

MARKET RESEARCH IN PHARMACEUTICAL INDUSTRY

Guide -
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PROBLEM:

What	India is one of the top contributors in the diseases Tb, Diabetes, Cancer, CVDs.
Why	<ul style="list-style-type: none">• Patient non-adherence<ul style="list-style-type: none">◦ Pain Points :<ul style="list-style-type: none">■ Economic barriers.■ Low Bioavailability of drugs.
	Primary Research : Through Surveys & Interviews
How	Secondary Research : Through Research papers, Articles, Journals and Literature reviews.

ECONOMIC BARRIERS:

Economic Constraints

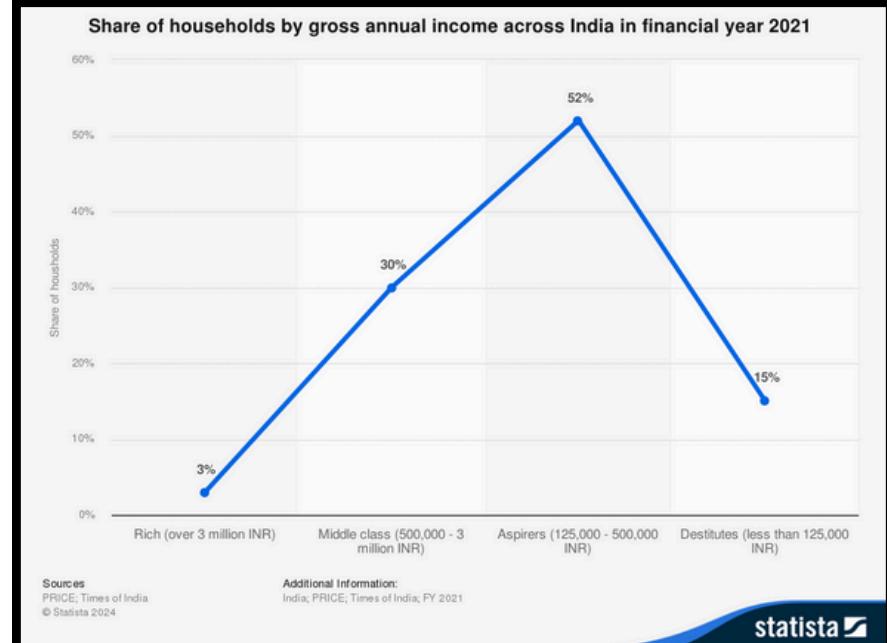
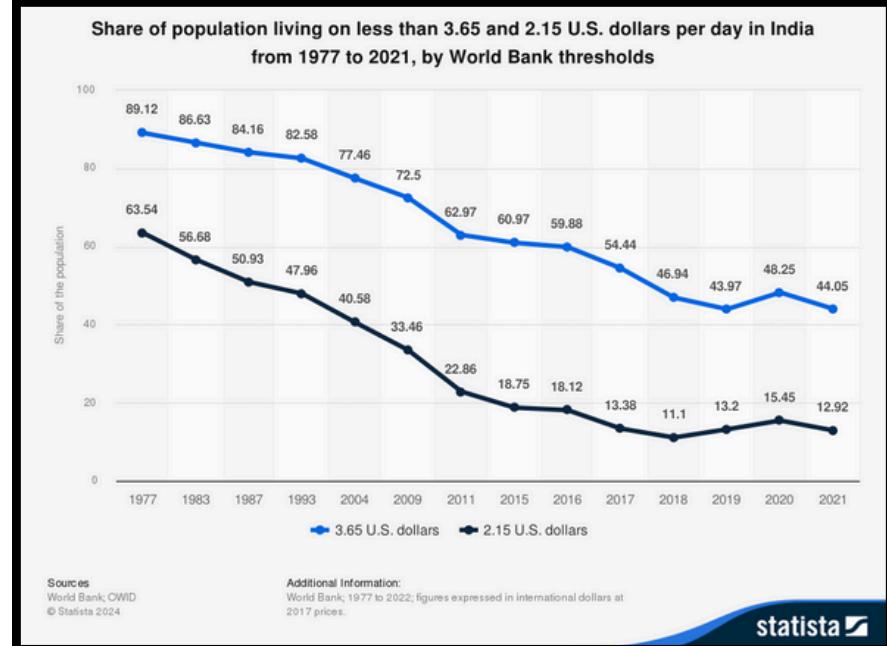
- **1.2 Billion** Lower-Income Individuals (Pew Research, 2021)
 - Annual income: **₹1–1.5 lakh** (~₹10,000/month for the entire family).
- **44%** living on **<\$3.65/day** (World Bank, 2021)
- **Chronic conditions** like diabetes:
 - Avg. monthly expenditure: **₹1,265/patient.**
 - Medications account for **65%** of costs.

Preference for alternate Drugs

- Affordability: **High-quality drugs** are too **expensive** for many as they involve **high development costs**.
- Accessibility: **Limited availability** of standard medications

Quality Concerns in Indian Market

- **3%** of Medicines: **Counterfeit** (Govt. studies over 15 years).
- **The Hindu** Reports: Claim **25–30%** are **SALA**.
- **CDSCO Study**: **1 in 7** Indian drugs found to be **SALA**.



