



Challenges in Implementation of Green Chemistry in Indian Pharmaceutical Sector

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Authors' contributions

This work was carried out in collaboration between both authors. All authors read and approved the final manuscript.

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ABSTRACT

The alarming environmental pollution caused by pharmaceutical Industries has led to the growing importance of Green Chemistry in India. It is high time that the pharmaceutical industry that is considered as a red category by the environment ministry, adopts green chemistry & green technology to address this issue. This study aims to find out the major barriers to implementing green technology in the pharmaceutical sector. Integrated Structural Modelling method & MICMAC Analysis has been adopted to identify a structure by which the pharmaceutical industries can implement green technology. An extensive literature review & discussions with industry experts led to identifying ten major challenges to the adoption of green technology in the pharmaceuticals. Economic & financial barriers & regulatory barriers have been identified as the major barriers. This study brought out a lack of consolidation of knowledge in this field as a challenge to the implementation of green practices, which has been largely ignored in previous studies and needs to be addressed.

Keywords: *Green Pharma; ISM; Green Chemistry; pharmaceutical Industry; Sustainability, pharmaceutical; green Chemistry Barriers; MICMAC analysis; Interpretive structural modeling; Green Technology*

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1. INTRODUCTION

The global pharmaceutical industry is expanding at an accelerating rate, with the United States as the leader, followed by Russia, Brazil, China, and India [1]. The pharmaceutical sector is one of the fastest-growing sectors of the Indian Economy, with the potential to grow to USD 100 billion by 2025 [2]. India has captured the global market with its innovation in generic drugs and active pharmaceutical ingredients engineering. The development of the pharmaceutical industry in India and across the globe has led to many environmental degradation instances. The report of the presence of pharmaceuticals in the environment was first filed in the 1970s, but it was only in the 1990s that it became a matter of concern when its traces were found in drinking water [3].

The Indian pharmaceutical sector is categorized as a "Red Category" by the environment ministry about the pollution caused by it over several years. India, a global manufacturing hub, generates highly acidic & alkaline waste due to large-scale chemical processing, including nitration, chlorosulphonation, sulphonation, etc. Groundwater near pharmaceutical units contains toxins like lead, cadmium, arsenic, etc. thousand times more than what is permissible in drinking water by WHO & Bureau of Indian Standards [4].

Green Chemistry in India commenced some 20 years back with a few conferences and began to gain recognition in the 2000s through industry initiatives like Industrial Green Chemistry World. In the past few years, Green Chemistry has gained importance in India for the government, industries, consumers, and media. India is moving towards the implementation of Green Chemistry. Companies are training their employees on the Green Chemistry tools & principles & are willing to invest time & resources in Green Chemistry Innovation. Most of the companies also have a dedicated team for Green Chemistry [5]

Despite much advancement & awareness about Green Chemistry & sustainability, the pharmaceutical industry is reluctant to adopt it. Study in this domain has been inclined towards the economic aspect, ignoring other aspects that can affect its adoption in the pharmaceutical industry [6].

This study addresses this gap by looking at the existing challenges and constructing a model to

help pharmaceutical companies understand the hierarchical nature of the issue and the interrelationships of the challenges identified to adopt green chemistry [6] in India. Finally, these challenges have been classified using MICMAC analysis based on driving and depending on power [7]. The paper starts with a detailed literature review highlighting the ten major challenges identified. Further, an interrelation is found out between the disablers after discussion with industry experts. The paper concludes with a summary & implications for the pharmaceutical organizations.

2. LITERATURE REVIEW

2.1 Economic and Financial Barrier

According to [8], a green chemistry product should be both economic & environmentally friendly. A product should focus on improving the environment & health making profits as well. According to [9], business focuses primarily on economic stability rather than social and economic stability as a measurement for success. A small decrease in the cost of waste, implementation of less harmful processes, and marginal efficiency improvements are not enough to outweigh the cost of large investments when the amount of savings is uncertain or difficult to quantify.

According to [10], the GC process can be brought in only if it can pay back the investment within few years to attract the investors. Highlight basic economic and financial barriers: the high cost of capital, uncertainty to future benefits, and unwillingness to abandon sunken capital [11]. It is not feasible for firms to abandon their old capital-intensive technology and invest in new green technology [12]. Difference between traditional unsustainable methods and modern green methods is made to shed light on the economic and environmental benefits of greener methods [13]. It is found that the government scientists were using patented techniques extensively without knowing effects of green methodologies in some cases or don't know whether not caring about it.

