ISSN: 2835-7914

Research Article

Biomedical Science and Clinical Research

Assessment of Operational Challenges for Capacity Utilization for the Pharmaceutical Manufacturing Industries in Ethiopia

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Submitted: 2025, Jun 05; **Accepted:** 2025, Aug 06; **Published:** 2025, Aug 11

Citation: Boru, A.G., Banti, D. U. (2025). Assessment of Operational Challenges for Capacity Utilization for the Pharmaceutical Manufacturing Industries in Ethiopia. *Biomed Sci Clin Res, 4*(3), 01-14.

Abstract

Background

The Ethiopian pharmaceutical manufacturing industry is vital for public health and economic development, offering essential, affordable medicines and decreasing dependence on expensive imports. However, it faces significant challenges, such as financial constraints, reliance on imported raw materials, outdated technology, and operational inefficiencies. These issues result in higher costs, production delays, and lower product quality. Overcoming these challenges is essential for enhancing capacity, ensuring a consistent supply of essential medicines, and increasing the industry's competitiveness and contribution to Ethiopia's economic growth.

Objective

To assess the operational challenges faced by the Ethiopian pharmaceutical manufacturing industry and propose strategies to enhance its capacity utilization and competitiveness.

Methods

An institution-based cross-sectional study was conducted from 1th January to 0th June – 2024 on 256 pharmaceutical industries employees. Systematic sampling technique was used and data were collected using a pretested self-administered structured questionnaire. The collected data were entered into excel sheet, and transformed and analysed with SPSS version 23. Binary logistic regression analysis was performed to estimate the crude odds ratios for capacity utilization performance for the industries. In the multivariate model, a significant level at a p-value of < 0.05 and Adjusted Odds Ratio with 95%CI was used to determine the statistical association between the capacity utilization and explanatory variables.

Result

A total of 256 employees responded to the questionnaire, making a 92.1% response rate. The average capacity utilization for local pharmaceutical manufacturers in Ethiopia was below 30% for 202 (78.9%) and 54(21.1%) reported capacity utilization ranging from 31-50%. Importing raw materials for their consumption [AOR = 0.02; 95% CI (0.003, 0.037)], firms' internal operational inefficiency [AOR = 0.05; 95% CI (0.001, 0.071)], inadequate infrastructure [AOR = 0.039; 95% CI (0.003, 0.063)], and lack of skilled labor and experts in the market made [AOR = 0.028; 95% CI (0.001, 0.049)] showed significant negative association with the capacity utilization of the industries, while working collaboratively with local pharmaceutical manufacturers [AOR= 3.02; 95% CI (1.31, 6.98)] and trusts on government's initiative and strategies [(AOR = 2.82; 95% CI (1.23, 6.38) are associated positively for capacity utilization by local pharmaceutical manufacturing industries. Conclusions: Ethiopian local pharmaceutical industries are operating below their capacity. Key factors contributing to this low capacity utilization include limited access to foreign exchange, reliance on imported raw materials, a shortage of skilled labor, and significant operational challenges. Addressing these issues along with supportive regulatory frameworks and collaboration with local manufacturers could enhance their capacity utilization.

Keywords: Local Manufacturers, Pharmaceutical Industries, Capacity Utilization, Challenging Factors, Ethiopia

1. Introduction

1.1 Background

More than two billion people worldwide cannot get the medicines they need. Local Pharmaceutical Production (LPP) can help vulnerable populations, especially those in remote rural areas, to access quality medicines, thus contributing to "leaving no one behind, and reaching the furthest behind first", the overarching principle of the 2030 Agenda for Sustainable Development. LPP can reduce the dependency on international donations and a shrinking number of overseas companies who dominate the global market [1].

African nations have heavily depended on external sources for critical health-security items, including diagnostics, medications, vaccines, personal protective equipments, and other medical supplies [2]. Africa, which accounts for almost 17% of the world's population, represents only 3% of global drug production. The continent imports more than 80% of its consumed pharmaceuticals [3].

The Ethiopian pharmaceutical manufacturing industry is a cornerstone of the nation's healthcare system and plays a pivotal role in the economic development of the country. This industry is responsible for producing essential medicines that are critical for maintaining public health and managing various diseases [4]. The availability of locally manufactured pharmaceuticals ensures that the population has access to affordable and necessary medications, reducing dependency on imported drugs, which can be cost-prohibitive and subject to supply chain disruptions [5].

Despite its importance, the Ethiopian pharmaceutical manufacturing sector faces numerous operational challenges that significantly hinder its effectiveness and efficiency [6]. One of the primary issues is the stringent regulatory environment, which, while necessary for ensuring drug safety and efficacy, often results in prolonged approval times and bureaucratic hurdles that delay the introduction of new products to the market. This regulatory bottleneck can stifle innovation and discourage investment in new manufacturing technologies and facilities [7].

Financial constraints are another major hurdle for the industry. Limited access to credit and high-interest rates make it difficult for pharmaceutical companies to secure the necessary funds for expanding production capacities, upgrading equipment, and investing in research and development. This financial strain is compounded by the high costs associated with regulatory compliance and maintaining quality standards, which further squeeze the margins of local manufacturers [8–10].

The supply chain for raw materials is also a significant challenge. Ethiopian pharmaceutical manufacturers largely depend on imported raw materials, which expose them to global supply chain disruptions, foreign exchange rate fluctuations, and geopolitical instabilities. These dependencies can lead to inconsistent supply, increased costs, and production delays, adversely affecting the availability of finished pharmaceutical products in the market [11].

