

A Study on Challenges And Opportunities in Pharmaceutical Industry With Special Reference to Pithampur Industrial Estate M.P.

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Abstract- The present study identify challenges and opportunities of Pithampur Industrial Estate and will focus on the strategies formulated by pharma manufacturing units at Pithampur to stay competitive against various threats, opportunities and will also study the role of government policies and viability in terms of industry structure. It also provides an overview of pharmaceutical industries at pithampur including contract manufacturing and research and examines contracting models and need for developments to make Pithampur Industrial Estate as a vibrant Pharmacy hub. Observations emerge from the analysis of the selected leading pharmaceutical companies of Madhya Pradesh; Indore and Pithampur. Data analysis done at the industry level depicts the changing scenario of the pharmaceutical industry.

Keywords- Globalization, Innovation and Information, Pharmaceuticals.

I. OBJECTIVE

To analyse different opportunities and challenges faced by Pharma industry at Pithampur Industrial Estate.

1. Analysis of Challenges at Firm Level – To analyze various challenges of Pithampur Industrial Estate, 52 companies from Madhya Pradesh, Indore and Pithampur Industrial estate has been selected and likert type scale has been used with a five point interval scale. The results of size-wise analysis and various challenges as per survey conducted are described in detail. Following are the challenges discussed in detail:

1.1 Domestic and International Regulatory Controls

India has moved away from its traditional socialist system and accelerated efforts to liberalize economic reforms. As a result, India today is recognized as one of the most competitive nations in the world, providing a strong talent pool in the areas of science, technology and research, as well as some of the lowest labor costs in the world.

Table 1: Firm Size and Regulatory Controls

Firm Size	Does Domestic or International Regulatory Controls are Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	12 (75%)	4 (25%)	-	-	-	16 (100%)
Medium	18 (78.27%)	5 (21.73%)	-	-	-	23 (100%)
Small	6 (46.15%)	7 (53.85%)	-	-	-	13 (100%)
Total	36 (69.23%)	16 (30.77%)	-	-	-	52 (100%)

Most firms participating in the discussions agreed that the “Regulatory Controls” whether they are domestic or international, need to stop moving in India and that the inconsistency and unpredictability of regulations is a hindrance to making investments.

Figure 1: Firm Size and Regulatory Controls



As shown in above Table 1 and Figure 1, almost all Executives i.e. 100% of 52 firms said the lack of transparency diminishes private sector confidence and opens the door for increased levels of corruption. Many noted that the National

Manufacturing Policy cites regulatory reform as a key pillar in strengthening the manufacturing base, as it aims to centralize and rationalize business and environmental regulations among the various states and agencies.

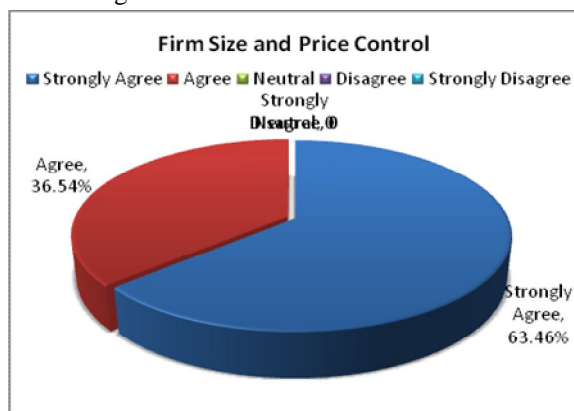
1.2 Price Control

As we already know Price controls are governmental restrictions on the prices that can be charged for goods and services in a market. The intent behind implementing such controls can restrict from the desire to maintain affordability of essential foods and goods, to prevent price gouging during shortages and to slow inflation or alternatively, to insure a minimum income for providers of certain goods or a minimum wage. There are two primary forms of price control, a price ceiling, the maximum price that can be charged and a price floor, the minimum price that can be charged.

Table 2: Firm Size and Price Control

Firm Size	Does Price Control is Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	9 (56.25%)	7 (43.75%)	-	-	-	16 (100%)
Medium	15 (65.22%)	8 (34.78%)	-	-	-	23 (100%)
Small	9 (69.23%)	4 (30.77%)	-	-	-	13 (100%)
Total	33 (63.46%)	19 (36.54%)	-	-	-	52 (100%)

Figure 2: Firm Size and Price Control



It is clear from Table 2 and Figure 2 that two-third of all the firms i.e. large, medium and small firms strongly agreed that irrational price control, inadequate regulatory

standards along with lack of resources to compete with MNCs are key issues impacting the growth of the Indian pharmaceutical industry.

