

RAW MATERIALS SHORTAGE AND THEIR IMPACT ON THE MANUFACTURING BUSINESS – AN EMPIRICAL STUDY IN THE PHARMACEUTICAL SECTOR OF BANGLADESH

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Abstract: *Pharmaceutical companies of Bangladesh suffer from many supply chain disturbances such as raw material shortages, short product life cycle, quality of the product, and seasonal demand which are noteworthy to be mentioned. Among these disturbances raw materials shortage cause significant problems to the organizations in terms of production loss, property loss, monetary loss and above all business loss. Therefore, the target for the pharmaceutical companies should be to minimize the occurrence of raw materials shortage. This requires having prior knowledge about the causes and consequences of raw materials shortage. This research has been performed as an exploratory study including 25 pharmaceutical companies. This paper delineates the scenario of causes for raw materials shortage that exists in the pharmaceutical sector and discusses their consequences. Data were collected by direct observation, interview and mail survey system through a structured questionnaire. The study has identified eight immediate causes behind raw materials shortage. Three causes are accountable for transportation related problems. Out of 19 causes some root causes are figured out that dominates the other causes. In this research, 11 consequences were identified; among them some consequences happen repeatedly for raw materials shortage. Some notable consequences are: degradation of reputation and increased lead time. Some recommendations are provided to minimize or solve these immediate causes and root causes of raw materials shortage.*

Keywords: Raw Material Shortage; Pharmaceutical; Cause-effect; Root cause.

JEL Classification: L69

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1. Introduction

Pharmaceutical is one of the highest priority sectors in Bangladesh (UK Trade & Investment, 2011). With an annual two-digit growth rate, the pharmaceutical industry is now heading towards self-sufficiency in meeting the local demand in Bangladesh. Pharmaceutical industry of Bangladesh has emerged as one of the most hi-tech industry with an investment of over US\$250 million. It is the one that contributes significantly to the national economy. There are more than 240 small, medium, large and multinational pharmaceutical companies operating in the country producing around 97% of the total demand (UK Trade & Investment, 2011). Because of its significant importance to the national economy, the pharmaceutical sector needs to cope with the dynamic market demands. This requires to deliver quality products at low price to the market. To take the competitive advantage over the competitors, the manufacturing system of an organization should be flexible, reliable as well as of world-standard.

Generally, two steps are involved in pharmaceutical manufacturing. The first is Active Pharmaceutical Ingredients (API) manufacturing. As Bangladesh API capacity is insignificant, pharmaceutical companies import approximately 80% of their APIs. Fifteen to seventeen Bangladeshi firms are involved in the manufacture of about twenty APIs; however, they usually run the final chemical synthesis stage with API intermediaries, instead of the complete chemical synthesis. The other 1,000 required APIs are imported. Approximately 75-80% of the imported APIs are generic. The second step, final formulations, belongs to the manufacturing sector. In final formulations, firms mix APIs and excipients (other non-active ingredients), press them into pills, tablets, or solutions, and then package them for the consumer market (World Bank, 2007).

In reality, manufacturing is a complex system that includes several functional areas which are mutually dependent to each other from procurement of raw materials to the finished products and the failure in one function has an impact on the other. It is found that the manufacturing enterprises encounter some internal and external disturbances, which have potential to put them at risks in the context of production, safety and business operations (Islam et al., 2012). The production system may fluctuate from the actual performance because of presence of some disturbance agent.

They interact with the system component and disturb them to do their normal work. Raw material shortage is one of them. The consequences of such disturbances may be realized through high lead time, high production cost, low reliability of product, wastage of time, materials etc. (Islam et al., 2012).

In that context, the research has been conducted to build a scenario of raw material shortage that occur in particular pharmaceutical companies in Bangladesh and also to identify production interruption caused by raw materials shortage. By conducting the research, we focus on the following: to identify the root causes behind the raw materials shortage and also to figure out the consequences of raw materials shortage.

2. Literature review

Manufacturing in its broadest sense, is the process of converting raw materials into products. It encompasses,

- The design of the product
- The selection of raw materials
- The sequence of processes through which the product will be manufactured (Kalpakjian S. & Schmid R. S.).

