

Survey on Foreign Particle Contamination in Drug Substances

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ABSTRACT

Medical products contain the drug substance, or active pharmaceutical ingredient, that is the primary substance in a medicine that elicits the desired therapeutic effect of the drug. Drug substances contaminated with foreign particles are highly hazardous to the health of patients, the impact of which remains undetermined. Thus, there is a need to conduct a study on foreign particle contamination. There are six pharmaceutical quality systems that regulate the production of drug substances. Gap analysis has been evaluated by means of a survey through a structured questionnaire that has been used by Google Forms to survey six pharmaceutical quality systems having pharmaceutical employees. One hundred and eighty-eight respondents filled out 98 good manufacturing practices-related questionnaires, and the analysis revealed that 42 of the 98 questions failed the acceptance test. All the questions posed are aimed at revealing the effectiveness of the system used by the pharmaceutical company at the level of controlling the foreign particle contamination in the drug substance and the extent to which the company complies with the rules and regulations. The results of the survey established the following as the most poorly managed systems: pharmaceutical quality, laboratory control, and production systems. The survey has identified a number of nonconformity aspects that are important in regard to good manufacturing practices. Such a survey gives a clear image of the gaps in six pharmaceutical quality systems, and it will contribute towards strengthen the manufacturing systems and processes of the drug substance.

Keywords: Foreign Particles, Contamination, Active Pharmaceutical Ingredients, Pharmaceutical Standards, Good Manufacturing Practices, Quality Management System

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1. INTRODUCTION

Pharmaceutical products contain foreign substances that interfere with the integrity of the product [1]. No one knows how the unknown foreign particles that are present in medicine will affect the body of the patient.

No prescriber/doctor desires foreign particle contaminated pharmaceutical products. The patient that does not know any information about the drug and is already diseased should be isolated and kept away from the contaminated drug.

Medicine that patients are provided with in different forms is produced by using several ingredients. Active Pharmaceutical Ingredients is the main ingredient that is compulsory [2]. The pharmaceutical industry attempts to eliminate foreign particles in medicine with different processes. It is, however, not technically feasible that any external substance or foreign particles do not exist in the active pharmaceutical ingredients.

Any API manufacturer cannot eliminate the presence of foreign matter in the API. Therefore, attempting to lessen the amount of foreign content in the API is the appropriate

course of action in this situation. In this case, it is difficult to please all investigators completely. As a result, investigators, customers, and other authorized persons make comments, complaints, and other statutory actions for the API manufacturer.

The fact that the API contains foreign matter is also highly harmful when it comes to the health of the consumer/patient. Thus, the correct action in this situation would be to aim at minimizing the level of foreign matter in the API [3]. The health authorities of the world (USFDA, EMA, and others) and pharmacopoeias (USP, EP, and others) are scarcely referred to when it comes to defining external substances and principles of their eradication. It should find and eliminate the foreign material during the time of API and manufacturing thereof, and he must prepare it in a proper format. The necessity to work in this context is associated with the risk of life of commoners and patients.

APIC (ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE) has come up with a guidance document on the above topic [4]. The Guidance, Handling of Insoluble

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Matter and Foreign Particles in APIs document, provides the best industry practice and guidance as to the right controls over the unavoidable occurrence of minute quantities of particles in APIs[5]. The guideline points to the possible aspects of reducing to a reasonable level the risk of a patient.

Active pharmaceutical ingredients are produced in many companies and are subject to GMP[6]. Nevertheless, due to certain reasons and other factors, certain foreign particles still remain in the active pharmaceutical ingredient. This study will determine and extract these foreign substances in active pharmaceutical ingredients.