2.2 Regulatory Barrier

Regulatory risk has been reported as one of the two top challenges for the adoption & implementation of Green Chemistry in pharmaceuticals for both Generic & API

industries. Increased environmental rules and regulations over time have an important impact on pharmaceutical industries. In 2005 in the United States of America, Chemical Industries spent more on pollution reduction than any other sector [14].

Suppose any industry needs to change a process or method. In that case, it has to go through many time-consuming and costly legal procedures that are mandatory and may vary from a few months to a few years worldwide, posing a great barrier [15]. Going through legal processes, documentation, and filling and approval from internal affairs teams and external agencies like the FDA also acts as a major barrier [16].

Financial regulations like write off old infrastructure, accounting details, etc., also add to the barriers. Further, no quick approval process for green drugs makes the process more cumbersome [11]. The lack of funding for R and D are major reasons for regulatory barriers.

2.3 Leadership and Management

Top management plays a major role in taking all major decisions. Limited support from top management makes green chemistry adoption a less priority. The absence of common organizational goals and power struggles within an organization also acts as a major challenge [12]. Further lack of clear vision & mission of top management for green chemistry application makes it difficult for it to be adopted by the entire organization. Management is responsible for training the employees & making them ready with knowledge and skills to implement green chemistry technology.

2.4 Lack of Expertise

Green Chemistry has some disciplines that act as a barrier. The chemists and engineers have limited knowledge about the adoption of green engineering [8]. Lack of expertise is a major barrier to the adoption of GC in the case of API industries. There are different branches in Green Chemistry [14]. Expert in one branch does not know another very essential branch. Nanotechnology also faces the problem of lack of expertise. The chemists' greatest challenge is to eliminate the environmentally harmful chemical products from the drugs [10]. Lack of expertise also includes lack of technical knowledge of chemists who deal with the end customer [17].

2.5 Lack of Standardization Regarding Definition and Metrics

GC is governed by "The Twelve Principles of Green Chemistry." People often consider green chemistry the same as sustainable development or chemical sustainability. There is ambiguity in deciding whether a process or a product can be categorized under Green Chemistry or not. There is no recognized certificate or standard set to mark a product under green chemistry. According to [8], lack of metrics and loose definition makes it hard to declare a product green. This ambiguity in the definition & metrics to decide what green chemistry is and what it is not is a major barrier [18].

2.6 Lack of Awareness and Knowledge among Stakeholders

According to [10], even though GC has made quite a progress in recent years, still the concept is misunderstood by most consumers & chemists. The industry witnesses a lack of training about tools & techniques to chemists & managers [6]. Further, the marketing & the operations department is more aloof about the entire concept. Green Chemistry is many times related to green washing practices by various companies. The general public is unaware of the concept & considers green products either expensive or ineffective. Green Chemistry should be included in the curriculum & working knowledge should be imparted to chemists and chemical engineers [16].

2.7 Organizational Barrier

An organization's structure also acts as a major barrier to green chemistry implementation [5]. Even if the implementation is beneficial for the organization, a particular division may be unwilling to adapt if it affects its profits. According to [17], industries face a lack of adaptability & flexibility while adopting green chemistry. Many times, a product made through green chemistry hinders the sales of another product of the same industry. This lack of flexibility & interdepartmental chaos while implementing a green process acts as a major organizational barrier.

According to [10], the pharmaceutical industry has shifted from internal manufacturing to external manufacturing, where the degree of unsustainable manufacturing is higher.

2.8 Time Pressure

The pressure to deliver drugs fast is a major barrier to adopting the pharmaceutical industry to green chemistry. Time pressure is an important barrier to the implementation of GC in generic industries [14]. Usually, researchers need approximately two years to develop a synthesis, but the average is just half a year for the entire industry. Further redesigning an existing product according to green chemistry is burdensome and costly. Even if the drug is ready, regulatory approval time differs from few months to few years, varying in different countries. It further creates financial and operational problems for the pharmaceutical industry [15].

2.9 Technological Barrier

We do not have adequate green technologies for many processes like sulphonation and nitration. In the absence of these technologies, the pharmaceutical industries have to stick to using conventional processes that involve high usage of acids, alkalis, and other chemicals is a major barrier [16].

According to [10], one of the major barriers is that green chemistry technologies are not easily procurable, and old technologies are easier to implement than green technologies. The cost of operating green technology & of the solvents also acts as a disabler [19]. The difficulties in sharing information across industries and lack of available substitutes for solvents and chemical reactions also hinder barriers.