A country's level of manufacturing activity is directly related to its economic health. Manufacturing also involves activity in which the manufactured product is itself used to make other products.

Lead time is very important for pharmaceutical companies because it needs to supply the products to the market as quickly as possible to take competitive advantage. Not only is it important to supply product in due time but also customers' health and safety related to this. Therefore, it is necessary to achieve shorter lead time through the reduction of the occurrence of causes and the consequences of raw material shortages.

According to Barnes-Jewish hospital, 2016 report, raw materials shortage has an impact on drug shortage and the percentage is three (3%). The causes for raw materials shortage are-sole source (required time to develop or purchase raw materials, often not disclosed to the public, noted as the "greatest vulnerability to our supply"), over 70% of raw materials obtained overseas, few manufacturers for parenteral injections, one production line for multiple items, batch failures (Barnes-Jewish hospital, 2016).

Another report on "National drug policy" identifies some reasons include budgetary constrains, improper distribution and shortage of raw materials, mismanagement and other related factors (National drug policy, 2016). N. Ahmed identifies some reasons of raw materials shortage including labour mishandling, potency losses, lead time problem, Government problems etc. (Ahmed, 2009).

The pharmaceutical industry in Bangladesh is one of the most developed hi-tech sectors within the country's economy. The country is producing more than USD 973 million worth of drugs and pharmaceuticals in about 12,500 plus brands. Domestic manufacturers dominate the Bangladesh pharmaceutical industry with local companies enjoying a market share of around 80%, while the multi-national companies are having a market share of 20%. Out of top ten pharmaceutical companies in Bangladesh, seven are local pharmaceutical companies. The top two domestic manufacturers, namely Square & Beximco are having a market share of about 25%, while the other manufacturers contribute about 60% to the total pharmaceutical market of Bangladesh (Shamsuddin AKM, 2004).

The manufacturing process of pharmaceutical is shown in figure 1 (Wang, X., 2010). There are generally two steps to pharmaceutical manufacturing. The first is Active Pharmaceutical Ingredients (API) manufacturing. API production is a highly sophisticated task based on technically demanding chemical and biochemical fermentation and synthesis processes. There are two basic types of APIs: specialty APIs (tend to be hard to manufacture) and commodity APIs (tend to have many suppliers and price competition becomes more important). A significant portion of the manufacturing cost of a drug lies in APIs. For example, 40-50% of the cost of goods sold for generic oral solids, on average, comes from APIs. As commodity, API manufacturing tends to be a high volume, low margin business based extensively on scale economies and large dedicated manufacturing lines, smaller manufacturers have limited opportunities to globally compete. Excluding specialty items, the average API margin is less than 10%. In fact, many large bulk API exporters from India consider three percentage (3%) margins on export to be good enough. Firms can either manufacture their own APIs or purchase them on the open market (World Bank, 2008).

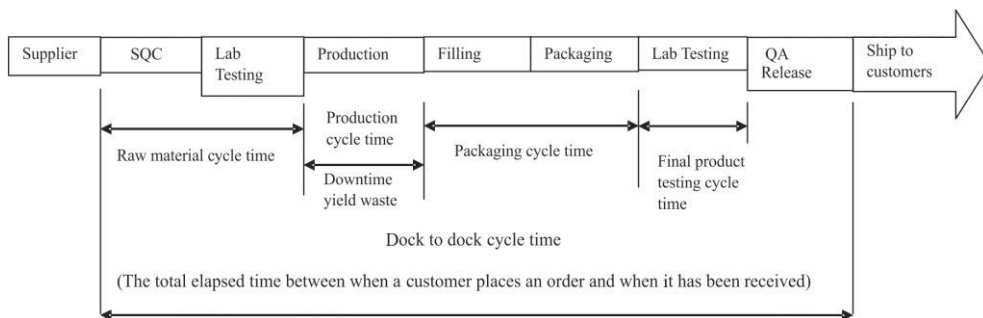


Figure no.1. Pharmaceutical Manufacturing process.

Source: Wang, X., 2010

Unlike the chemical business of API production, the second step, final formulations, belongs to the manufacturing sector. In final formulations, firms mix APIs and excipients (other non-active ingredients), press them into pills, tablets, or solutions, and then package them for the consumer market. As firms can produce fifty or more products in a single plant with flexible equipment, scale economies matter less for formulations. Margins for final formulations average from 20% to 30%.

