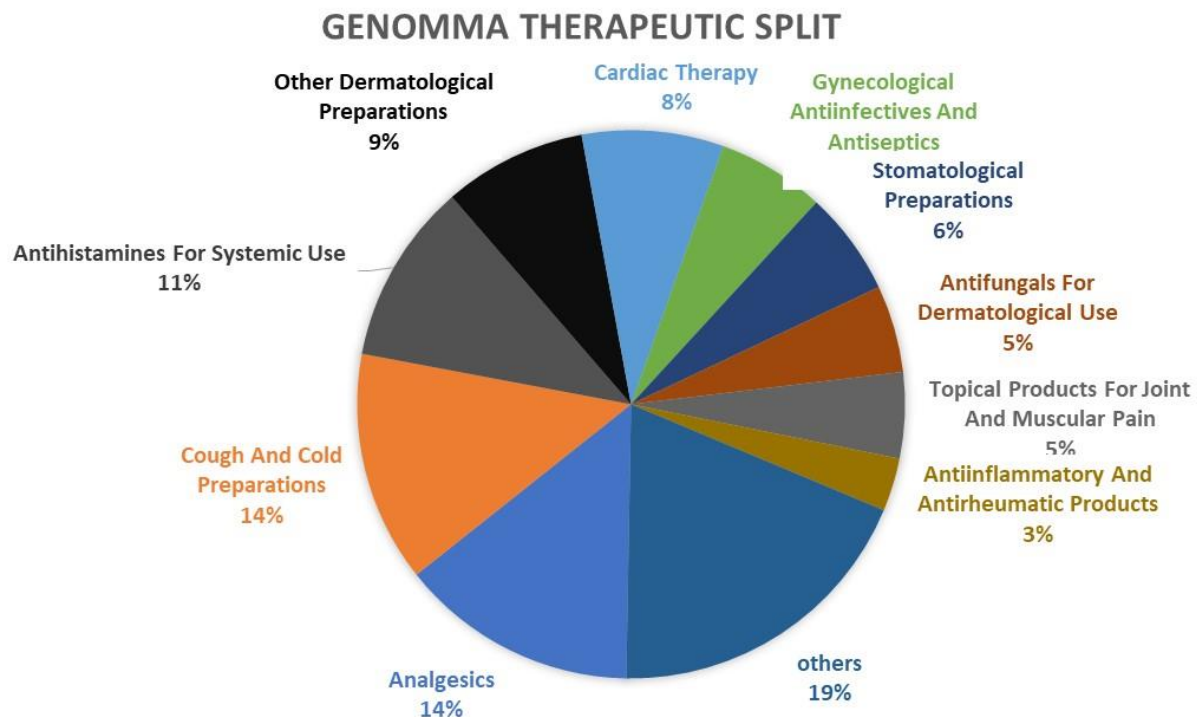
BAGO THERAPEUTIC CATEGORIES



- ✓ Immunostimulants account for 17% of the sale making it the largest market of focus for APL. This is the major segment to focus for APL
- ✓ Antidiarrheals, Intestinal Antiinflammatory/Anti-infective Agents account for 13% of the sale in which APL has a good presence and it can also be alternate for the Bago
- ✓ Psycholeptics account for 9% of the sale where APL is well positioned in this market
- ✓ Antiepileptics and other categories contribute to small segments of Bago's market in Mexico. APL has good presence in all these markets and there are good opportunities to target