2.10 Lack of Consolidation of Knowledge

According to [16], many Green Chemistry solutions are proven by scientists, researchers, and startups. Still, the industry does not know of it because of the researchers' lack of marketing or lack of initiatives taken by the industry. According to [11], there is no formal database or repository for green chemistry developments for major reasons like trade secrets. This lack of consolidation of knowledge or a consolidated database also acts as a barrier.

3. METHODS AND MATERIALS

Interpretive Structural Modeling (ISM) follows a procedure starting with identifying the most relevant variables through literature review followed by a brainstorming session conducted

with a group of experts where a relationship is derived between various variables. This method helps the manager assess the priorities & and understand the relationship between various variables.

3.1 ISM Model Development

Ten disablers to Green Chemistry have been identified from the literature review &, after discussions with industry experts [13]; have been used to develop the ISM model. The relationship between these disablers has been identified & shown in various matrices explained further. The model development process has been categorized under these heads for ease of understanding:

- Structural Self-Interaction Matrix
- Reach ability Matrix
- Partitioning the Reach ability Matrix
- Developing Conical Matrix
- Developing Digraph.

3.2 Structural Self-Interaction Matrix

A structural self-interaction matrix has been formulated after determining ten major challengers for determining the relation between them. Industry specialists were brainstormed & to identify, as shows in Table 1.

This rating system is used to identify the relation between 10 disablers that is showcased in Table 1.

3.3 Reachability Matrix

Initial Reachability Matrix has been formed with the help of SSIM. IRM symbolizes binary relations between various challengers. Here the symbols V, A, X, O are interchanged by binary numbers 0 & 1. The given parameters are observed for the formation of the Initial Reachability Matrix, which is shown in Table 2:

- If the (i, j) is V, then the (i, j) in the IRM is changed to 1, and the (j, i) is changed to 0
- If the (i, j) is A, then the (i, j) in the IRM is changed to 0, and the (j, i) is changed to 1
- If the (i, j) is X, then the (i, j) in the IRM is changed to 1, and the (j, i) is also changed to 1
- If the (i, j) is O, then the (i, j) in the IRM is changed to 0, and the (j, i) is also changed to 0

Table 1. SSIM

Challenges	10	9	8	7	6	5	4	3	2	1
Economic & Financial Barrier	V	V	V	V	V	V	V	X	X	
Regulatory Barrier	V	V	A	X	V	V	V	A		
Leadership & Management	V	V	X	X	V	A	X			
Lack of Expertise	V	X	X	V	V	V				
Lack of Standardization Regarding Definition & Metrics	V	O	X	A	A					
Lack of Awareness & Knowledge Among Stakeholders	X	A	A	V						
Organizational Barrier	V	V	X							
Time Pressure	V	V								
Technological Barriers	V									
Lack of Consolidation of Knowledge										

If one variable is affected by another or if there is no relation etc. based on the rating system mentioned below:

- V- Variable I is affected by Variable J
- A- Variable J is affected by variable I
- X- Variable I & J affects each other
- O- Variable I & J have no relation

Table 2. IRM

Challenges	1	2	3	4	5	6	7	8	9	10	Driving Power
1	1	1	1	1	1	1	1	1	1	1	10
2	1	1	0	1	1	1	1	0	1	1	8
3	1	1	1	1	0	1	1	1	1	1	9
4	0	0	1	1	1	1	1	1	1	1	8
5	0	0	1	0	1	0	0	1	0	1	4
6	0	0	0	0	1	1	1	0	0	1	4
7	0	1	1	0	1	0	1	1	1	1	7
8	0	1	1	1	1	1	1	1	1	1	9
9	0	0	0	1	0	1	0	0	1	1	4
10	0	0	0	0	0	1	0	0	0	1	2
Dependence Power	3	5	6	6	7	8	7	6	7	10	

Table 3. Final reach ability matrix

Challenges	1	2	3	4	5	6	7	8	9	10	SUM	RANK
1	1	1	1	1	1	1	1	1	1	1	10	1
2	1	1	1*	1	1	1	1	1*	1	1	10	1
3	1	1	1	1	1*	1	1	1	1	1	10	1
4	1*	1*	1	1	1	1	1	1	1	1	10	1
5	1*	1*	1	1*	1	1*	1*	1	1*	1	10	1
6	0	1*	1*	0	1	1	1	1*	1*	1	8	3
7	1*	1	1	1*	1	1*	1	1	1	1	10	1
8	1*	1	1	1	1	1	1	1	1	1	10	1
9	0	0	1*	1	1*	1	1*	1*	1	1	8	3
10	0	0	0	0	1*	1	1*	0	0	1	4	4
SUM	7	8	9	8	10	10	10	9	9	10		
RANK	4	3	2	3	1	1	1	2	2	1		