A raw material or feedstock is the basic material from which a product is manufactured or made, frequently used with an extended meaning. Raw materials of pharmaceutical company can be classified in three categories such as, Active ingredient, Excipient and Packing material. An Active Ingredient (AI) is the substance in a pharmaceutical drug or a pesticide that is biologically active (Wikipedia, Active ingredients, 2016).

An Excipient is generally a pharmacologically inactive substance used as a carrier for the active ingredients of a medication. Excipients are also sometimes used to bulk up formulations that contain very potent active ingredients, to allow for convenient and accurate dosage. In addition to their use in the single-dosage quantity, excipients can be used in the manufacturing process to aid in the handling of the active substance concerned (Wikipedia, Excipient, 2016).

Pharmaceutical packaging has to be carried out for the purpose of the safety of the pharmaceutical preparations in order to keep them free from contamination, hinder microbial growth, and ensure product safety through the intended shelf life for the pharmaceuticals. As packaging is a critical

tool in the pharmaceutical industry for product delivery and regulatory compliance, many pharmaceutical companies perform all their packaging within a contamination free environment or clean room. Some common pharmaceutical packaging techniques include foil and heat sealing; polyester and olefin package printing; polyethylene and flatbed die cutting (Wikipedia, Pharmaceutical Packing Material, 2016).

Drug shortages are a challenge for health-care community, particularly since they typically appear with little or no warning and significant resources may be needed to manage patients when a particular therapy is in short supply. The shortage makes the job of pharmacy procurement more difficult, and occasionally adversely impacting patient care. There are multiple reasons possible for drug shortages, raw materials shortages is one of them (Tyler, L. S., 2016).

Raw materials shortages or availability problems can degrade a manufacturer's ability to produce enough of a product to meet the demand. Shortages may have a profound impact on drug supply. This is especially true when multiple manufacturers are producing a drug product for which there is only one source of raw materials. Problems can also arise when the raw materials are difficult to get in process.

Manufacturing involves making products from raw materials by means of various processes, machinery and operations, through a well-organized plan for each activity required. The word product means something that is produced (Jeremy M. and Duncan M., 1998). There are many types of disturbances hamper the production processes, among them in our research, we only discuss about the root causes of raw material shortage and the overall consequences of the raw material shortage.

Cause and effect diagrams were developed by Kaoru Ishikawa in 1943 (Hasin, A. A.). Cause and effect diagrams are used to identify and systematically list the different causes that can be attributed to a problem. These diagrams thus help to determine which of several causes has the greatest effect. From the primary investigation and literature review, we find eight (08) sources of causes for raw materials shortages that mainly occur in pharmaceutical industries. The possible cause and effect diagram is shown in Figure no. 2.

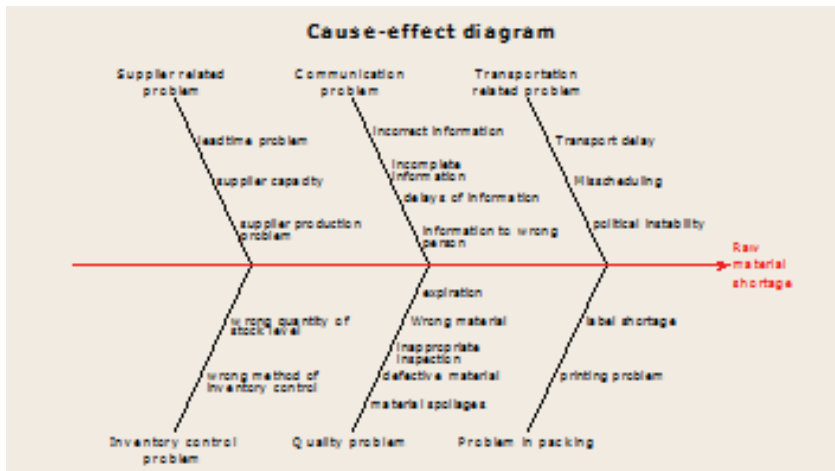


Figure no.2. Possible cause and effect diagram for raw materials shortage.