1.3 Lack of Awareness in Case of Exports

Government has taken several measures, including setting up of an inter-departmental committee to look into export-related issues and awareness programmes in emerging markets like Africa, to boost pharmaceutical exports. Pharmaceutical sector has huge potential in terms of increasing exports; the Commerce Ministry is taking many measures to boost overseas shipments. Awareness programmes about Indian pharma industry have also been started in these markets and workshops are being organized with USFDA for Indian drug regulators and the industry.

Table 3: Firm Size and Lack of Awareness in Case of Exports

Firm Size	Does Lack of Awareness in Case of Exports like Regulator Filings / Procedures is Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	-	-	4 (25%)	12 (75%)	-	16 (100%)
Medium	-	-	8 (34.78%)	15 (65.22%)	-	23 (100%)
Small	-	-	2 (15.38%)	11 (84.62%)	-	13 (100%)
Total	-	-	14 (26.92%)	38 (73.08%)	-	52 (100%)

Figure 3: Firm Size and Lack of Awareness in Case of Exports



Table 3 and Figure 3 shows that majority of firms i.e. overall 73% are disagreeing with the fact that lack of

awareness in case of export knowledge affects the growth. Although 4 large firms, 8 medium firms and 2 small firms i.e. 27% of overall are neutral on same issue. Exports of pharmaceutical industry, as well as of the leading pharmaceutical companies have improved considerably.

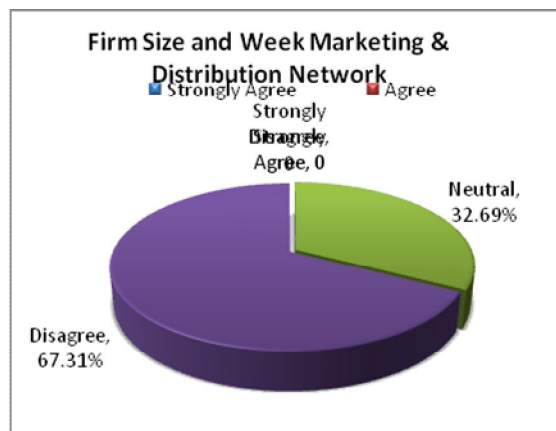
1.4 Weak Marketing and Distribution Network

This rapid growth in pharmaceutical industry has yet to create radical changes in the Indian distribution system. The main hurdles include the highly fragmented nature of the distribution network, limited advancement in regulatory reforms and presence of strong resistance from lobbies of traders involved in the supply chain of pharmaceutical products.

Table 4: Firm Size and Week Marketing & Distribution Network

Firm Size	Does Week Marketing and Distribution Network is Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	0	5 (31.25%)	11 (68.75%)	0	0	16 (100%)
Medium	0	9 (39.13%)	14 (60.87%)	0	0	23 (100%)
Small	0	3 (23.08%)	10 (76.92%)	0	0	13 (100%)
Total	0	17 (32.69%)	35 (67.31%)	0	0	52 (100%)

Figure 4: Firm Size and Weak Marketing & Distribution Network



Majority of firms are i.e. more than 67% of the firms are disagreeing with the fact that weak marketing and

distribution network affects the growth. About 5 large firms, 9 medium firms and 3 small firms i.e. 32% of overall firms are neutral on this issue. Here it is noted that, sometimes large companies acquire a fast growing small to mid-sized company to get into new markets and they often set it up as a subsidiary, so it can continue to make fast operational decisions without getting burdened by the corporate bureaucracy.