Technological deficiencies are prevalent within the industry. Many local manufacturers operate with outdated equipment and lack access to advanced manufacturing technologies. This technological gap results in lower production efficiency, higher operational costs, and challenges in meeting international quality standards [6]. Additionally, there is a shortage of skilled personnel trained in modern pharmaceutical manufacturing techniques, which further exacerbates the technological challenges.

Operational inefficiencies are rampant across the industry, driven by inadequate infrastructure, poor inventory management, and inefficient production processes. These inefficiencies not only reduce the competitiveness of Ethiopian pharmaceutical manufacturers but also contribute to higher production costs and lower product quality [11]. Addressing these operational inefficiencies is critical for enhancing the overall capacity utilization of the industry.

Addressing these multifaceted challenges is essential for improving the capacity of the Ethiopian pharmaceutical manufacturing industry to meet local demand. By overcoming regulatory barriers, financial constraints, supply chain issues, technological deficiencies, and operational inefficiencies, the industry can enhance its competitiveness both locally and globally. This improvement is vital for ensuring a steady supply of essential medicines, promoting public health, and contributing to the economic growth of Ethiopia.

2. Statement of the Problem

The Ethiopian pharmaceutical manufacturing industry faces a myriad of operational challenges that significantly hinder its growth and efficiency. These challenges are not unique to Ethiopia but are prevalent across many developing countries. Understanding these challenges and their root causes is essential for developing targeted interventions to enhance the sector's performance.

The regulatory environment in Ethiopia is often cited as a significant barrier to the efficient operation of pharmaceutical manufacturers. Stringent and complex regulatory requirements can lead to prolonged approval times for new products, creating delays that stifle innovation and limit the availability of essential medicines. Studies have shown that in many developing countries, including Ethiopia, regulatory frameworks are often not well-developed, leading to inconsistencies and inefficiencies in the approval processes [12].

Access to finance is another critical issue. Pharmaceutical companies in Ethiopia struggle to secure the necessary funds for expansion, technological upgrades, and research and development due to high-interest rates and limited access to credit [13,14]. Financial constraints have been identified as a major barrier to the growth of pharmaceutical industries in developing countries, where the cost of compliance with international standards and investment in modern manufacturing facilities can be prohibitive [15].

The dependency on imported raw materials poses a significant challenge to Ethiopian pharmaceutical manufacturers. Global

supply chain disruptions, foreign exchange rate fluctuations, and geopolitical instabilities can lead to inconsistent supplies and increased costs [16]. Research indicates that supply chain vulnerabilities are a common problem in developing countries, impacting the availability and affordability of essential medicines [17].

Technological advancement is crucial for improving the efficiency and quality of pharmaceutical manufacturing. Technology continues to be seen as a key element in the move to sustainable development, international efforts around technology to support sustainable development transitions in developing countries have failed to yield results congruent with the needs [18]. The main means through which developing countries can catch-up with the technological advancement are domestic R&D, technology transfer, imitation and absorption, and foreign direct investment. Africa is reliant on technology transfers from non-African pharmaceutical manufacturers. But there are insufficient technology transfers in place to support the majority of current and planned manufacturing capacity [19]. However, many Ethiopian manufacturers operate with outdated equipment and lack access to advanced manufacturing technologies. This technological gap results in lower production efficiency and challenges in meeting international quality standards. Studies have highlighted the importance of technology transfer and the adoption of modern manufacturing processes to enhance productivity and quality in the pharmaceutical industry [20].

Inadequate infrastructure, poor inventory management, and inefficient production processes further exacerbate the operational challenges faced by Ethiopian pharmaceutical manufacturers. Operational inefficiencies are prevalent in many developing countries, where inadequate investment in infrastructure and poor management practices can significantly reduce competitiveness [21]. The cumulative effect of these challenges is a pharmaceutical industry that struggles to meet local demand for essential medicines, limiting its ability to contribute effectively to public health and economic development. Addressing these operational challenges is critical for improving the capacity and competitiveness of the Ethiopian pharmaceutical manufacturing industry.

3. Literature Review

3.1 Global Perspective on Pharmaceutical Manufacturing Challenge

3.1.1 Regulatory Environment

Regulatory compliance is a significant challenge in the pharmaceutical manufacturing industry, particularly in developing countries where regulatory frameworks are still evolving. The requirements for compliance with standards such as Good Manufacturing Practices (GMP) are complex and can be burdensome for manufacturers [22]. The stringent regulatory environment aims to ensure the safety and efficacy of pharmaceutical products [23]. However, the complexity and strictness of these regulations often result in lengthy approval processes, creating delays that hinder timely market entry for new drugs. This regulatory bottleneck can discourage investment in the pharmaceutical sector and stifle innovation, as manufacturers may find it difficult to keep up with evolving standards [24–26].

3.2 Access to Finance

Securing financial resources is a significant barrier for pharmaceutical manufacturers, particularly in developing countries. The high costs associated with research and development (R&D), production facilities, and regulatory compliance make it challenging for companies to access the necessary funds for expansion and innovation [6,27]. The financial constraints are a critical barrier to the growth of the pharmaceutical industry [28]. These constraints limit the ability of manufacturers to invest in new technologies, expand production capacities, and improve product quality [29]. In many developing countries, limited access to affordable credit and high-interest rates exacerbate these financial challenges, further hindering the growth and competitiveness of the pharmaceutical sector [17,30].

3.3 Supply Chain and Raw Materials

The pharmaceutical supply chain is complex and relies heavily on the importation of raw materials. This dependence makes the supply chain vulnerable to disruptions caused by geopolitical and economic fluctuations [31,32]. The supply chain vulnerabilities can lead to inconsistent supplies of raw materials, increased costs, and production delays. These disruptions can severely impact the availability and affordability of essential medicines, particularly in developing countries where local production capacities are limited [33,34]. Effective supply chain management is crucial for ensuring a stable and reliable supply of raw materials, which in turn supports continuous and efficient production of pharmaceutical products [11,35].