To achieve this goal, studies were initiated with attention to the active pharmaceutical ingredient. To begin with, the mechanism of transformation into an active pharmaceutical ingredient was learned. A far analysis was carried out on the areas where the possibility of contamination could occur during construction. It conducted thorough research and discovered that there are certain locations and certain opportunities in which contamination might become feasible. Prepared a questionnaire and gave all those possibilities in the form of a question. The information in this questionnaire addressed all the potential contamination elements in the active pharmaceutical ingredients (API). The questionnaire is premised on Good Manufacturing Practices (GMP) and Quality Management Systems (QMS) used by pharmaceutical businesses[7,8].

After designing the questionnaire, the following questionnaire was placed on the Google form. The survey key application that can be used to respond to this questionnaire is Google Forms, which is easy to use. This is the reason why I prepared this questionnaire using Google Forms.

This Google Form was completed by the individual who is employed in a pharmaceutical firm, and the individual who is employed in a pharmaceutical firm is qualified to complete this form. This questionnaire was answered by the employees in the pharmaceutical company depending on their experience and knowledge. Then the pharmaceutical company caused the information regarding the possibility of contamination of the API to become known, and it was aware of the contamination possibility location in the API.

Through this Google form, relevant information has been obtained as to what should be done to prevent the contamination of active pharmaceutical ingredients and the motivation behind the contamination.

This survey-based study has found the gap in six important elements of the pharmaceutical quality system, which are the production system, packaging and labelling system, material system, facilities and equipment system, laboratory control system, and quality system. The knowledge contained in this report would help all the concerned parties to improve the existing procedures and

systems that comply with the current good manufacturing practices.

2. MATERIALS AND METHODS

A technical survey was conducted to gather insights on foreign particle contamination in Active Pharmaceutical Ingredients (API). First, questionnaires were prepared with the help of subject matter experts/employees in the pharmaceutical industry. Questionnaires are in two forms: Optional and Descriptive. After creating the questionnaire, it was put this questionnaire on the Google form. Google Forms is a survey key application that allows users to answer this questionnaire easily. The survey questionnaire has been distributed via a Google Form, ensuring easy access for participants.

2.1 Distribution Methods of Survey Questionnaire:

i. Email:

- The link to the Google Form was sent to selected contacts in pharmaceutical companies.
- Emails were crafted to explain the purpose of the survey and encourage participation.

ii. Paper Copies:

- Paper copies of the survey instructions and a QR code linking to the Google Form were provided for companies that prefer traditional methods.

iii. Social Media:

- The survey link was shared on appropriate social media platforms and professional networking sites to reach a broader audience.

iv. Volunteer Involvement:

- Only trusted volunteers were used to send the survey link to technical staff and employees within their networks.
- Volunteers have been instructed to ensure the participants understand the importance of the survey.

v. Verification Measures:

- To prevent fraudulent submissions, measures have been implemented to ensure that only legitimate participants fill out the form: First, Single Submission Policy: Each participant is allowed to fill out the Google Form only once. Second, Validation Process: Only the first complete submission has been validated, and duplicates have been filtered out.

2.2 Assessment Plan for Technical Survey Responses

The responses received from Google Forms have been evaluated using various statistical tools for practical data analysis.

Evaluation Methodology:

i. Response Analysis:

- Each question has been assessed individually to identify trends in foreign particle contamination in APIs.

ii. Statistical Tools: (If applicable)

- Pie Charts: These are used to visualize categorical data distribution.
- Bar Charts: To compare responses across categories.
- Additional Tools: Other Google Forms visualization options may be used as needed.

iii. Summary Statistics:

- Aggregate data has been summarized, including mean, median, and mode where applicable.

iv. Further Analysis: (If applicable)

- Additional insights may include:
- Cross-tabulation for variable relationships.
- Trend analysis for patterns over time.

2.3 Collection of Data and Analysis of the Evidence for the Technical Survey

Only data completed through the Google Form has been validated. Participants must answer all mandatory questions before clicking the submit button, which then generates the responses. Google Forms provides a summary report in the response section, which was utilized to analyse each question effectively.