Disturbances are not rare in the supply of raw materials. Shortage of raw materials is becoming common phenomena for various industries especially manufacturing. These sources and their relative causes are:

- (i) Transportation related problem, (ii) Problem in Packing, (iii) communication problem, (iv) quality problem (Santhirasegaran N, 2011), (v) design change, (vi) demand for critical material (Santhirasegaran N, 2011), (vii) supplier related problem and (viii) Inventory control problem (Silver, E., et al., 1998).

3. Materials and methods

The reasearch methodology adopted for this study is a combination of a questionnaire survey and direct observation. The questionnaire survey and direct observation were conducted in pharnaceutical companies from Dhaka and Sylhet. It should be noted that the interview is conducted in person with a structured questionnaire. This study gives an idea about the existing scenarios of pharnaceutical companies in Bangladesh. This study deals with various immediate causes behind raw materials shortages in the manufacturing process, their causes and consequences.

This research is conducted in 25 pharmaceutical organisations. This research deals with various types of immediate causes, causes behind the sources and its related consequences. For analysis purpose we used a

ranking scale such as, Never = 1, rarely = 2, sometimes = 3, often = 4 and always=5. The information as well as data is gathered through the questionnaire, interview, direct observation and some past record from the related department of the selected company.

The demography of the studied organizations is presented in Table no. 1. The number within the bracket indicates the number of organizations.

Table no. 1

Demography of the organizations

Annual turnover (in million TK)	5M-50M (5)	50M-500M (9)	Over 500M (11)
Name of area	Dhaka (24)	Sylhet (1)	

4. Results and discussion

Eight types of immediate causes behind raw materials shortage are identified as they mainly occur in the pharmaceutical industry. The frequency of occurrences of these immediate causes varies from organization to organization. The mean and standard deviation of the immediate causes occurred in the different pharmaceuticals industries are shown in Table no. 2.

Tabele no. 2

Mean and standard deviation of the immediate causes

Immediate causes	N	Mean	Standard Deviation	Maximum	Minimum
Transportation related problem	25	2.28	1.02	5.00	1.00
Problem in packing	25	2.92	0.95	5.00	1.00
Communication Problem	25	2.80	0.95	5.00	1.00
Quality problem	25	1.68	0.74	3.00	1.00
Supplier related problem	25	2.12	0.92	5.00	1.00
Inventory control problem	25	1.80	0.86	4.00	1.00
Design change	25	3.32	0.94	5.00	2.00
Demand for critical material	25	2.28	1.02	5.00	1.00
Valid N (list wise)	25				

The percentage of the occurrence of most of the immediate causes is significant because according to our five point scale the average value is “03” and most of the mean of immediate causes are near average value. The eight types of immediate causes behind raw materials shortage can be divided into two groups as shown in Table no. 3.

Table no. 3

Internal and External immediate causes behind raw materials shortage

External immediate causes	Internal immediate causes
Transportation related problem	Problem in Packing
Supplier related problem	Communication problem
Fluctuating Demand for critical material	Quality problem
	Inventory control problem
	Design Change

4.1. Reliability Test for Immediate Causes of Causes behind Raw Materials Shortage

For this analysis, a software named “SPSS” is used to test the reliability that it is either reliable or not (Imam Faruk M., 2009). From the reliability analysis, it is found that the reliability value for sources of causes is 0.730 and all the values for causes and consequences behind raw materials shortage are more than 0.60.

4.2. Inter Relationship between immediate causes (Pearson Correlation Method)

To find out the relationship among the immediate causes, Pearson correlation method can be used. Karl Pearson’s coefficient of correlation is the most widely used method of measuring the degree of relationship between two variables. The correlation value ranges from -1 to +1. The positive value implies that there is a strong positive correlation which means that if one variable changes then the other variable also changes in the same direction. On the other hand, the negative correlation value indicates that if one variable changes then the other variable also changes inversely.