This economic burden leads patients to opt for cheaper alternatives of prescribed drugs, resulting in poor adherence and suboptimal treatment.

LOW BIOAVAILABILITY OF DRUGS:

Drug solubility	<ul style="list-style-type: none">• BCS Class II drugs often have intricate molecular configurations and are highly lipophilic, resulting in poor water solubility.• Larger particle sizes decrease the surface area available for dissolution, thereby limiting solubility.
Preference for Substandard drugs	<ul style="list-style-type: none">• Manufacturing and R&D for standard drugs can cost between \$300 million to \$4 billion.• The process includes preclinical & clinical trials, regulatory approval, and quality assurance.• Low Cost of Substandard Drugs:<ul style="list-style-type: none">◦ Substandard drugs cost as low as \$16 million to manufacture.◦ Key processes like clinical trials, regulatory approval, and quality control are often ignored to reduce costs.
Market share	<ul style="list-style-type: none">• Market share of these Drugs in India is approximately 20% of India's pharmaceutical sector, which is ₹8000 CR.
Consequences	<ul style="list-style-type: none">• Temporary Symptom Relief, recurrent Health Issues or even death in some cases.• Patients face financial strain from continuous visits and treatments or even discontinue the medication.

LOW BIOAVAILABILITY OF DRUGS:

Scope of the issue	<ul style="list-style-type: none">• 90% of drugs in Indian pharmaceutical industry field belong to the generic drug class (WHO, NCBI).• 35% are substandard are drugs with reduced therapeutic effectiveness due to poor quality.• Poor drug efficacy impacting treatment outcomes. Especially low-income groups, face significant risks.• Indian pharma manufactures around 20% of global generics, which is valued at around \$60.9B (2023). Crucial supplier generic drugs in United States.
Outcomes	<ul style="list-style-type: none">• 2019: Intake of substandard cough syrup by a child in Delhi death in India.• 2022: Deaths of 66 children in Gambia from contaminated Drug (Maiden Pharmaceuticals).• 2023: 18 children in Uzbekistan died due to substandard cough syrup (Marion Biotech).

To address these challenges effectively, two key areas require significant focus:

1. **Greater attention to drug pricing to ensure affordable and accessible medications in the market.**
2. **Development of drugs with improved solubility to enhance bioavailability and therapeutic efficacy.**

SECONDARY RESEARCH

Need for oral formulation	<ul style="list-style-type: none">Estimates indicate that oral formulations represent about 90% of the global market share of all pharma formulations.Around 84% of the best-selling pharmaceutical products are orally administeredCurrently valued at \$35 billion, with an annual growth rate of 10%.
Nanotechnology	<ul style="list-style-type: none">Reducing drug particles to the nanoscale, increasing the surface area & enhancing dissolution rates.Carriers like liposomes, dendrimers, or polymeric nanoparticles are used to encapsulate the drug.Targeted Drug Delivery: Directly to specific tissues or cells, enhancing efficacy & reducing side effects.Controlled Release which is maintaining therapeutic drug levels over extended periods.Applicable in treating chronic conditions like including cancer, cardiovascular diseases & infections.
Innovation of methods to increase solubility	<ul style="list-style-type: none">The global pharmaceutical drug delivery market, encompassing nanotechnology-based systems, was valued at approximately \$1,498.72 billion in 2022.Expected to reach at a value of \$2,307.27 billion by 2032, growing at a CAGR of 4.4%.
Co-crystals	<ul style="list-style-type: none">Composed of an API and a co-former like Nicotinamide, Benzoic Acid, Saccharin.Bonded through non-covalent interactions.This arrangement alters the physicochemical properties of the API, enhancing its solubility and dissolution rate notably without modifying its pharmacological activity.Exhibits significant solubility advantages over stable crystalline drugs, comparable to amorphous also.Better physical and chemical stability compared to amorphous forms.
	<ul style="list-style-type: none">The global market was estimated at USD 3.63 billion in 2023.Expected to reach USD 5.33 billion by 2030, growing at a CAGR of 5.62%.

SECONDARY RESEARCH

Innovation of methods to increase solubility	Amorphous Solid Dispersions	<ul style="list-style-type: none">These involve dispersing the drug in an amorphous state within a polymer matrix.ASDs have been shown to significantly improve the bioavailability of drugs like Niclosamide.Mostly they are thermodynamically unstable, potentially leading to recrystallization over time.Manufacturing Complexities as ASD formulations require careful consideration of processing parameters to ensure product consistency. <ul style="list-style-type: none">The market is projected to reach USD 2.4 billion by 2032, exhibiting a growth CAGR of 4.83%.
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Factors dependent on solubility		<ul style="list-style-type: none">Bioavailability: the lower the drug's aqueous solubility the less the bioavailability of the drug.Absorption: the lower the drug's solubility the lower the absorption of the drug at desired place.Pharmacokinetics: it's the overall as low solubility leads to low bioavailability & absorption so the drug just remains in the body till excreted and might show side effects till then.
Challenges faced (Improving solubility)	pH	<ul style="list-style-type: none">Solutions with strong pH levels fully dissociate and those with weak pH levels only partially dissociate. Lower pKa value means the drug substance is a stronger acid, which more fully dissociates in water.
	Polarity of Solvent & Drug	<ul style="list-style-type: none">Ionization is important for a drug to be soluble for oral drug consumption. In the stomach or intestines, the drug is non-ionized so it can be absorbed. When it enters the bloodstream, it needs to become ionized again to prevent it from going back to the GIT and to ensure it is absorbed.
	Particle size	<ul style="list-style-type: none">Typically, larger particles are less soluble, especially if the temperature, pressure and polarity for the solutes is the same