2.4 Statistical Considerations

With over 1,000 pharmaceutical companies operating in India, it is unlikely that every employee from each organization will complete the Google Form. To ensure meaningful insights, the survey link has been distributed randomly among employees in the sector according to their relevance. A randomly chosen sample is crucial for an unbiased representation of the overall workforce. Engaging hundreds of employees from various companies in the pharmaceutical industry has yielded accurate and impactful results.

2.5 Limitations

The technical questionnaire was completed by at least 100 or more technical staff from various pharmaceutical companies, ensuring that statistical analysis can be effectively applied. The scope was focused on employees of Indian pharmaceutical companies.

To encourage participation and maintain confidentiality, the questionnaire did not require complete personal information. This approach aims to alleviate any concerns

participants may have about privacy, thereby increasing the likelihood of form completion.

2.6 Evaluation

Each question and answer has been evaluated on the basis of their quality risk assessment. The impact assessment was also done for each question and answer (where applicable). Each question answer has been evaluated on the basis of suitable statistical tools. Both pros and cons have been considered, and there has been no favouritism.

2.7 Acceptance Ariteria

All questions posed have been pertaining to Good Manufacturing Practices (GMP) within the pharmaceutical industry. Each prepared question maintained an unbiased perspective, ensuring that there was no target of any specific company or organization.

Each question has a unique and independent identity, and the acceptance criteria for responses were defined in each respective question. This ensures a fair evaluation process that considers relevant factors for assessment.

80% of participants/count/population kept within the Acceptance Criteria / Specification Limit for each question except specific questions. As per the above-mentioned acceptance criteria, out-of-limit results have been further assessed using suitable statistical tools.

Example of question: Some of the employees do not follow SOP (Standard Operating Procedure) by wearing a uniform, hair cap, and shoe cover in the production area in the Pharmaceutical Industry. How much do you agree with this statement?

Range: Linear scale - Low 0 to High 10

Acceptance Criteria: This is a negative question, so the outcome should be low or disagree with the prescribed limit. 80% of participants/count/population should be within the Acceptance Criteria / Specification Limit.

3. RESULTS

All questions and answers are assessed in terms of their risk in quality and GMP. Each question and answer was also done through impact assessment. All the question answers have been rated based on the appropriateness of the statistical tools. Any merits and downsides are taken into account, and there is no meritocracy. The quality management system-wise queries are ready, and short information is tabulated as under:

Sr. No.	Quality Management System	No. of Questions	Meet in Acceptance Criteria	Not Meet in Acceptance Criteria	% Failure
1.	Pharmaceutical Production System	36	24	12	33.33%
2.	Pharmaceutical Packaging & Labeling System	04	03	01	25.00%
3.	Pharmaceutical Material System	05	05	00	00.00%
4.	Pharmaceutical Facilities & Equipment System	18	13	05	27.77%

5.	Pharmaceutical Laboratory Control System	25	09	16	64.00%
6.	Pharmaceutical Quality System	06	00	06	100.00%
7.	Other	04	02	02	50.00%
Total		98	56	42	42.85%

Table 1: Summary of survey questions assessed for GMP compliance, showing system-wise acceptance, non-acceptance, and percentage failure. Cumulative Analysis:

In the case of the below cumulative chart, it is established that there are several important pharmaceutical management systems, i.e., the Pharmaceutical Quality System, the Pharmaceutical Laboratory Control System,

the Pharmaceutical Production System, etc., that are the most affected/uncontrolled systems and are the biggest contributing factors to contamination in API (Active Pharmaceutical Ingredients).