3.4 Technological Gaps

Access to advanced technologies is essential for improving productivity and quality in pharmaceutical manufacturing. However, many manufacturers in developing countries face significant technological gaps [36,37]. The lack of modern manufacturing technologies and challenges in adopting new processes hinder productivity and quality improvements. These technological deficiencies result in lower production efficiency, higher operational costs, and difficulties in meeting international quality standards [38,39]. Bridging the technological gap through investments in modern equipment and training for skilled personnel is vital for enhancing the competitiveness of pharmaceutical manufacturers in developing countries [40].

4. Local Context Ethiopian Pharmaceutical Manufacturing Industry

4.1 Regulatory Barriers

The regulatory process in Ethiopia is particularly stringent and time-consuming, which delays product approvals and market entry. Gebre-Mariam et al. (2016) note that the regulatory environment in Ethiopia, while intended to ensure the safety and efficacy of pharmaceutical products, often results in significant delays that can hinder the timely availability of new drugs [12,41]. The complex regulatory requirements can also discourage foreign

investment and limit the growth of the local pharmaceutical industry. Streamlining regulatory processes and adopting a more risk-based approach to regulation could help mitigate these barriers and support the growth of the industry [42,43].

4.2 Financial Constraints

Financial constraints are a major barrier for pharmaceutical manufacturers in Ethiopia. Limited access to credit and high-interest rates makes it difficult for companies to secure the necessary funds for expansion and technological upgrades [44]. The financial constraints are a critical barrier to the growth of the pharmaceutical industry in Ethiopia. These constraints limit the ability of manufacturers to invest in new technologies, expand production capacities, and improve product quality [45]. Addressing these financial challenges through improved access to affordable credit and financial incentives for investment could help support the growth and competitiveness of the Ethiopian pharmaceutical industry [4,6].

4.3 Supply Chain Issues

The dependence on imported raw materials poses a significant challenge for Ethiopian pharmaceutical manufacturers [46]. The logistical challenges and foreign exchange constraints disrupt production schedules and increase costs. The reliance on imports makes the supply chain vulnerable to global disruptions, which can lead to inconsistent supplies of raw materials and production delays. Enhancing local production capacities and improving supply chain management are crucial for reducing dependency on imports and ensuring a stable supply of raw materials [47].

4.4 Technological Deficiencies

Outdated technology and a lack of skilled personnel limit production efficiency and quality in the Ethiopian pharmaceutical industry [48]. Many manufacturers operate with outdated equipment and lack access to advanced manufacturing technologies [49]. These technological deficiencies result in lower production efficiency, higher operational costs, and difficulties in meeting international quality standards [50]. Investing in modern manufacturing technologies and providing training programs for skilled personnel are essential for improving the productivity and competitiveness of the Ethiopian pharmaceutical industry [7,51].

4.5 Operational Inefficiencies

Operational inefficiencies are prevalent in the Ethiopian pharmaceutical industry, driven by inadequate infrastructure, poor inventory management, and inefficient production processes [52]. These operational inefficiencies reduce the competitiveness of the industry and contribute to higher production costs. Addressing operational inefficiencies through investments in infrastructure, adoption of best practices in inventory management, and improvements in production processes are crucial for enhancing the overall capacity utilization of the industry [53]. Implementing these changes can help reduce costs, improve product quality, and increase the competitiveness of the Ethiopian pharmaceutical manufacturing sector [54].

4.6 Conceptual Framework of the Study

Following theoretical reviews illustration, the conceptual framework of the study is presented in figure-1 below. The figure explains the relationship of Operational Challenges of Pharmaceutical Manufacturing Industry in Ethiopia with firm's variability. There is close association of the capacity utilization of pharmaceutical manufacturing industry in Ethiopia and operational challenges both globally (regulatory environment, access to finance, supply chain for raw materials and technological gaps), and locally (regulatory barriers, financial constraints, supply chain issues, technological deficiencies, and operational inefficiencies).