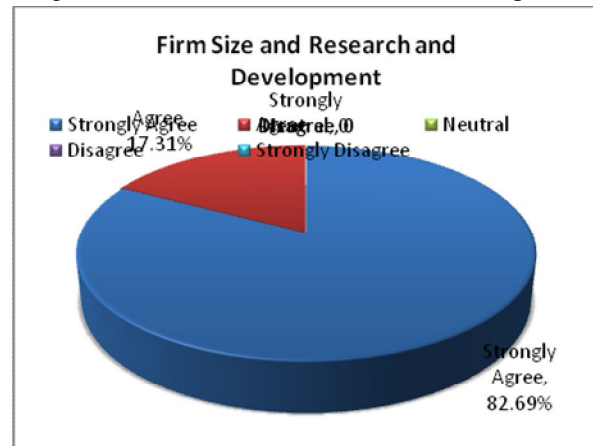
1.5 Investment in Research and Development

According to basic economic theory, a firms R&D investment decision is determined by the intersection of the marginal rate of return on investment schedule and the marginal rate of return on investment schedule and the marginal cost of capital schedule. These are obtain by arranging potential investment projects in order of decreasing rates of return and the opportunity costs of alternative investment in increasing order.

Table 5: Firm Size and Research and Development

Firm Size	Does Constraint in Investment in Research and Development is Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	13 (81.25%)	3 (18.75%)	0	0	0	16 (100%)
Medium	18 (78.26%)	5 (21.74%)	0	0	0	23 (100%)
Small	12 (92.31%)	1 (7.69%)	0	0	0	13 (100%)
Total	43 (82.69%)	9 (17.31%)	0	0	0	52 (100%)

Figure 5: Firm Size and Research and Development



As illustrated in above Table 5 and Figure 5, majority of firms i.e. more than 82% strongly agrees that lack of investment in research and development via a strong support sector emerges as one of the top constraints that slows down the growth and competitiveness of the pharmaceutical industry. Firms believes that price caps would inhibit the development of R&D in the country as companies would be less inclined to invest in R&D without the possibility of high returns.

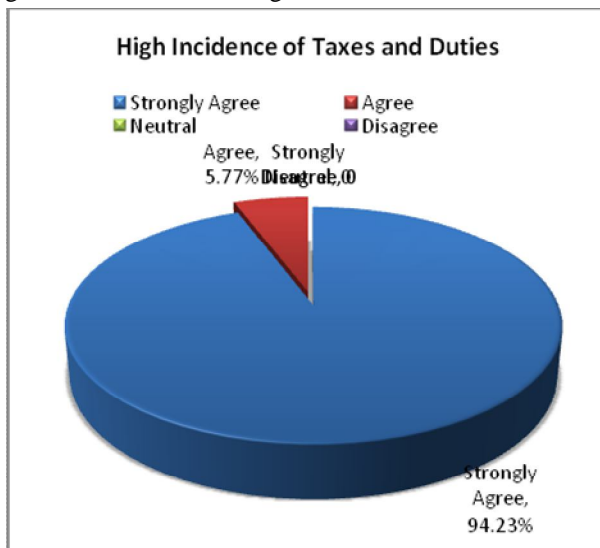
1.6 High Incidence of Taxes and Duties

Taxation plays an important role in economic growth and national development. Fiscal policy is one of the most powerful tools which governments have for achieving their overall social and economic objectives. Taxes and duties are necessary for governments and medicine taxes can be an important source of revenue.

Table 6: Firm Size and High Incidence of Taxes and Duties

Firm Size	Does High Incidence of Taxes and Duties is Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	14 (87.50%)	2 (12.50%)	-	-	-	16 (100%)
Medium	22 (95.65%)	1 (4.35%)	-	-	-	23 (100%)
Small	13 (100%)	-	-	-	-	13 (100%)
Total	49 (94.23%)	3 (5.77%)	-	-	-	52 (100%)

Figure 6: Firm Size and High Incidence of Taxes and Duties



The Table 6 and Figure 6 clearly highlights that all firms are strongly agreed that high incidence of taxes and duties are hindrance to growth.

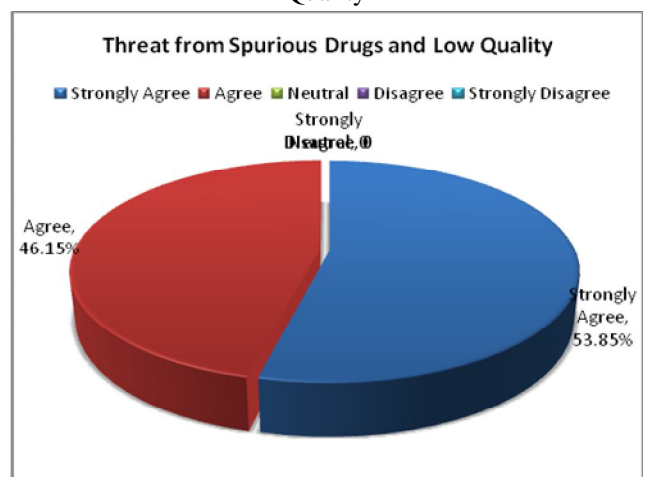
1.7 Threat from Spurious Drugs and Low Quality

According to the World Health Organization (WHO), the prevalence of spurious, falsely-labelled, falsified or counterfeit medicines or SFFC medicines are deliberately and fraudulently produced, packaged and/or mislabeled, is a growing trend worldwide which threatens both patient safety as well as public confidence in the health systems and regulatory bodies designed to provide oversight and control.