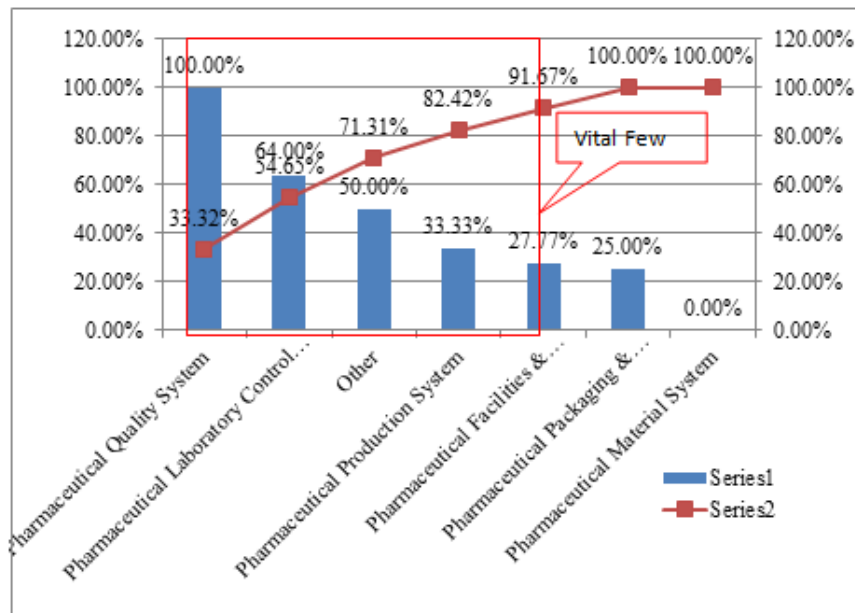


Fig. 1: Cumulative analysis of pharmaceutical management systems contributing to API contamination.

The table below shows the cumulative study of defects:

SR NO.	System	DEFECT	Cumm	Cumm%
1	Pharmaceutical Quality System	100.00%	100.00%	33.32%
2	Pharmaceutical Laboratory Control System	64.00%	164.00%	54.65%
3	Other	50.00%	214.00%	71.31%
4	Pharmaceutical Production System	33.33%	247.33%	82.42%
5	Pharmaceutical Facilities & Equipment System	27.77%	275.10%	91.67%
6	Pharmaceutical Packaging & Labeling System	25.00%	300.10%	100.00%
7	Pharmaceutical Material System	0.00%	300.10%	100.00%

Table 2: Cumulative defect analysis by quality management system.

Run Chart: The graphical representation depicts that the following results are obtained:

The Pharmaceutical Quality System has the highest percentage of failure, with 100% failure.

The maximum number of questions in the Pharmaceutical Production System: 36 questions.

Largest proportion of pass in Pharmaceutical Material System: 0% failure.