PRIMARY RESEARCH

Initial Survey Plan	<ul style="list-style-type: none">Planned an online survey targeting:<ul style="list-style-type: none">Mailing doctors of medical colleges & Pharmacology professors.
Poor response rate	<ul style="list-style-type: none">Only 3/156 pharmacology professors and 2/158 doctors responded.Majority requested in-person meetings, leading to a shift in strategy.
Revised Survey Approach	<ul style="list-style-type: none">Conducted the survey in person with doctors in Chennai.Total participants were 23 doctors from various specialties.
Doctor Participation Breakdown	<ul style="list-style-type: none">10 General Physicians, 5 Diabetologists, 5 Pulmonologists & 3 Cardiologists.
Survey Focus Areas	<ul style="list-style-type: none">Challenges faced by doctors when prescribing medications.Medical and financial issues faced by patients.Current healthcare and pharmaceutical industry challenges in India.
Survey Questions	<ul style="list-style-type: none">7 key questions explored:<ul style="list-style-type: none">Doctor's perspective on medication challenges.Insights into patient affordability and medical access.Assessment of the unmet needs in India's healthcare system.

ANALYSIS FROM THE SURVEY

Drug solubility	<ul style="list-style-type: none">• 15 rated 4 on a 5-point scale & 8 rated it as 5.• Majority (65%) consider drug solubility to have high significance.
Poor solubility of drugs	<ul style="list-style-type: none">• Diabetologists frequently encountered issues due to the GI tract's role in drug absorption.• TB specialists and cardiologists emphasized the challenges in long-term therapies, highlighting increased side effects and the potential for multi-morbidity.• General physicians reported rare instances of such issues but are more critical in chronic diseases.
Drug Distribution (Oral or IV)	<ul style="list-style-type: none">• General physicians mentioned low-income patients, particularly those relying on daily wages, prefer injections due to their quicker action, which minimizes disruption to their work. However, most other patients prefer tablets because they are easier to take.• Diabetologists indicated that 90% of patients prefer tablets over injections, as tablets are more affordable, less risky, and more accessible. Although tablets take longer to show results, their lower cost makes them the preferred option.• TB specialists noted that both tablets and injections are prescribed, but tablets are more commonly used. They emphasized on the need for the dosage and timing due to the severe side effects of TB medications.• Oncologists prescribe a combination of tablets and injections, depending on the stage of the disease & the patient's condition.
Drug formulation	<ul style="list-style-type: none">• 85% of doctors preferred combination drugs, citing their convenience and suitability for managing co-morbid conditions while ensuring appropriate therapeutic outcomes. Such drugs are easier for patients to follow prescribed therapies consistently.<ul style="list-style-type: none">◦ Complex diabetes medication, 5-6 tablets, patient's drug intake at wrong time, causing lung water accumulation.• 70% doctors emphasized the importance of starting treatment with low or basic dosages rather than high doses.• This approach aims to minimize side effects and improve patient comfort, thereby enhancing adherence.• 65% doctors stressed that drug availability is a crucial factor in prescribing medications.• Also noted that while availability is important, prescribing substandard drugs should be avoided to maintain treatment efficacy and patient trust.

ANALYSIS FROM THE SURVEY

Challenges faced

- Challenges faced by doctors when prescribing medications.
- Medical and **financial issues** faced by patients.
- Current healthcare and pharmaceutical industry challenges in India.

Need for better soluble drugs

- **Diabetologists** highlighted:
 - The challenge of **substandard drugs** in India
 - Better drugs with **improved solubility exist abroad**, their **high cost limits accessibility** in the Indian market.
 - **Financial constraints** often force patients to **switch to substandard medications or discontinue** treatment altogether.
- **TB specialists** highlighted:
 - The importance of better soluble drugs to address drug-resistant TB cases.
 - They emphasized that faster-acting, soluble drugs with fewer side effects could prevent bacterial resistance and improve patient outcomes.
- **Oncologists** highlighted:
 - the necessity of **soluble drugs for cancer** patients, as they are often **multi-morbid**.
 - Improved solubility could **reduce GI and liver complications**, enhancing the overall treatment.
- **General physicians** highlighted:
 - Noted that **better soluble oral formulations** could be a **cost-effective alternative** to injections, **especially for low-income** patients who rely on **daily wages** and prefer treatments that **minimize disruption to their work**.

THANK YOU