Table 7: Firm Size & Threat from Spurious Drugs & Low Quality

Firm Size	Does Threat from Spurious Drugs and Low Quality are Hindrance to Growth?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	8 (50.00%)	8 (50.00%)	-	-	-	16 (100%)
Medium	12 (52.17%)	11 (47.83%)	-	-	-	23 (100%)
Small	8 (61.54%)	5 (38.46%)	-	-	-	13 (100%)
Total	28 (53.85%)	24 (46.16%)	-	-	-	52 (100%)

Figure 7: Firm Size & Threat from Spurious Drugs & Low Quality



The result of size-wise analysis highlights in Table 7 and Figure 7 that the majority of firms are in favour i.e. 54%

are strongly agree and 46% are agree, when asked about threat from spurious drugs and low quality are hindrance to growth.

2. Analysis Of Opportunities At Firm Level - To analyze various opportunities of Pithampur Industrial Estate, 52 companies from Madhya Pradesh, Indore and Pithampur Industrial estate has been selected and liker type scale has been used with a five point interval scale. Here results of diverse opportunities listed below with size-wise analysis on different parameter as per survey conducted on sample firms are described in detail:

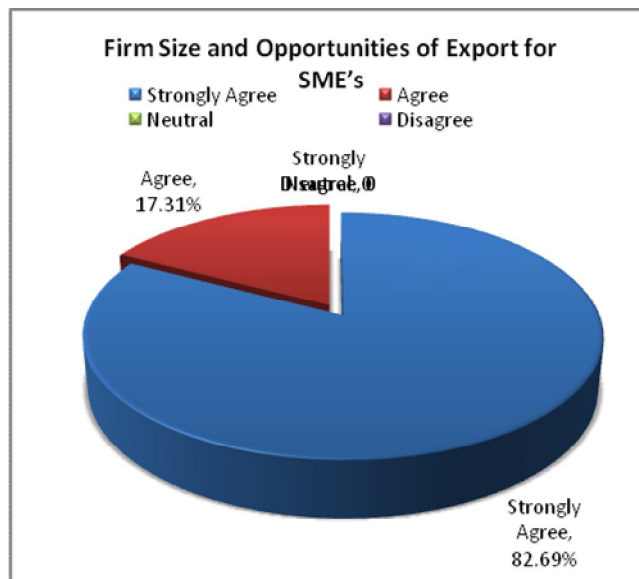
2.1 Exports

The pharmaceutical sector is one of India’s most important sectors in terms of projected revenue growth from exports and for meeting the needs of Indian population. There are a larger number of markets to which Indian pharmaceutical companies can now export as a result of global trade liberalization and capacity building by Indian companies over the last decade. India, considered as a knowledge intensive economy, is looked upon to make available drugs that are affordable to the developing countries. The recent contribution of Indian generics in fighting AIDS and its contribution to affordable healthcare in USA and elsewhere is widely acknowledged.

Table 8: Firm Size and Opportunities of Export for SME’s

Firm Size	Does Export is an Opportunities for SME’s?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	14 (87.50%)	2 (12.50%)	-	-	-	16 (100%)
Medium	17 (73.91%)	6 (26.09%)	-	-	-	23 (100%)
Small	12 (92.31%)	1 (7.69%)	-	-	-	13 (100%)
Total	43 (82.69%)	9 (17.31%)	-	-	-	52 (100%)

Figure 8: Firm Size and Opportunities of Export for SME’s



The size-wise analysis depicted in above Table 8 and Figure 8 highlights that mostly 87.50% large firms are strongly agreed that export is an opportunity for pharmaceutical companies whereas overall 82.69% firms are agreed on the same.