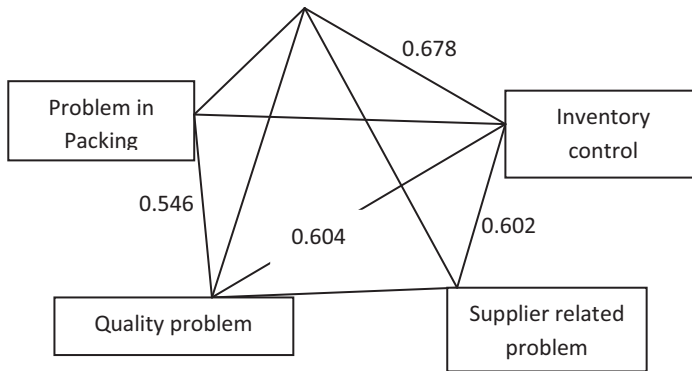


Figure no. 3. Correlation among root immediate causes behind raw materials shortage

From the correlation matrix as shown in Figure no. 3, it can be seen that the immediate cause “Problem in Packing” is correlated with “Quality problem” and the correlation coefficient is 0.546 which means that there are strong relations between them. According to the data, 12 pharmaceutical companies out of 25 claims that Quality problem has no impact to their industry. However, this research indicates that, there is a strong relationship between them. This relationship can be shown in Figure no. 4.

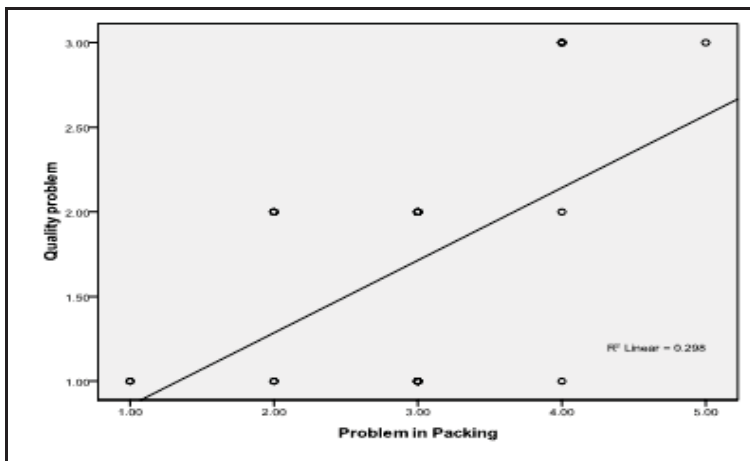


Figure no. 4. Correlation between Problems in Packing vs. Quality Problem by using scatter plot.

The summary of the analysis of the number correlation with other immediate causes behind raw materials shortage can be shown in Figure no. 5.

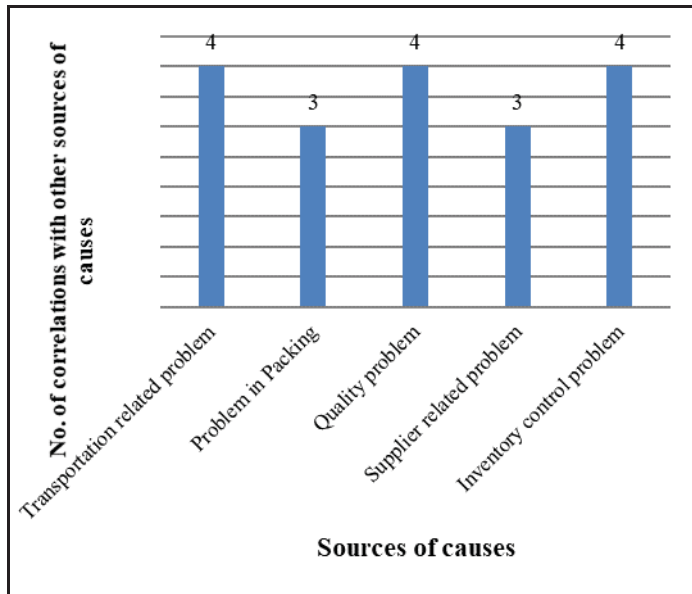


Figure no. 5. Sources of causes against number of correlation with other immediate causes.

4.3. Root Causes for Raw Material Shortage

In the particular organizations, 19 causes have been identified behind the raw materials shortage. However, the intensity of every cause is different and the causes vary from one to other sources of causes behind raw materials shortage. Some causes dominate other causes and these dominating causes are called “root cause”.