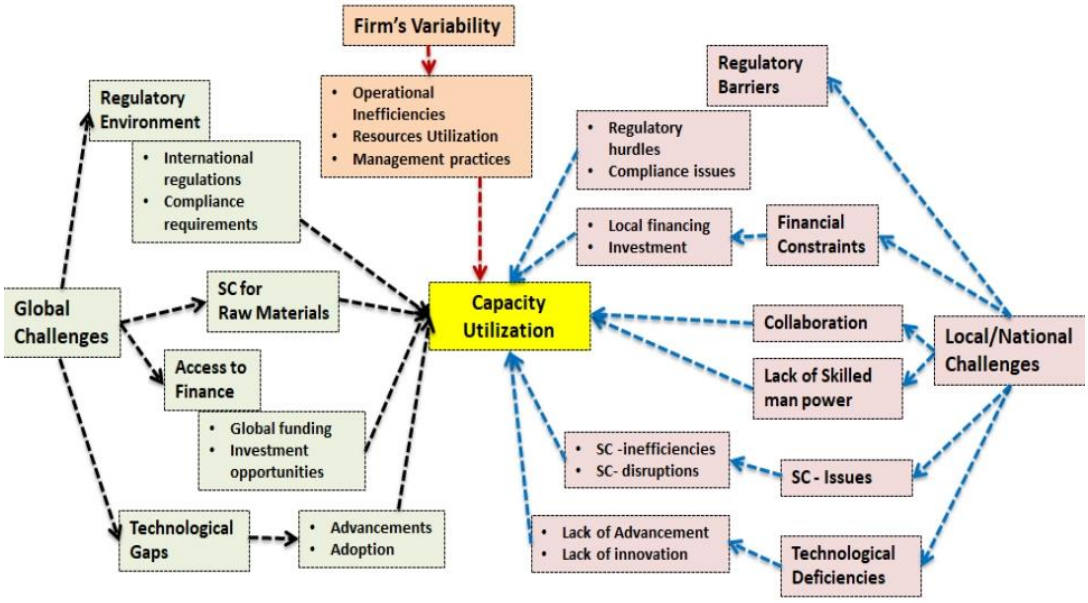

Figure 1: Conceptual Framework of Factors that affecting the Capacity Utilization of Pharmaceutical manufacturing industries in Ethiopia (Source: Developed from review of related literature[3,4,7,12,15,17,19,21,22,24,32,34,38,39,43,45,47,50–52,55–59])

4.7 Significance of the Study

The rationale for this study is to provide a comprehensive understanding of the operational challenges faced by the Ethiopian pharmaceutical manufacturing industry and to propose actionable strategies to address these challenges. This study aims to bridge the gap in existing research by offering detailed insights into the causes and impacts of these challenges, ultimately contributing to the development of effective interventions. The findings from this study will be valuable for industry stakeholders, policymakers, and researchers, providing them with the information needed to make informed decisions and implement changes that will enhance the capacity utilization and competitiveness of the Ethiopian pharmaceutical manufacturing industry

5. Objectives

5.1 The General Objective

- To assess the operational challenges faced by the Ethiopian pharmaceutical manufacturing industry and propose strategies to enhance its capacity utilization and competitiveness.

5.2 Specific Objectives

- Identify the key operational challenges in the Ethiopian pharmaceutical manufacturing industry.
- Analyze the causes and effects of these challenges on the sector's performance.
- Propose actionable strategies to mitigate the identified challenges.
- Assess the impact of government policies on the industry.
- Encourage stakeholder collaboration to foster industry growth.

6. Research Methodology

6.1 Study Area and Period

The study was conducted across various pharmaceutical manufacturing firms in Ethiopia over six months, from January to June 2024

Study Design: An institution-based cross-sectional study was conducted from 1th January to 0th June –2024

Study Population: The source of population for the research was all employees, managers, and key stakeholders within the Ethiopian pharmaceutical manufacturing sector.

Study Subjects: Selected employees and managers from different departments within pharmaceutical manufacturing firms, and key stakeholders such as representatives from regulatory bodies and supply chain partners

Sample Size Determination: Using Cochran's formula, the sample size was 278. To maximizes the sample size; P(0.5) estimated of unknown proportion of the population was used [60,61]. The margin of error 0.05 (5%) and 95% Confidence level were applied with adjustment for finite population

Sampling Procedures: A stratified random sampling technique was used to ensure representation across different categories.

Out of the total sample of 256 respondents (92.1%), 135 (52.7%) were from thirteen pharmaceutical manufacturing companies, 37 (14.5%) from the Ethiopian Pharmaceutical Supply Service (EPSS), 30 (11.7%) from the Ministry of Health (MoH), 21 (8.2%) from the Ethiopian Food and Drug Authority (EFDA), 19 (7.4%) from the Ethiopian Public Health Institute (EPHI), and 14 (5.5%) from the Armauer Hansen Research Institute (AHRI). These respondents were proportionally allocated. Therefore, 256 study subjects who fulfill the inclusion criteria in their respective industries were recruited by systematic random sampling from sampling frame based on proportionate to size.

6.2 Study Variables

Outcome Variables: Capacity Utilization: The extent to which pharmaceutical manufacturers are utilizing their production capacity.

Predictor Variables: Regulatory Barriers: Measured by the number and complexity of regulatory requirements and the time taken for product approvals.

Financial Constraints: Measured by the availability of credit, interest rates, and the financial resources allocated to infrastructure and technological upgrades.

Supply Chain Issues: Measured by the reliability of raw material supply, logistical challenges, and dependency on imports.

Technological Deficiencies: Measured by the level of technology adoption, availability of modern equipment, and workforce skills. Operational Inefficiencies: Measured by production process efficiency, infrastructure adequacy, and management practices.

7. Data Collection Tools & Procedures

A structured self-administered questionnaire was developed by reviewing the literature on the factors affecting the capacity utilization of pharmaceutical manufacturing industries. Regulatory Barriers (number of regulatory requirements, complexity of regulatory requirements and the time taken for product approvals), financial constraints (the availability of credit, interest rates, and the financial resources allocated to infrastructure and technological upgrades), supply chain issues (the reliability of raw material supply, logistical challenges, and dependency on imports), technological deficiencies (the level of technology adoption, availability of modern equipment, and workforce skills), operational inefficiencies (production process efficiency, infrastructure adequacy, and management practices) were included in self-administered structured questioner tool. The questionnaire were adopted, modified and contextualized to the local situation and the research objective. After identified of the study subjects, self – administered data collection method was employed. Employees having a three month and above period of service and currently working in pharmaceutical manufacturing industries in Ethiopia at the time of data collection were the study subjects. After the aim of the study, confidentiality issue and written consent was explained and ensured for the participants from January 01 to June 30/ 2024.