Now, after the Initial Reach ability Matrix, the Final Reach ability Matrix is formed by integrating transitivity. Transitivity indicates that disabler X is affected by disabler Y & disabler Y affected by disabler Z; then disabler X will also be affected by disabler Z. This transitivity is incorporated in Final Reach ability Matrix & is represented by one* in the matrix. The matrix is given in Table 3

3.4 Partition of Final Reach ability Matrix

Final Reach ability Matrix is partitioned to identify the level of the hierarchy of all the disablers. This

hierarchy is necessarily used in the formation of a conical matrix. Reach ability & Antecedent sets have been obtained from the Final Reach ability Matrix & Intersection Sets are identified from the

two [20]. The Reach ability set includes the variables affected by it & the Antecedent set includes the variables that affect that particular variable or have control over it. Intersection sets are variables that are common in both the Reach ability & Antecedent set. The elements for which antecedent & reachable variables are common are topmost level variables in the ISM model pyramid. After they are determined, they are detached from other elements where the procedure is repeated till the level of every variable is found, as shown in Table 4. This is used for the formation of the conical matrix & the diagram.

3.5 Conical Matrix

After the partition on the Final Reach ability Matrix, the disablers are arranged according to their level vertically & horizontally in the Conical Matrix. Level 1 includes variables 5, 6,7,10 & level 2 includes variables 3,4,8,9, and all are arranged accordingly in the conical matrix as shown in Table 5.

3.6 Developing Digraph

Referring to the Conical Matrix & the transitivity links, an initial digraph is formed. According to their hierarchy in the conical matrix, all variables in level 1 are placed above, followed by level 2. Indirect links have not been considered for ease of simplicity. This model shows the relationship between the disablers using links that denote "Leads to" [20].

The disablers or challengers to Green Chemistry have been classified into three levels. The third level is the most significant amongst all. Economic & financial barriers & regulatory barriers are the most significant challenges that the industry needs to address. These two barriers further lead to 4 other barriers that are leadership & management, lack of expertise, time pressure & technological barriers. A smart energy tracker is used for energy transfer [2].

Table 4. Partition of final reach ability matrix

Disabler Code	Antecedent Set	Reach ability Set	Intersection Set	Level
1	1,2,3,4,5,7,8	1,2,3,4,5,6,7,8,9,10	1,2,3,4,7,8,5	3
2	1,2,3,4,5,6,7,8	1,2,3,4,5,6,7,8,9,10	1,2,3,4,5,6,7,8	3
3	1,2,3,4,5,6,7,8,9	1,2,3,4,5,6,7,8,9,10	1,2,3,4,5,6,7,8,9	2
4	1,2,3,4,5,7,8,9	1,2,3,4,5,6,7,8,9,10	1,2,3,4,5,7,8,9	2
5	1,2,3,4,5,6,7,8,9,10	1, 2,3,4,5,6,7,8,9,10	1, 2,3,4,5,6,7,8,9,10	1
6	1,2,3,4,5,6,7,8,9,10	2,3,5,6,7,8,9,10	2,3,5,6,7,8,9,10	1
7	1,2,3,4,5,6,7,8,9,10	1,2,3,4,5,6,7,8,9,10	1,2,3,4,5,6,7,8,9,10	1
8	1,2,3,4,5,6,7,8,9	1,2,3,4,5,6,7,8,9,10	1,2,3,4,5,6,7,8,9	2
9	1,2,3,4,5,6,7,8,9	3,4,5,6,7,8,9,10	3,4,5,6,7,8,9	2
10	1,2,3,4,5,6,7,8,9,10	5,6,7,10	5,6,7,10	1

Table 5. Conical matrix

Disabler	D5	D6	D7	D10	D3	D4	D8	D9	D1	D2
D5 Lack of standardization regarding definition & metrics	1	1	1	1	1	1	1	1	1	1
D6 Lack of awareness & knowledge among stakeholders	1	1	1	1	1	0	1	1	0	1
D7 Organizational Barrier	1	1	1	1	1	1	1	1	1	1
D10 Lack of consolidation of knowledge	1	1	1	1	0	0	0	0	0	0
D3 leadership & management	1	1	1	1	1	1	1	1	1	1
D4 Lack of expertise	1	1	1	1	1	1	1	1	1	1
D8 Time Pressure	1	1	1	1	1	1	1	1	1	1
D9 Technological Barriers	1	1	1	1	1	1	1	1	0	0
D1 Economic & Financial Barrier	1	1	1	1	1	1	1	1	1	1
D2 Regulatory Barrier	1	1	1	1	1	1	1	1	1	1

Lack of consolidation of knowledge is still missed by most of the firms. The management, the industry & the regulatory authorities should work on having a common knowledge repository. Fig. 1 refers to the block diagram of the ISM model.