Genomma

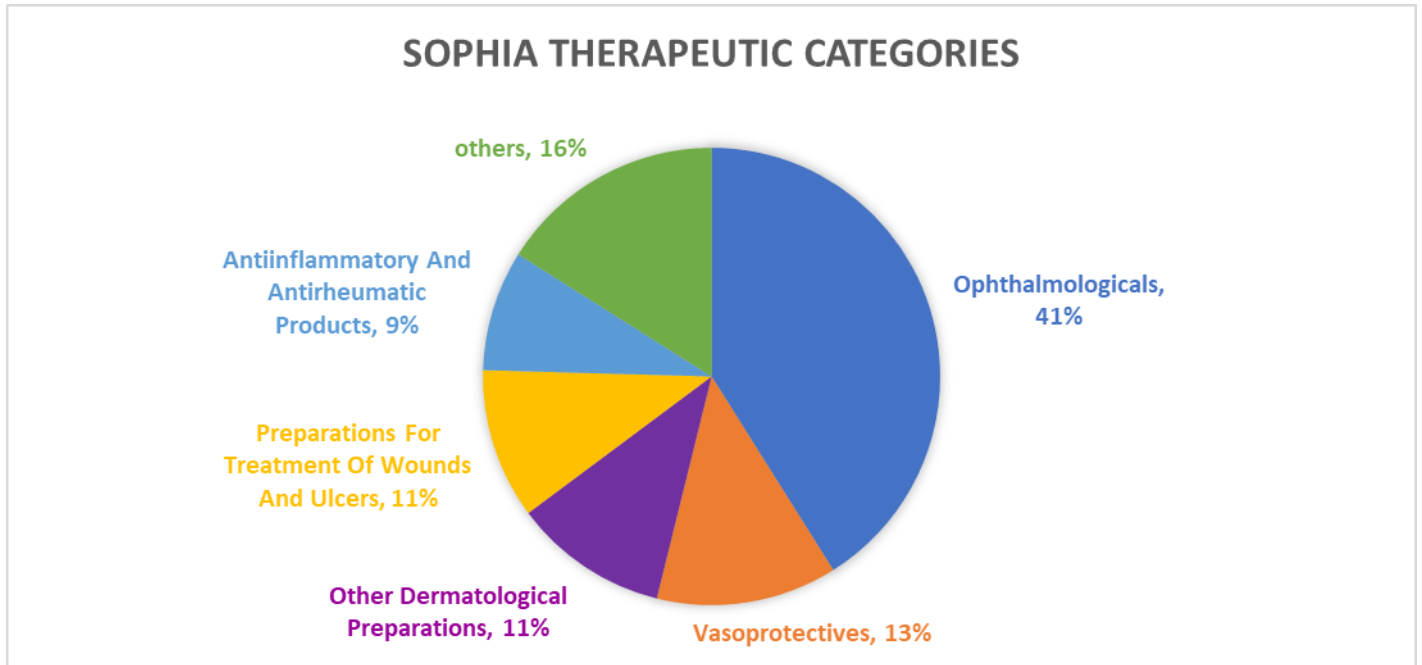
Genomma was established in 1966, as a Direct-to-customer company. It is a Mexican pharmaceutical company which focuses on research, manufacture and marketing of pharmaceutical and derma cosmetic products. They have presence in entire Mexican republic and with exports to over 30 countries, having commercial offices in Spain, Argentina, Peru, and China



- ✓ Analgesics account for 14% of the revenue of Genomma where APL has a good presence to target in this segment
- ✓ Antihistamines for Systemic use contribute to 11% of their sale and it is the second biggest segment to target
- ✓ Other Dermatological Preparations account for 9% of their sale, Gynaecological Anti-infective and Antiseptics of 7% where all other therapeutic categories like Antifungals for Dermatological use, Anti-inflammatory and Anti-rheumatic contribute to a smaller segments individually

Sophia

Laboratorios Sophia, S.A. de C.V. was founded in 1946, headquartered at Guadalajara. It includes the manufacturing, fabricating, or processing of drugs in pharmaceutical preparations for human or veterinary use.



- ✓ Ophthalmological account for 41% of their sales revenue which can be seen as the major target segment to venture for APL
- ✓ Other Dermatological preparations account for 11% of their sale, where Sophia has Brimonidine Tartrate in their portfolio
- ✓ Anti-inflammatory and Anti-rheumatic Products account for 9% of their sale, APL is offering most of the products in their portfolio and hence the product can be offered as new developments and secondary sources, other segments like Anti-diarrheals, Intestinal Anti-inflammatory/Anti-infective Agents etc contribute to smaller segments individually.

Partners & Distributors

- Partners based out of Mexico.

- ✓ Molecular Finas
- ✓ Sinbiotica
- ✓ CPQ – based out of Mexico, EU
- ✓ Merquimia - based out of Mexico, Columbia
- ✓ Gaffel - based out of Mexico, Columbia

- Partners based out of India.

- ✓ Gencur pacific
- ✓ Shiva pharma Casa

They have minimum presence in Mexico compared to other LATAM countries

- Partners based in other countries (EU)

- ✓ Helm
- ✓ Chemo
- ✓ Suan Farma
- ✓ Retecma
- ✓ Disproquimica
- ✓ Pronaquim
- ✓ Grupo Gilsa
- ✓ Wincera AG
- ✓ Selectchemic AG

Regulatory framework

Regulatory requirements surrounding the registration process.

- Federal Commission for Protection from Sanitary Risks, or COFEPRIS, is a decentralised, independent entity that was established in Mexico as a regulatory authority in 2001. It controls manufacturing, import, export, and advertising for healthcare products.
- Mexico is a member of PIC/S nations. PIC/S is a co-operation between regulatory authorities for Good Manufacturing Practices (GMP), it develops common standards for GMP and provides training to Inspectors for inspection. To reduce duplication of effort, if an inspection is conducted by officials in a member country, it will be accepted as valid by other members.

Special regulatory requirements specific to Mexico

- Considering genetic variation of Mexican population, the regulatory authority of Mexico i.e., COFEPRIS has made mandatory that the BA/BE studies of the drug must be performed on the Mexican population for approval of the product into the country
- Post covid-19, they have eased this regulatory requirement to shorten the approval of drug into the market and accept the BA/BE studies that have been performed on any human population.