8. Data Management and Quality

Data collectors were trained on the study objectives, data collection tools, and ethical considerations Three weeks prior to data collection, the instruments were pre-tested in order to check some inconsistency in the questions, Pretest was conducted on

13 (5% of the sample) who were excluded in the study from sample frame. Necessary modification was done after the pretest. For additional 13 employees; Seven (6) self-administered questionnaires data and seven (7) interviewer data were produced and triangulation was done to compare data on the same behavior, but from different data collection method. The data were compared and found no difference between the two methods among two groups of employee for the quantitative structured questionnaires [62]. Daily review and monitoring of the data collection process was supervised by the principal investigator for completeness and consistency Double data entry was conducted by two reviewers through verification with the original data.

9. Data Analysis Procedures

All collected data were checked for the completion, clarity and proper identification of the respondents, and no inconsistencies and missing values were found. The data were coded, entered into Epi Info version 7.2.4, and exported to and analysed using SPSS version 23. Descriptive statistics (frequencies distribution) and inferential statistics ($\chi 2$) were used to generate results. The final descriptive results presented using tables; and inferential statistics ($\chi 2$) was used to determine the association of independent variables (predictors) with the dependent variable. The dependent variable i.e. capacity utilization of pharmaceutical manufacturing industries falls into one of two categories as a dichotomous dependent variable based on one or more independent variables that can be either continuous or categorical. Selection process of variables from a large set of covariates those that should be included in the best model was begun by a bivariate analysis of each independent variable, and any variable having a significant bivariate test is selected as a candidate for the multivariate model at the 0.05 alpha level based on the Wald chi-square statistic. p-value cut-off point of 0.25 used to candidate the predictor variables for the multivariate analysis models to see the effect of its association [63]. Variables that not significantly related to the outcome but make an important contribution in the presence of other variables and that did change remaining parameter estimates by more than 15% for the other covariate remained in the model as a confounder. Bivariate analysis for crude odds ratio was carried out. The goodness of fit of the model was checked using the Hosmer-Lemshow goodness of fit resulting in $\chi^2 = 3.79$, p-value = 0.81 which indicates the model was good goodness-of-fit tests for logistic regression models. The final binary logistic regression models to see the strength of association used to estimate the adjusted odds ratios for capacity utilization of pharmaceutical manufacturing at 95% confidence levels to answer the specific objectives of the study. Statistical significance were declared at $P<0.05$.

10. Operational Definitions

- **Regulatory Barriers:** These refer to obstacles related to compliance with government regulations and standards, including delays in obtaining product approvals and market entry due to stringent and complex regulatory requirements.
- **Financial Constraints:** Limitations in accessing sufficient financial resources for investments in infrastructure, technology, research, and development due to high-interest rates and limited credit availability.
- **Supply Chain Issues:** Challenges related to the procurement and transportation of raw materials and finished products, including dependency on imports, logistical challenges, and foreign exchange constraints.
- **Technological Deficiencies:** Gaps in the adoption and use of advanced manufacturing technologies, leading to lower production efficiency, higher operational costs, and difficulties in meeting international quality standards.
- **Operational Inefficiencies:** Inefficiencies in production processes, infrastructure, and management practices that reduce the overall productivity and competitiveness of the industry

11. Ethical Consideration

Prior to data collection, the researcher ensured the relevant people or authorities. Then they were consulted, informed and permission was gained. Once the permission was gained the data collector explained the respondents the purpose of the research, for how long and the right to withdraw at any time for any reason, explained the potential benefit to the participant and the society, and how privacy protected. Furthermore, consent of individuals to answer the question was checked ahead of information gathering. Collected information was kept confidential and was explained to the individual respondent.

12. Results

This section covers detailed description of the sample study population profile, knowledge status on employees on the regulatory barriers, financial constraints, supply chain issues, technological deficiencies, operational inefficiencies, and moreover, the factors that determine the capacity utilization to which pharmaceutical manufacturers are utilizing their production capacity nationally.

12.1 Socio-Demographic Characteristics of the Study Population

The study population was described by assessing their socio-demographic and socio-economic characteristics. Out of 256 employees from pharmaceutical manufacturing industries, 139 (54.3%) were female, with a response rate of 92.1%. The respondents' ages ranged from 19 to 55, with a mean age of 31.36 years. Professionally, 57 (22.3%) were in chemistry, 54 (21.1%) were pharmacists, 50 (19.5%) were in engineering, and 47 (13.6%) were in business management. Job positions included 62 (24.2%) in quality control, 55 (21.5%) as supervisors, 48 (18.8%) as technicians, and 44 (17.2%) as managers. Most respondents, 168 (65.6%), held a bachelor's degree, 75 (29.3%) had a master's degree, 9 (3.5%) had a diploma, and 4 (1.6%) held a PhD holder. Regarding their departments, 62 (24.2%) were in R&D, 53 (20.7%) in quality assurance, 58 (22.7%) in production, and 39 (15.2%) in administration as shown in Table – 1 below.

Value	Frequency	Percentage
Gender		
Male	117	45.7
Female	159	54.3
Professional Composition (Number)		
Chemistry	57	22.3
Pharmacy	54	21.1
Engineering	50	19.5
Business management	47	13.5
Others	48	18.8
Duration of Service (Years)		
< 6	77	30.1
6 – 10	45	17.6
> 10	134	52.3
Educational Status		
Diploma	9	3.5
Bachelor degree	168	65.6
Master's degree	75	29,3
PhD	4	1.6
Job's position in the firm		
Quality control	62	24.2
Supervisors	55	21.5
Technicians	48	18.8
Managers	44	17.2
Department		
R&D	62	24.2
Quality Assurance	53	20.7
Production	58	22.7
Administration	39	15.2
Others	44	17.2

Table 1: Frequency Distribution of Respondents by Selected Socio-Demographic Characteristics, Ethiopia, (n= 256); August 2024

More than 177 (70.0%) respondents had been employed in the pharmaceutical manufacturing industry for at least five years, with their experience spanning from 1 to 30 years and averaging 12.96 years with standard deviation of 8.668. Their tenure in their current positions varied from 0 to 20 years, with an average of 5.83 years, as shown in the table 2 below.