2.2 Marketing Alliance for Domestic or International Market

Indian companies are proving to be better at developing Active Pharmaceutical Ingredients (APIs) than their competitors from target markets and that too with non-infringing processes. Indian drugs are either entering in to strategic alliances with large generic companies in the world.

Table 9: Firm Size and Marketing Alliance for Domestic or International Market

Firm Size	Does Marketing Alliance for Domestic or International Market is an Opportunity for SME’s?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	11 (68.75%)	5 (31.25%)	-	-	-	16 (100%)
Medium	14 (60.87%)	9 (39.13%)	-	-	-	23 (100%)
Small	9 (69.23%)	4 (30.77%)	-	-	-	13 (100%)
Total	34 (65.38%)	18 (34.62%)	-	-	-	52 (100%)

Figure 9: Firm Size and Marketing Alliance for Domestic or International Market



The result of size-wise analysis highlights that 65.38% of including large, medium and small firms are strongly agreed that marketing alliance for domestic or international market generate opportunity for SME's while rest of 34.62% are agreed on the same.

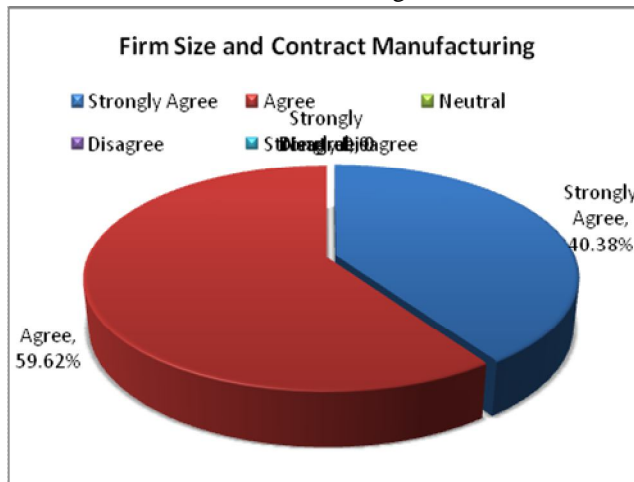
2.3 Contract Manufacturing

The pharmaceutical market uses outsourcing services from providers in the form of Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs). Currently their key area of strength in outsourcing is the manufacture of APIs. Some Indian pharma companies could probably benefit significantly by moving towards specialty APIs in the future.

Table 10: Firm Size and Contract Manufacturing

Firm Size	Does Contract Manufacturing is Opportunity for SME?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	6 (37.50%)	10 (62.50%)	-	-	-	16 (100%)
Medium	9 (39.13%)	14 (60.87%)	-	-	-	23 (100%)
Small	6 (46.15%)	7 (53.85%)	-	-	-	13 (100%)
Total	21 (40.38%)	31 (59.62%)	-	-	-	52 (100%)

Figure 10: Firm Size and Contract Manufacturing



As shown in Table 10 and Figure 10, all 52 firms responds positive for the contract manufacturing for SME's. 40.38% are strongly agreed whereas 59.62% are agreed.

2.4 Licensing Deals / Agreement

Licensing is a relatively new phenomenon in the Indian Pharmaceutical domain but has now taken immense importance in the business strategy for any Pharma firm that wants to make it big in the national and global level. The importance of licensing activity in the pharmaceutical industry has increased significantly over recent years. Many of the industry's biggest products were discovered and developed by one company and brought to market by another.

Table 11: Firm Size and Licensing Deals and Agreements

Firm Size	Whether Licensing Deals & Agreements are Opportunities for SME's?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	-	-	2 (12%)	14 (87.50%)	-	16 (100%)
Medium	-	-	6 (26.09%)	17 (73.91%)	-	23 (100%)
Small	-	-	2 (15.38%)	11 (84.62%)	-	13 (100%)
Total	-	-	10 (19.23%)	42 (80.77%)	-	52 (100%)

Figure 11: Firm Size and Licensing Deals and Agreements



Above Table 11 and Figure 11 shows that majority of firms 80.77% are disagreed with the licensing deals and agreements. Only 19.23% respondents are neutral on same.