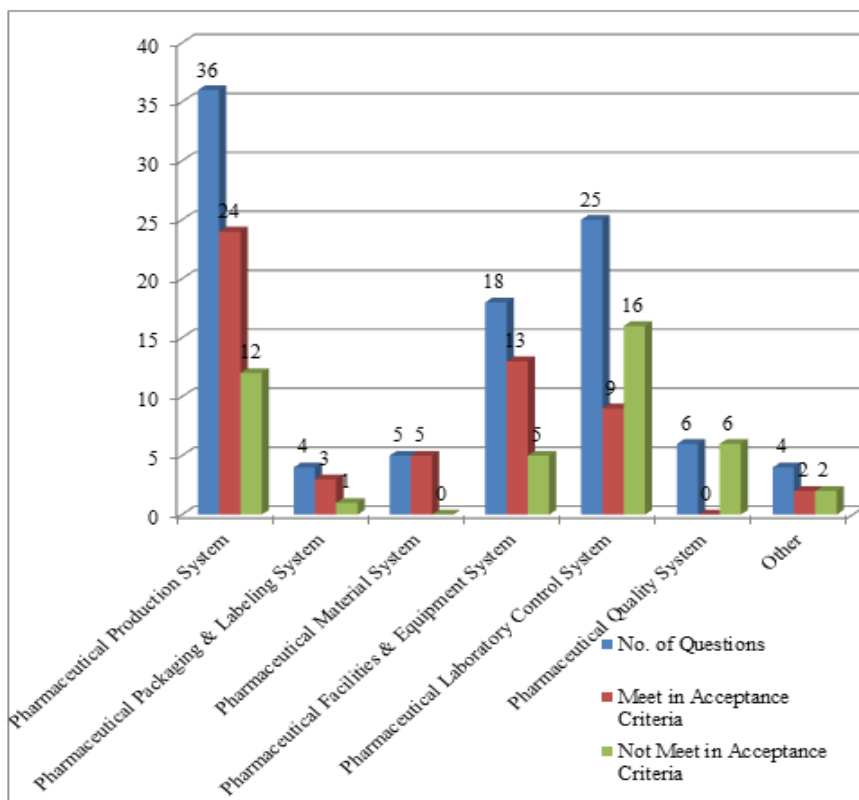


Fig.2: Bar chart of GMP acceptance and failure across quality management systems.

The gap analysis was carried out on six pharmaceutical quality systems. Instruments such as questionnaires on logistical, technical, and confounding and specific GMP were created, and the data was collected through structured questionnaires of 83 GMP questions. The survey was conducted using Google Forms, which is considered a good platform to receive responses from pharmaceutical professionals. The survey was distributed by volunteers so that there were around 188 survey responses with experts in the field.

The questions were evaluated in terms of their effect on the quality of products and safety of patients. An Acceptance Criteria/Special Specification A limit of 80% of the respondents or the population was also put as a benchmark for each question, with some exceptions to certain questions. The statistical analysis showed that a number of very important pharmaceutical management systems, such as the Pharmaceutical Quality System, Pharmaceutical Laboratory Control System, and Pharmaceutical Production System, among others, are significantly affected and present uncontrolled variables that cause API contamination.

Out of the 98 questions asked, 42 of them failed to satisfy the acceptance criteria (meaning 42.85%). This result shows a huge gap in the six pharmaceutical quality systems, which implies that the additional control system is necessary to be mandatory and reduce the risk of foreign particle contamination of pharmaceutical products.

The survey has revealed that there are a number of essential issues related to Good Manufacturing Practices

(GMP). These problems are analyzed with care, and they are as outlined. All of the concerns highlight specific points of GMP compliance that should be improved to provide better quality control and manufacturing standards.

- The workers in the pharmaceutical sector are not following the principles of standardized operating procedures (SOPs) when it comes to uniformity and individual protection equipment (PPE) compliance, and the threats of contamination of the active pharmaceutical ingredients (APIs) with particulate matter (hair, sweat, and cellular debris) are increasing considerably.
- The existing technologies of storing API, namely open chillers and uncovered drums, are rather dangerous in terms of safety and increase the potential of contamination. It is necessary to guarantee that pharmaceutical products are stored according to proper protocols to ensure the integrity of the products.
- It has been identified that there is a concern with the materials used for cleaning, lubrication, and pest control because they might unwillingly come in contact with APIs. These materials should be monitored vigilantly in order to maintain the safety of the products.
- The presence of adhesive tapes as applications in other fields like electrical cabling also poses a significant risk to the contamination of foreign particles in APIs, which is mainly caused by the displacement of residue.

This threat is growing; therefore, urgent action is needed to protect API security and performance.