	N	Minimum	Maximum	Mean	Std. Deviation
Years of service in the Industry	256	1	30	12.96	8.668
Years of service at Position level	256	0	20	5.83	5.741

Table 2: Descriptive Statistics for Total Years of Industry Service and Position-Level Tenure; August 2024

12.2 Financial Constraints and Raw Material Sources Challenges for the Production Capacity

Addressing these challenges, from the total 256 respondents, the constraints experienced over the past two years included access to foreign exchange 146 (57%), political instability 50 (19.5%), and customs procedures 11 (4.3%). Regarding the source of raw materials for pharmaceutical manufacturing, 245 respondents (95.7%) relied on imported raw materials, while 11 (4.3%) used

either local suppliers and/or in-house production as shown in below table – 3.

Value	Frequency	Percentage
Constraints for Production Capacity Development		
Access to forex	146	57.0
Political instability	50	19.5
Customs procedures	11	4.3
Source of raw material for manufacturing		
Imported	245	95.7
Local suppliers and In-house production	11	4.3

Table 3: Frequency Distribution for Financial Constraints and Raw Material Sources Challenges for the Production Capacity (n= 256); August 2024

12.3 Strategies of Pharmaceutical Manufacturing Industries for the Capacity Utilization

To overcome challenges for maximum capacity utilization, respondents employed strategies such as maintaining quality assurance, investing in technology, and securing external funding among 29 (11.3%), market diversification and improving human capacity for 35 (13.7%), and the cost reduction strategy for 39(15.2%). Almost all respondents 215 (84.0%) believed in the effectiveness of pooled procurement for raw materials by aggregating resources through a single, collaborative national procurement strategy, which is considered paramount for overcoming challenges related to raw material requisition from abroad as shown in below table – 4.

Value	Frequency	Percentage
Strategies of Industries to Overcome Challenges		
Quality assurance	29	11.3
Policy lobbying	30	11.7
Market diversification	35	13.7
Investing in technology	29	11.3
Improving HR	35	13.7
External funding	29	11.3
Cost reduction	39	15.2
Usefulness of Pooled Procurement of Inputs		
Yes	215	84.0
No	41	16.0

Table 4: Frequency Distribution for Strategies of Pharmaceutical Manufacturing Industries for the Capacity Utilization (n= 256); August 2024

12.4 Government Support and Market Competitions for the Production Capacity

Regarding government support for policies and regulation of local pharmaceutical production in Ethiopia, out of 256 respondents, 38 (14.8%) believed the policies were too stringent, 22 (8.6%) found them supportive, 104 (40.6%) reported restrictive policies, and 43 (16.8%) felt the policies were neutral. As for governmental protection of local pharmaceutical manufacturing activities, 74 respondents (28.9%) considered it very good, 103 (40.2%) viewed it as inadequate and 65 (25.4%) believed that governmental protection could be effective with special consideration and support from the government.

Among 256 respondents regarding market competition for local pharmaceutical industries in Ethiopia, 66 (25.8%) reported weak local competition, and 8 (3.1%) noted weak global competition. Very tough competition was observed by 52 (20.3%) locally and 70 (27.3%) globally. Strong competition was reported by 126 (49.2%) locally and 133 (52.0%) globally. Additionally, 12 (4.7%) indicated no local competition, while 45 (17.6%) reported no global competition in terms of their production capacity utilization as shown by below table – 5.

Value	Frequency	Percentage
State of government policies and regulations support		
Too stringent	38	14.8
Supportive	22	8.6
Restrictive	104	40.6
Neutral	43	16.8
Governmental protection of local pharmaceutical manufacturers		
Very good	74	28.9
Not good	103	40.2
No idea	14	5.5
Has some effect	65	25.4
State of competition among local pharmaceutical manufacturers		
Weak	66	25.8
Very tough	52	20.3
Strong	126	49.2
No competition	12	4.7
State of Competition with pharmaceutical Global Manufacturers		
Weak	8	3.1
Very tough	70	27.3
Strong	133	52.0
No competition	45	17.6

Table 5: Frequency Distribution for Government Support and Market Competitions for the Production Capacity (n= 256); August 2024

12.5 Prevalence of Capacity Utilization for Local Pharmaceutical Manufacturing Industries in Ethiopia

Among 256 respondents, over the two years preceding the study period (January 1, 2022, to December 31, 2024), the average capacity utilization for local pharmaceutical manufacturers in Ethiopia was below 30% for 202 (78.9%) respondents. The remaining 54(21.1%) reported capacity utilization ranging from 31-50%, with none able to utilize more than 50% of the available capacity, as shown in the figure – 2 below.