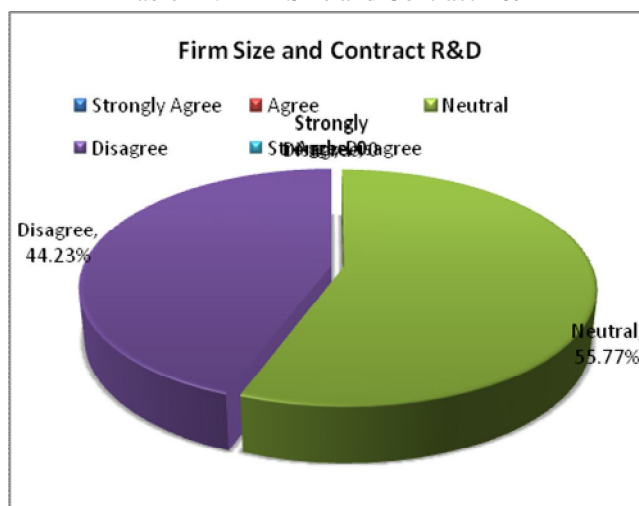
2.5 Contract R&D

Research & Development (R&D) is crucial for the growth of pharmaceutical industry. The success of a pharmaceutical industry depends more on successful Research & Development (R&D) activities. Thus, it is important for Indian pharmaceutical industry to scale up their Research & Development (R&D) intensity to strengthen their position in the global market place.

Table 12: Firm Size and Contract R&D

Firm Size	Does Contract R&D is Opportunities for SME's?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	-	-	7 (43.75%)	9 (56.25%)	-	16 (100%)
Medium	-	-	14 (60.87%)	9 (39.13%)	-	23 (100%)
Small	-	-	8 (61.54%)	5 (38.46%)	-	13 (100%)
Total	-	-	29 (55.77%)	23 (44.23%)	-	52 (100%)

Table 12: Firm Size and Contract R&D



The above result in Table 12 and Figure 12 shows that almost 55.77% of all respondents are neutral on this question and about 44.23% of respondents are disagreed with the fact that contract research and development produce any kind opportunity for SME's.

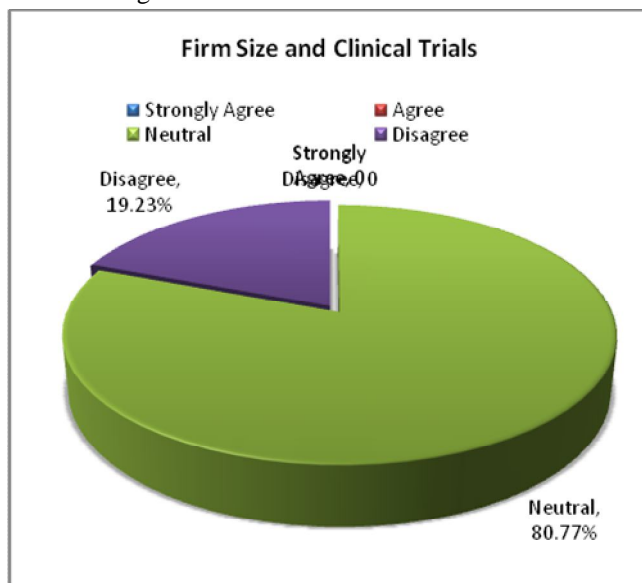
2.6 Clinical Trials

Clinical trials are used to evaluate potential treatments that have had some effect against disease in the lab. Clinical trials to establish safety and efficacy of drugs constitute nearly 70% of R&D costs. Considering the low cost of research and development in India, several MNC Pharma companies as well as global Clinical Research Organizations are increasingly making India a clinical research hub.

Table 13: Firm Size and Clinical Trials

Firm Size	Does Clinical Trials is an Opportunity for SME's?					Total
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
Large	-	-	12 (75%)	4 (25%)	-	16 (100%)
Medium	-	-	18 (78.26%)	5 (21.74%)	-	23 (100%)
Small	-	-	12 (92.31%)	1 (7.69%)	-	13 (100%)
Total	-	-	42 (80.77%)	10 (19.23%)	-	52 (100%)

Figure 13: Firm Size and Clinical Trials



The 52 firms have been asked to give their opinion about whether they see Clinical Trials as opportunity for SME's. As illustrated in Table 13 and Figure 13: 80.77% of the respondents firms are neutral on this issue and 19.23% are claimed that they are disagree with this as India's research and developing In conclusion firm size and clinical trials in India has made a promising start wherein at least five to six potential candidates in the areas of major diseases and Infections are likely to reach next clinical trials.

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