

## Quality Perspective of ‘Good Distribution Practices’ in Indian Pharmaceutical Industry

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### **Abstract:**

*The operation of Supply Chain of Management (SCM) is predominantly perceived from commercial facet of a business. Pharmaceutical products affect the health of the user hence it is obligatory to produce and deliver the products of predetermined quality standards. This can only be achieved by designing quality centric procedures and pursue them at each stage during distribution process. Quality is considered as the most sensitive aspect of pharmaceutical business during manufacturing as well as distribution. Quality of medicinal products is concurrent to its objective of curing the patients. Many drug regulatory agencies have issued guidance ‘Good distribution practices (GDP)’ for pharmaceutical manufactures. The Good Distribution Practices (GDP) is considered an essential basis of pharmaceutical SCM to ensure systematic distribution of medicinal products. Due to lack of proper understanding and commitment, product quality issues are noticed by manufacturer’s quality assurance department. Since most of the quality aspects of pharmaceutical products are not known to the common patients, the survey to characterise them with help of quality professionals has been found useful. This research study finds that there is an enhanced need of control over the supply chain management operations to align its procedure and practices with quality objectives of pharmaceutical ‘Good Manufacturing Practices (GMP)’.*

**Keywords:** GMP, GDP, SCM, Pharmaceutical Quality, Pharmaceutical Product Defects

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The good quality of medicines is sustained by the efforts of multiple agencies and their synchronised activities. Achieving a high degree of quality requires effective medicines legislation and regulation, a competent medicines regulatory authority and manufacturing practices with adequate medicines quality assurance.

Leading pharmaceutical companies of India have established Supply Chain Management (SCM) department to look after Good Distribution Practices. Supply Chain Management (SCM) of pharmaceutical products have different and stringent requirement as compared to other business. The handling, storage and distribution of medicinal products need special attention to avoid degradation and deterioration. To overcome this challenge the regulatory agencies across the world have issued guidance standard “Good Distribution Practices (GDP)” for pharmaceutical products.

Good distribution practices (GDP) is an essential concept of pharmaceutical SCM to ensure systematic distribution of medicinal products from manufacturing site to retailers. The main concerns arising during pharmaceutical distribution are: deterioration, counterfeit drugs and pilferages.

The GDP guidance is the most relevant standard which governs the quality system during pharmaceutical supply chain management. It is noted worthy that the guidance paper by World Health Organization (WHO) is identical to that issued by European Union in many ways. Both of the guidance papers emphasise awareness about quality during transit and distribution.

The reinforcement of GDP by European regulator is observed to be stern and inflexible. The European regulatory inspectors verify the distribution system and practices through periodic audit process. Even during inspection of regulatory audit of manufacturing plant the international auditors, verify the adequacy of GDP.

In principle, quality is considered as the most sensitive aspect of pharmaceutical business during manufacturing as well as distribution. Quality of medicinal products is concurrent to its objective of curing the patients.

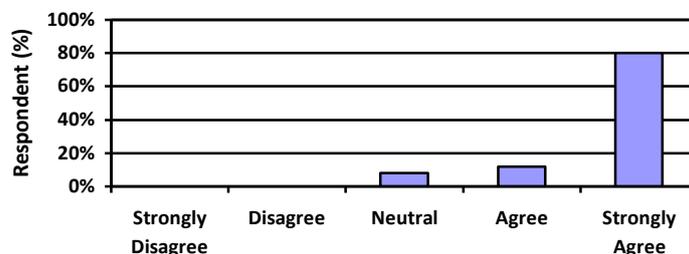
A survey was carried out amongst the pharmaceutical professional to gather opinion on distribution practices in Indian pharmaceutical industry. The survey reveals that even though there are serious implications of quality defects, but consumers are unaware of the consequences. The survey was conducted amongst the pharmaceutical professionals, who are aware about the Following quality defects of pharmaceutical products are often generated during distribution:

### **(a) Exposure beyond specified temperature shall cause degradation**

The products are manufactured at a temperature never exceeding 27<sup>o</sup> C. The studies indicate that beyond this temperature the product shall not survive and there shall be substantial generation of impurities as result of product degradation. In many cases such impurities shall be harmful to patient’s health.

Moreover, in case of cold chain products the specified storage temperature is 2<sup>o</sup> to 8<sup>o</sup> Celcius. Storage of such medicines at room temperature shall cease the efficacy of products.