By using the factor analysis, relatively unimportant causes can be reduced. The data obtained from the 25 pharmaceutical companies have been used for this purpose. For making calculation easy, the factor loading more than 0.50 is considered and the values below 0.50 are out of consideration. There are nine (09) causes above 0.50 which are shown in Table no. 4.

Table no. 4

Relatively important causes identified by factor analysis

Causes	Factor analysis value	Causes	Factor analysis value
Transport delay	0.780	Incomplete information	0.834
Printing problem	0.879	Delays of information	0.805
Label shortage	0.840	Information to wrong person	0.805
Incorrect information	0.840	Expiration	0.502
Wrong method of inventory control	0.840		

4.4. Interrelationship between sources of causes and cause

To find out the relationship among the immediate causes and causes, Pearson correlation method is used. For the analysis, the correlation between the sources of causes and the nine (09) relatively important causes are found.

For the analysis purpose, the correlation coefficient value that is more than 0.40 is considered, i.e., there are strong correlations between them. This relationship can be shown by the following Figure no. 6.

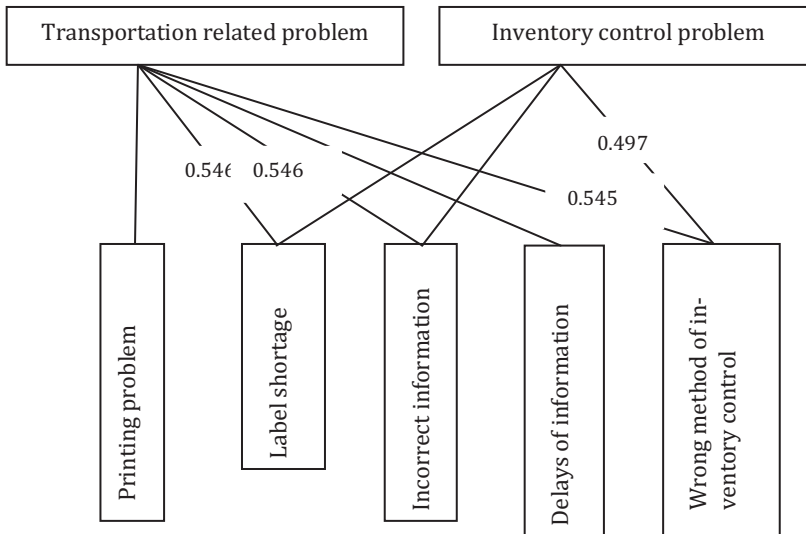


Figure no. 6. Relations among immediate causes and root causes.

From Figure no.6, it is clear that none one of the 9 causes is responsible significantly for the immediate causes “Transport delay”, “Incomplete information” and “Information to wrong person”. Maybe other causes are responsible for this; however, the relationships among them are not strong enough and for this reason, they are ignored. Our main concern is the root causes which dominate other causes and mainly responsible for most of the immediate causes. Here, the two sources out of eight are the main immediate causes that are found from the analysis. Among the 19 causes, 5 causes are mainly significant. For this reason, Pearson correlation method is used among them to find out the root causes.

Now, the root causes can be found from fig.6. The most effective causes e.g. the root causes are given below:

- (a) Printing problem;
- (b) Label shortage;
- (c) Incorrect information;
- (d) Delays of information;
- (e) Wrong method of inventory control.

At first the condition of “Printing problem” in the 25 pharmaceutical companies of Bangladesh has been observed and it is given below, in Figure no. 7.

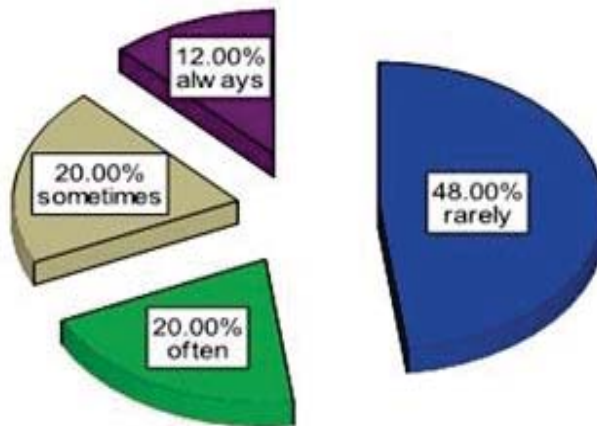


Figure no. 7. Frequency of occurrence for printing problem.