Registration with COFEPRIS and timelines

Old process:

- For a foreign manufacturer, if prior registration with reference country (USA, Canada, Switzerland, Australia, and Europe) is available, they can request meeting with COFEPRIS, new molecules committee. They can use third party (notified body designated by COFEPRIS to assess medicinal products before they get placed in market) to evaluate technical files. This third party issues evaluated report to manufacturer or Mexican authorized holder. Then submit the registration request to COFEPRIS.
- If prior registration with reference country is not available, they should request GMP certificate in country of origin, make clinical studies on Mexican population, request meeting with COFEPRIS and the same process continues till submitting registration request to COFEPRIS.

New process

Products are divided into two different categories

- ✓ High risk products
- ✓ Low risk products
- The COFEPRIS audit is required for product registration for high risk drugs (such as cancer treatments, steroids, etc.). Following the audit request, COFEPRIS travels to the manufacturing location to issue the GMP. We can approach any manufacturer if our products are published in COFEPRIS GMP. For two to three years, COFEPRIS GMP certificate is valid.
- Idea timeline for approval for registration process can be observed as 12-16 months
- Customers must obtain an import permission from COFEPRIS prior to dispatch for each order. Businesses are unable to import any goods from international clients without an import permission.
- In order to obtain an import permission, each product must previously be listed in COFEPRIS GMP. However, these rules have lately been relaxed, making it simpler to get an import permission for low-risk products. COFEPRIS GMP has a greater priority for high risk products.
- Even if they haven't conducted clinical research on the Mexican population, the adjustments to the new regulatory process aid to shorten the registration process and allow all FDF producers to register with COFEPRIS.

Timelines

For Generics

Time of response - 180 days (Natural days)

Fee (Mexican Pesos) - \$82,011

For new molecule

Time of response – 180 days (Natural days)

Fee (Mexican Pesos) - \$146,641

For GMP Inspection time of response varies and the fee (Mexican Pesos) includes \$96,666

Changes in regulations

- The categorisation of the product as higher risk products and lower risk products is part of a recent legislative framework change. COFEPRIS audits are mandatory for high risk products, whereas for low risk products customer audits are carried out when the customer submits the report to COFEPRIS.

Regulatory inspections and Cooperative treaties

PIC/S

- Mexico is a PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme). It is meant to improve co-operation between Good Manufacturing Practices between regulatory authorities and pharmaceutical industry. By being a part of meetings, PIC/S participating authorities involve in development and harmonization of international GMP guidelines. Some of the non-PIC/S authorities accept GMP certificates from PIC/S participating authorities as they have greater confidence in medicines manufactured in countries where regulatory authority is a PIC/S participant. Being a part of PIC/S country benefits in terms of cost savings, enhanced market access and reduced duplication of inspections.

Regulatory Constraints

Compliance with Mexico's stringent medication registration procedure is one of the key regulatory restrictions there. The country's drug and API registration is under the control of COFEPRIS. In order to complete the process, thorough documentation that proves the API's reliability, dependability, and effectiveness must be submitted.

The need that pharmaceutical firms follow the Mexican Pharmacopoeia, which outlines the quality requirements that APIs must satisfy, is another regulatory restraint.

The import laws of the nation must also be followed, which can be difficult and time-consuming for pharmaceutical enterprises. To import APIs into Mexico, COFEPRIS must receive thorough documentation, including certificates of analysis and product specifications.

The Mexican government has also taken steps to regulate the cost of pharmaceuticals and APIs in the nation. Pharmaceutical businesses must adhere to these rules when setting the prices for their products because the government can set maximum prices for pharmaceuticals.

Overall, pharmaceutical businesses may find it difficult to register APIs due to regulatory restrictions in Mexico. Companies wishing to register APIs in Mexico must consider a number of crucial aspects, including compliance with the country's stringent drug registration procedure, compliance with the Mexican Pharmacopoeia, compliance with import rules, and compliance with pricing regulations. Pharmaceutical businesses can successfully register their APIs and take advantage of the prospects in the Mexican market by comprehending and managing these regulatory restrictions.

Top 5 leading countries of destination of pharma products exporting from Mexico, 2021

- ✓ USA
- ✓ France
- ✓ Panama
- ✓ Columbia
- ✓ Brazil

- Major API source nations to Mexico

- ✓ China
- ✓ India
- ✓ Europe

• Key strengths of Aurobindo and areas of focus compared to Competitors.

- Key strengths of Aurobindo

- ✓ Regulatory capabilities
- ✓ Product portfolio
- ✓ Backend and frontend capabilities
- ✓ Financial capability

EXECUTIVE SUMMARY

With the aging population and increase in chronic diseases, Mexican generic pharma market is expected to rise considering the economic situation of the country, which is opting for more affordable medicines. Generic companies are identified in order to concentrate the therapeutic categories and products which can be offered to the identified customers.

The regulatory norms has been relaxed for the companies to register their products with COFEPRIS, which is the regulatory body of the country. The products are categorized into high risk and low risk products where depending on the type of products, the registration process varies.

Major therapeutic segments occupying 80% of the individual customer are identified and the products in their portfolio, overlapping products and the unique products which are not present in the customer's portfolio but can be offered by APL are identified and proposed

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