**Survey :Exposure beyond specified temperature cause degradation**

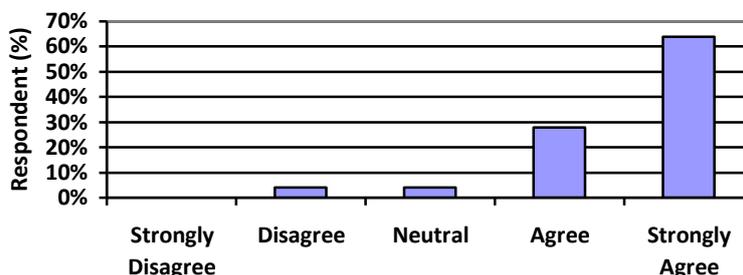


**(b) Mishandling shall cause defect related to product integrity**

Product integrity is referred for the intactness of medicinal dose. As medicine shape and size construes an important part of pharmacological action. The shape of dosage and its packaging are designed for appropriate biological action. The packaging components are decided by keeping the standard way of handling and exposure of products. Whether the dosage are in tablet, capsule, syrup or injectable forms, there is requirement of handling them with due care. Even tablets or capsules may lose its activity as result of surface abrasion.

If the pharmaceutical product is not handled as per standard procedure during distribution process, it may no longer remain appropriate for intended use.

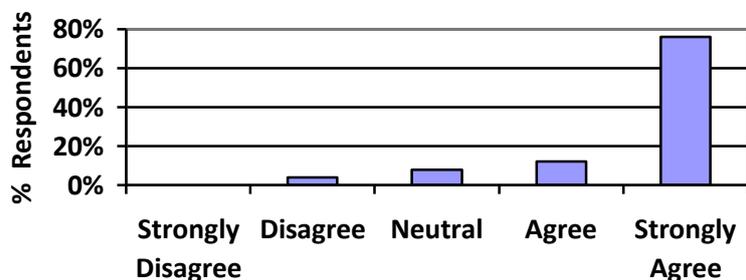
**Survey: Mishandling of product shall cause defect related to product integrity**



**(c) Seal break shall cause microbial contamination:**

Different kind of seals on pharmaceutical products is provided on the basis of the study on respective dosage form. Products in tablet or capsule form are protected through effective sealing on blister or strips. The liquid suspension products are provided induction seal. Injectable products are protected through seamless seal of vials. Environmental stress and rough handling during the course of transit and distribution may cause product seal damage.

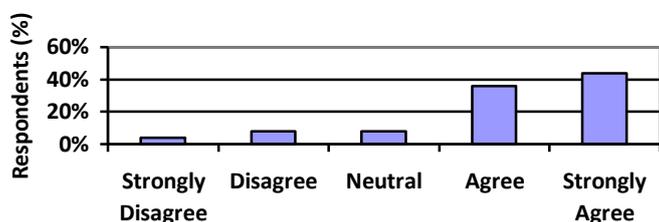
**Survey : Seal break often occur during distribution, which have potential to cause microbial contamination**



**(d) Transit in common cargo (eg shared with paint/cement etc) shall cause bad smell and taste:**

There are many ingredients in pharmaceutical products which have potential to absorb smell. Few patients in pharmaceutical industry observe an abnormal smell and taste of product. This could be due to inherent characteristics of medicinal formulation or due to the contamination caused during distribution. Often, it is considered that pharmaceutical products are sealed pack hence shall not have impact of materials being transported along with such products. The contaminants may adhere to the external surfaces of pharmaceutical pack and may be proliferated into the pack.

**Survey: Transit in common cargo used for non medical items shall cause bad smell and taste**

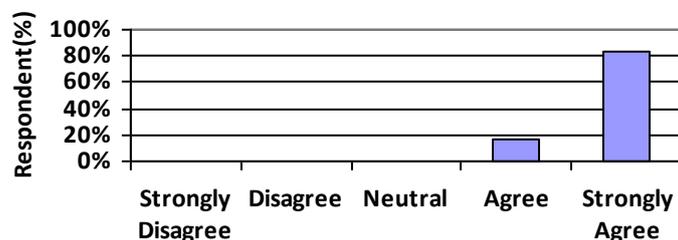


**(e) Label scratching or ink smudging shall cause illegible product information**

Deliberate or accidental factors may alter product information during the distribution operation. The product information on primary packs as well on secondary pack of products is provided either through pre-printed or over coded texts. Product Strength, Batch number, price, manufacturing date and expiration date are compulsorily available on each pack. The main cause of confusion on product information is:

- ✓ Rattling between unit pack during transit
- ✓ rough handling at the time of replenishment
- ✓ Smudging of coding information due to exposure to moisture or other solvent

**Survey: Illegible product information are observed due to label scratching or ink smudging**



The survey concluded that that illegible product information is the biggest quality concern, which has potential to impact the user’s perception about the dosage.