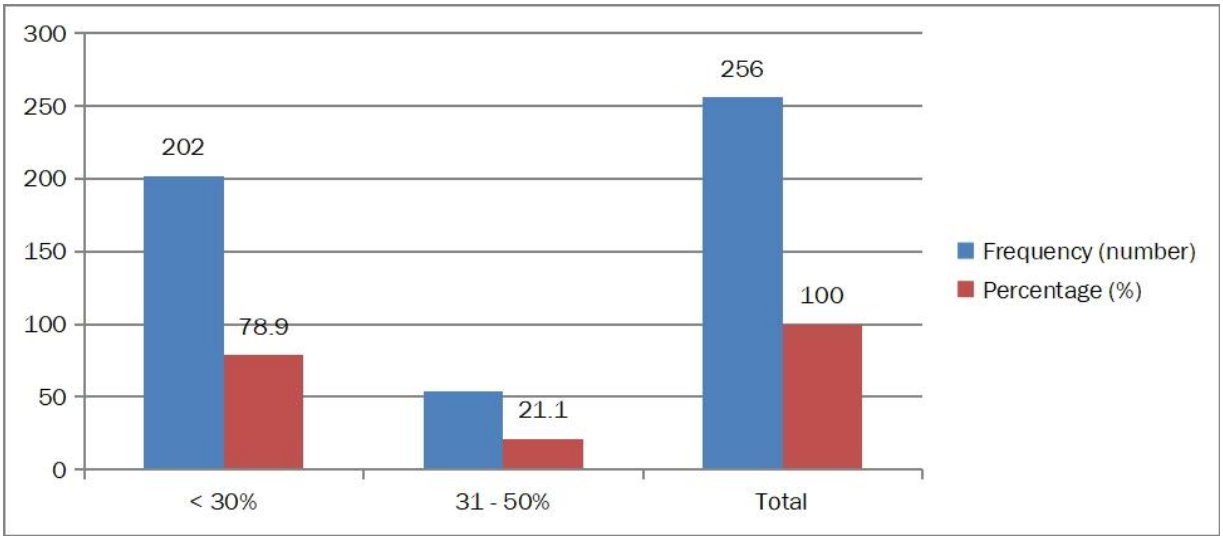

Figure 2: Local Pharmaceutical Manufacturers' Capacity Utilization in Ethiopia; August 2024

Factors identified for low capacity utilization in pharmaceutical manufacturing industries include inadequate forex access from the national bank, affecting the amount requested, timing of payment, and currency required, 256(100%); inadequate access to loans from local banks, 165 (64.5%); and dependence on imported raw materials 215(84%). Additionally, significant shortages of skilled labor and experts in the local market, 176(68.8%) and the high cost of pharmaceutical manufacturing, 160(62.5%) were among the challenges faced by the pharmaceutical manufacturing industries in Ethiopia. Weak support from stakeholders, 194(75.8%), low technology adoption and transfer by firms, 135(52.7%), and operational challenges, 216(84.3%) significantly affected capacity utilization. Despite these challenges, 216(84.4%) believe that the local pharmaceutical industry significantly contributes to national in-house pharmaceutical production and can enhance and sustain local manufacturing capacity. The positively identified enablers for local manufacturers include cooperation among local manufacturers, 205(80.0%); collaboration with customers, 187(73.0%), and partnerships with other recommended sectors, 178(69.5%). These factors, combined with better governmental support, incentive packages, regulatory support, and prioritization of local production in national development plans, can positively impact local manufacturers as shown by the below table – 6.

Description of variables	Value	Frequency	Percentage
Local pharmaceutical industries for national contribution	Yes	216	84.4%
	No	40	15.6%
Cooperation for local manufacturers (N= 256)	With local pharma manufacturers	205	80.0%
	With local other manufacturers	146	57.0%
	With customer	187	73.0%
	With other recommend sector	178	69.5%
Government Price Control	Yes	71	27.7%
	No	185	72.3%
Reason for under capacity utilization (N = 256)	Importing of raw material sources	215	84.0%
	Inadequate forex access	256	100.0%
	Inadequate finance access to loan	165	64.5%
	Lack of skilled labor and experts	176	68.8%
	High production cost	160	62.5%
	Firm's associated operational challenges	216	84.3%
	Firms' un access to infrastructure	188	73.4%
	Low technology adoption & Transfer by firm	135	52.7%
	Weak support from other stakeholder	194	75.8%

Table 6: Factors for Low Capacity Utilization for Ethiopian Pharmaceutical Manufacturing Industries

12.6 Factors Associated with the Low Capacity Utilization for Local Pharmaceutical Manufacturing Industries in Ethiopia

In the unadjusted regression analysis, after controlling for various confounding factors such as educational level, field of study, department of work, position in the industries, market competition, production cost, financial loans, government price control, and technology adoption and transfer by firms, these factors were not significantly associated with the low capacity utilization of pharmaceutical manufacturing industries.

Industries that imported raw materials for their consumption were 0.02(AOR = 0.02; 95% CI: 0.003, 0.037) times more likely to experience low capacity utilization compared to those producing in-house and sourcing locally. Industries facing internal operational challenges were 0.05(AOR = 0.05; 95% CI: 0.001, 0.071) times less likely to utilize their capacity compared to firms that utilized their available resources. Firms with inadequate infrastructure were 0.039 times (AOR = 0.039; 95% CI: 0.003, 0.063) more likely to have a history of difficulty accessing resources compared to those with adequate infrastructure. The lack of skilled labor and experts in the market made firms 0.028 times (AOR = 0.028; 95% CI: 0.001, 0.049) less likely to utilize production capacity compared to those equipped with skilled labor and experts from various professional disciplines.

Pharmaceutical manufacturing industries working collaboratively with local pharmaceutical manufacturers were 3.02 times (AOR = 3.02; 95% CI: 1.31, 6.98) more likely to utilize production capacity. Industries that have a trust on government's initiative, strategies and local pharmaceutical manufacturing policy to offer the intended incentive packages were 2.82(AOR = 2.82; 95% CI: 1.23, 6.38) times more likely to utilize production capacity compared to those lost the trust on governments policy.