From the pie chart (fig. 7), we can see that 12% of the pharmaceutical companies out of 25 always face this problem, 20% sometimes; often 20%, rarely 48% face this problem.

Figure no. 8 shows the cause-effect diagram representing the root immediate causes and its root causes behind raw materials shortage.

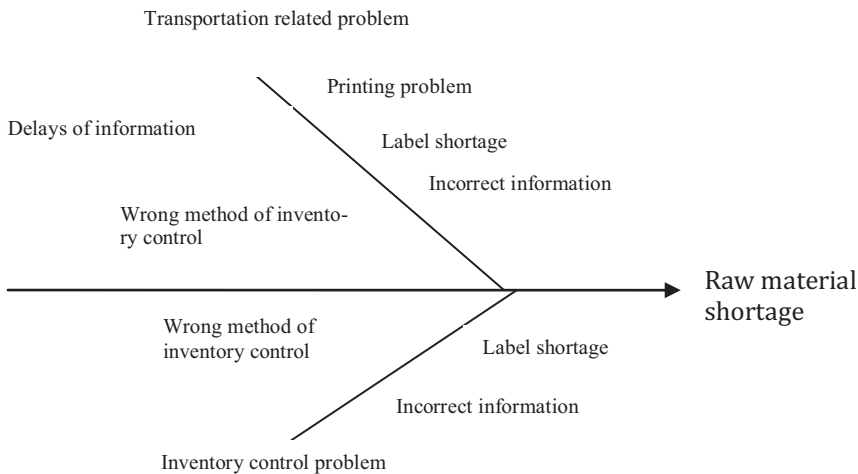


Figure no. 8. Cause-effect diagram for root causes and immediate causes behind raw materials shortage.

4.5. Findings of the consequences for raw materials shortage

Consequence is the result of raw materials shortage for which the organizations have to pay money and time. In the research, 11 consequences are found that the organizations have to face. These are: interruption of production schedule, increased production cost, late delivery to customer, production stoppage, increased rework, loss of goodwill, increased production lead-time, increased non-value added time, increased WIP, increased materials wastage, and increased holding cost.

These consequences have frequency of occurrence ranges from very high to very low. For example, the consequence “Increased WIP stock” results in 24 pharmaceutical companies out of 25 and the percentage is 96.

4.6 Identifying the root Consequences

By using the factor analysis, the relatively unimportant consequences can be reduced. The data obtained from the 25 pharmaceutical companies have been used for this purpose. The values above 0.50 are shown in Table no. 5.

Table no. 5

Factor analysis for consequences

Consequences	Factor Analysis Value
Late delivery to customer	0.827
Increased rework	0.732
Increased WIP	0..710
Increased production lead-time	0.797

The major consequences are late delivery to customer, increased rework, increased WIP, and increased production lead-time. As a result, organizations need extra money and time to complete their scheduled works instead of their normal time and money. And ultimately organizations fail to meet customer demand and loss good will as well as decrease the profit.

Conclusions

Current study delineates the scenario of common immediate causes for shortages in the pharmaceutical sector and discusses the causes and consequences of those immediate causes. Based on the obtained results the following conclusions can be drawn:

- Eight immediate causes have been identified. Among the eight factors three are internal and five are external.
- Some dominating immediate causes are transportation related problem, inventory control, supplier related problem etc.
- Same causes are responsible for different immediate causes. Three causes are accountable for transportation related problem.
- Overall, 19 causes are responsible for creating eight immediate causes. From them some root causes are figured out that dominates

the other causes. Some root causes are: wrong method of inventory control, incorrect information, label shortage, delays of information etc.

- 11 consequences are identified; from them some consequences happen repeatedly for raw materials shortage. Some notable consequences are: degradation of reputation, increased lead time etc.

Finally, it can be said that the escalating increase in the shortage of raw material has compromised patient's quality of care and imposed a tremendous burden on our health care system.

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