The attention to quality must continue beyond manufacturing premises throughout the supply and distribution network. This authorized pharmaceutical product should be distributed and handled by retail pharmacists and others licensed to sell medicinal products to the general public without any alteration. This precaution is not required only at one or few unit operation of supply chain management.

As per US Pharmacopoeia, the shelf-life of a medicine is a function of the temperature and humidity under which it is packaged, stored, and transported as much as a function of the chemical and physical properties of the pharmaceutical formulation. Appropriate containers and packaging materials are essential to preventing or minimizing the quality problem caused by handling during product distribution.

The proclaimed objectives of SCM in pharmaceutical sector are to uphold Product cost, to maximize the capacity, to provide the flexibility in supply, to coordinate between manufacturing department and marketing, to maintain the lead time

Responsible business behaviour throughout SCM is important for sound, uninterrupted, competitive and cost effective global business as well as environmental protection.

For technical support, the pharmacist can reach out to the online community IAHP (Internal Association of Public Health Logistician). The review of online comments and blog indicates that only 4-5 percent participants were from India, whereas from western countries the statistics is much higher. The reason for poor participation is probably the fact that discussion regarding GDP concept is less popular in India.

An effective SCM is characterized by the timely, reliable movement of health commodities and date up and down the SCM from the service delivery point (such as health post, clinics, and hospitals where health commodities are dispensed) to the district, regional and national levels and block. The data from the service delivery points are most relevant for supply chain managers to make informed decisions of how much and what type of health commodities should be delivered. In paper based logistics management information systems, as mostly used in low income countries. The right data doesn’t normally got the right person at right time. Supply Chain based on information and communications technology (ICT) on the contrary offer the potential to accelerate the data transmission to multiple stakeholders simultaneously and reduce the reporting burden.

The supply chain management in pharmaceutical industry plays with very unpredictable demand trend. The pharmaceutical products have defined shelf life hence distribution schedule is altered to compensate the other delays.

A research study says that western countries have a very stringent regulatory system; hence the quality problems like degradation are not possible during distribution. But in India the possibilities cannot rule out the quality issues arising due to inadequate distribution system. An updated GDP guideline for EU distribution of medicinal products for human use was published in the Official Journal of the European Union on March 7, 2013. Under the guidelines, distributors will be required to maintain quality system that clearly define and document all responsibilities, processes and risk management policies. The quality system must extend to the control and review of any outsourced activities related to the procurement, storage, supply, transport and import/export of medicinal products, putting clear emphasis on the need for valid third-party vendor qualification.

The Centre for International Public Health Policy led a research study and identified pilferages during drugs distribution is a potential quality issue during distribution. The State governments of several provinces have started centralised drug procurement systems as an attempt to overcome such problems.

Purchases are made not through agents or distributors but only from manufactures with Good manufacturing Practices (GMP) certificate, a market standing for at least three years and a minimum turnover,

to eliminate very small firms that may fail to meet their delivery commitments. It also follows WHO's recommendation in using international non-priority or generic names.

With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules are procured with only strip or blister packing, as against the earlier practices of bulk packing which requires manual handling at the time of distribution.

#### **Way Forward:**

Ironically the quality professionals of pharmaceutical industry have rare or no control over distribution practices followed in market place. The survey amongst the pharmaceutical quality professionals shows an eye opening trend of quality defects. Indian consumers face an ordinary problem of illegible information on pack of pharmaceutical products. This is mainly due to erroneous practices followed during supply chain channel. As a result of detailed study, it is concluded that sometimes efficacy of medicines are questioned by medical practitioners and the patients, without differentiating the origin of problem either during manufacturing or during distribution. As the research findings divulge that bad distribution practices have potential to cause maximum number of customer complaints. By and large the medicine manufacturer's brand of medicines prescribed for treatment is under question due to consumer's inconvenience. Ultimately the consumers are sufferers of inadequate practices and the brand value of product is lost. The training and awareness to all personnel engaged in supply chain operation for pharmaceutical products may address this issue. This shall help the concerned personnel to understand the impact of mishandling during distribution of pharmaceutical products

- Accurate forecasting of demand and proper resource planning can reduce the problem arising during the course of Good Distribution, which subsequently lead to compromises with respect to engage dedicated transportation cargo.
- Due to economic constraints the delivery compliance with respect to time is often breached and products are kept under unsecured environmental condition thereby impacting quality.

It is noteworthy that inferior quality of products is not only originated due to inadequacy at the manufacture's end rather procedure and practices adopted by supply chain management personnel are significantly responsible.

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