Variables	Capacity Utilization		COR (95% C.I.)	AOR (95% C.I.)
	< 30%	≥ 30%		
Raw Material Source				
In – house and local	9(3.5%)	2(0.8%)	1	1
Imported	193(75.4%)	52(20.3%)	0.03(0.001, 0.081) **	0.02(0.003, 0.037)**
Firm's Operational Efficiency				
Agree	49(19.1%)	15(5.9%)	1	1
Disagree	153(59.8%)	39 (15.2%)	0.02(0.001, 0.032) **	0.05(0.001, 0.071) **
Adequate for Local Infrastructure				
Yes	66(25.8%)	20(7.8%)	1	1
No	136(53.1%)	34(13.3)	0.04(0.002, 0.069) **	0.039(0.002, 0.063) **
Skilled Labor and Experts				
Yes	98(38.3%)	26(10.2%)	1	1
No	104(40.6%)	28(10.9%)	0.03(0.007, 0.082) **	0.028(0.001, 0.049) **
Collaboratively Working with Local Pharmaceutical Manufacturers				
Yes	181(70.7%)	51(19.9%)	1	1
No	21(8.2%)	3(1.2%)	3.09(1.01, 10.78) **	3.02(1.31, 6.98) **
Trust on a governmental support, initiatives and strategic plan for local manufacturers				
Yes	145(56.6%)	50(19.5%)	1	1
No	57(22.4%)	14(5.5%)	2.90(1.98, 9.23) **	2.82(1.23, 6.38)**
The goodness of fit of the model was checked using the Hosmer-Lemshow goodness of fit resulting in X2 = 3.79, p-value = 0.81which indicates the model was good				

Table 7: Factors Associated with the Low Capacity Utilization for Local Pharmaceutical Manufacturing Industries in Ethiopia

13. Discussion

In this study, the average capacity utilization for Ethiopian local pharmaceutical manufacturers was below 30%, with only 21.1% reporting utilization between 31-50%. Although the average capacity utilization was around 41% in 2019, limited access to foreign exchange from the national bank (100%)—a measure aligned with the Ministry of Finance's directive to the Ethiopian central bank to restrict foreign currency use to conserve dwindling reserves in October 2023 and a lack of financial loans from local banks may have restricted capacity utilization, despite the government's special treatment of the pharmaceutical sector, it is still difficult to get the necessary foreign exchange on time to acquire materials and supplies [64].

Local pharmaceutical industries are operating below their capacity and experiencing low productivity levels. Their reliance on imported raw materials (84.0%) makes them 0.02(AOR = 0.02; 95% CI: 0.003, 0.037) times more likely to experience low capacity utilization compared to those producing in-house and sourcing locally. This finding is consistent with the United Nations Conference on Trade and Development (UNCTD-2023) report [6].

The pharmaceutical industry in Ethiopia faces significant challenges, primarily due to a shortage of skilled labor and experts (68.8%). This shortage makes firms 0.028(AOR = 0.028; 95% CI: 0.001, 0.049) times less likely to utilize their production capacity compared to those with skilled professionals from various disciplines. This issue is compounded by poor knowledge transfer, imbalanced scientific exchange[, a lack of local scientific capacity, and the emigration of highly trained professionals [65,66].

Operational challenges (84.3%) can significantly impact the capacity utilization of the local pharmaceutical industries. Firms facing these internal operational challenges are 0.05(AOR = 0.05; 95% CI: 0.001, 0.071) times less likely to utilize their capacity compared to those that effectively utilize their available resources. This finding aligns with insights from Deloitte, which emphasize the importance of improving supply chain management, investing in modern technologies, enhancing workforce training, and advocating for more supportive regulatory frameworks [67].

Limited access to infrastructure (73.4%) can significantly impact the capacity utilization of local pharmaceutical industries. Firms with inadequate infrastructure are 0.039(AOR = 0.039; 95% CI: 0.003, 0.063) times more likely to experience difficulties accessing resources compared to those with adequate infrastructure. However, addressing challenges related to power supply, water supply, transportation, communication, and waste management can enhance their operational efficiency and capacity utilization [68].

This study found no significant connection between technology adoption and transfer and the low capacity utilization of pharmaceutical manufacturing industries. However, limited access to appropriate technology was reported as major factors for low average capacity utilization by Ethiopian local pharmaceutical facilities in 2019, and many Ethiopian pharmaceutical manufacturers were using outdated equipment and machinery in 2015 which showed the improvement with technology adoption in the sectors [51].

The local pharmaceutical industries that collaborate with local manufacturers and trust the government's initiatives, strategies, and policies for local pharmaceutical manufacturing are more likely to utilize their production capacity compared to those that have lost trust in government policies

13.1 Limitations and Strength of the Study

Obtaining ethical and institutional approval was straightforward. The study was cost-effective in terms of both money and time. The collected data were consistent and reliable, and the study was conducted according to the original design, successfully answering the research question and being judged as fair quality. However, the research relied solely on quantitative approaches. Information that was difficult to capture through quantitative methods was excluded, despite being included in the initial proposal for a mixed-methodology study. This was because it required detailed inquiries and expert engagement, which were not feasible. Consequently, the study lacked the depth needed to fully explore why pharmaceutical industries were not operating at full capacity in local production.

14. Conclusions

The study highlights that Ethiopian local pharmaceutical manufacturers are operating below their capacity, with an average utilization below 30%. Key factors contributing to this low capacity utilization include limited access to foreign exchange, reliance on imported raw materials, a shortage of skilled labor, and significant operational challenges. Addressing these issues through improved infrastructure, better supply chain management, investment in modern technologies, and supportive regulatory frameworks could enhance their capacity utilization. Collaboration with local manufacturers and trust in government initiatives also play a crucial role in improving production capacity.

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