4. RESULTS & DISCUSSION

4.1 MICMAC ANALYSIS

The MICMAC analysis confirms the relevance of certain variables to identify which variables are affected by them and classifies the variables in four segments based on the relationship between driving power & dependence of the variable. The four segments are:

- Autonomous elements have less dependence and less driving power & do not have much impact on other variables.

- Dependent variable - These elements have high dependence and low driving capacity.
- The third segment has elements that have a high driving capacity & low dependence. They are not affected by most of the variables but affect most of them. They need to be addressed first by the management.
- The fourth segment comprises elements that have both high dependence & high driving power.

As shown in Table 6, the Economic & Financial Barrier has a high driving power [21]. In contrast, regulatory barriers, organizational barriers, lack of expertise & time pressure possess both the driving and the dependence power. Lack of knowledge consolidation, lack of awareness among stakeholders & technological barriers has the most dependence power [22]

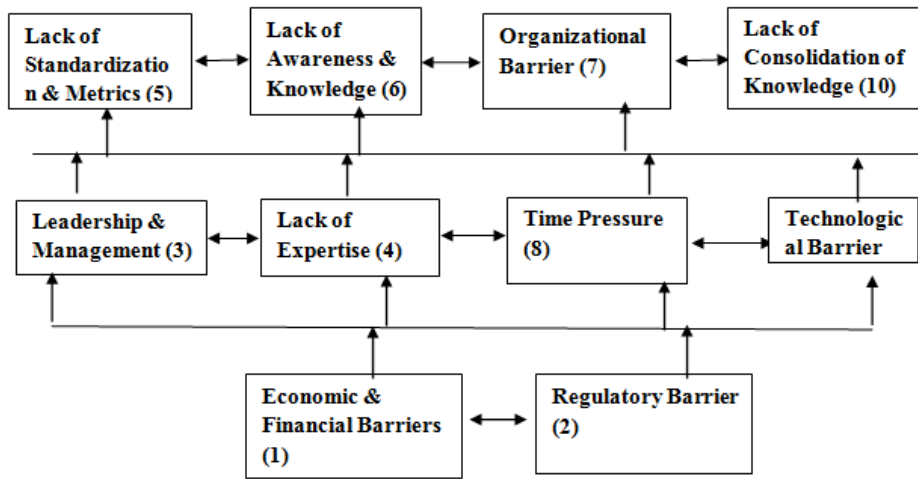


Fig. 1. ISM diagram

Table 6. MICMAC analysis

		Independent factors				Linkage factors							
Driving power	10			1									
	9							3,8					
	8					2		4					
	7								7				
	6												
	5												
	4								5,9	6			
	3												
	2												10
	1												
		1	2	3	4	5	6	7	8	9	10		
		Autonomous factors				Dependent factors							
		Dependence power											

5. CONCLUSION

The ISM diagram indicates that regulatory barriers & Economic & Financial Barriers are the most important factors that act as a challenge for implementing Green Chemistry in Indian Pharmaceutical Industry & leading to other barriers [23]. While transforming from conventional processes to green processes & coming out with a new green chemistry product, the company has to undergo multiple legal processes that lead to a financial burden on the company and time pressure.

Adopting green technology involves a high capital investment that small industries cannot make & large industries are reluctant to lock their funds when they are not sure of the return. These two major factors restrict top management from making the desired decisions. Economic & regulatory barriers lead to uncertainty where the industry is reluctant to take major decisions that lead to all the eight barriers, as shown in the diagram above. The first and the foremost step need to be taken by the government & regulatory authorities to ease legal formalities and give industries an incentive to embrace green chemistry. Economic & regulatory barriers are high driving variables & lack of definition & metrics, lack of awareness, technological barriers & consolidation of knowledge are dependent variables. The government, researchers, & industry experts should find solutions for the high driving variables that will ultimately solve dependent variables' problems.

CONSENT

It is not applicable.

ETHICAL APPROVAL

Not Applicable

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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