- Although activated carbon is being used in the process of active pharmaceutical ingredient production, the possibility of its occurrence in the end product is an issue of moderate contamination. Even though it is assumed to be safe with short-term exposure, it should be noted that its association with APIs should be approached with care.
- Other manufacturing processes of APIs usually incorporate the use of fibers or fabrics, which may accidentally introduce contaminants into the API, which jeopardizes the purity of the API and consequently the safety and efficacy of pharmaceutical products.
- The consumption of food by employees in production zones is a burning issue, where there is a higher chance of foreign contamination of APIs, and thus remedial measures must be taken immediately to avoid endangering human lives.
- The lack of use of the spark testing technique on glass-lined equipment is observed in pharmaceutical firms, contributing to the high possibility of contamination of APIs with glass particles and the necessity of taking corrective actions.
- The cleaning of equipment protocols in the pharmaceutical production systems is severely lacking, especially with the analysis of samples by filter disk being absent in many of the rinse samples. This negligence increases the possibility of foreign contamination of the final product.
- The drug industry is now evading the necessary visual checks during the handling of products, which undermines the ability to detect foreign particles in APIs.
- Moreover, the absence of automated methods of foreign particle detection in APIs undermines the safety of the products and compliance with regulations. The most essential aspect of purity of APIs and patient health protection is the use of a system that promotes detection.
- Reuse of any materials or batches that drop to the floor during production without proper scrutiny poses great chances of contamination because of the foreign particles at the expense of the integrity of the final product.
- Notably, extraneous matter analysis does not feature in process and cleaning validations in the pharmaceutical industry, but the problem of foreign particle contamination of APIs needs to be discussed because it directly affects the safety of the product and the health of the patient.
- The use of impaired gloves in production imposes a significant risk of contamination of APIs with rubber particles, which underlines an urgent need for safety interventions.
- The line clearance procedures by quality assurance inspectors are often poor, and there are high chances of non-conformity to the pharmaceutical industry.
- Lack of metal detectors and the metal separators in the API production processes increases the risk of contamination by metal particles, which has severe safety and efficacy concerns, requiring immediate remedial measures.
- High-intensity lighting in front of the powder processing area also attracts pests, and this multiplies the contamination risks further. Other solutions to lighting or proper pest management measures should be considered.
- In addition, the pharmaceutical market does not have automation of the procedure of foreign particle detection in APIs, which compromises the safety of the products and the ability to meet the regulations, which further supports the necessity of the effective detection system.
- The fact that the damaged equipment is labeled inappropriately and kept in use increases the chances of foreign particle contamination of APIs, having the effect of urging the need to act.
- There is also a major gap in the Pharmaceutical Laboratory Control System because the methodologies of detecting the foreign particles in the APIs are not very effective. This is very dangerous to the purity and safety of the products, which might result in regulatory non-compliance and risks to the safety of patients. It should have an elaborate system of detection.
- Filter disk analysis has a tendency not to conform to laminar standards of airflow; this has a high compliance risk in the pharmaceutical sector.
- Pharmaceutical companies have failed to gather all the possible contaminants, including stainless steel and plastic, in the Powder Processing Area and do not have a reference library to compare foreign particles to known contaminants in APIs.
- Also, no infrared (IR) or microscopic analyses of different components of the Powder Processing Area have been done, such as stainless steel, plastic, wall chips, floor paint, and floor stone, and no IR library of these materials has been developed.
- The pharmaceutical industry also faces risks of contamination of APIs that are affected by foreign substances such as glass, metal, and different colored and textured rubber stoppers that pose serious severity risks, meaning that they need to be addressed in time to ensure the safety and effectiveness of the products.
- The pharmaceutical industry is known to have high customer complaints on foreign particle contamination,

and not many deviations are logged, particularly during the manufacturing process. This problem needs to be addressed in active pharmaceutical ingredients (APIs) to guarantee the safety of products, the health of patients, and adherence to the standards of the industry.

- When an API batch/material does not satisfy the extraneous matter specifications of a customer, the pharmaceutical company can ship it to a different customer who does not have such requirements. This is very risky and has an implication on patient safety because of non-compliance.
- Quality of products is the responsibility of all drug manufacturing employees, and the survey results indicate that all employees favor a specific person.
- Participants of the study confirm that violations of Standard Operating Procedures, as well as data integrity issues in the pharmaceutical industry, are being contributed by the company owner, top management, site management, department heads, supervisors, and employees.
- The sphere of quality control has a big gap, as there is no effective way of eliminating foreign particles within the active pharmaceutical ingredients in Indian pharmaceutical companies. There must be a controlled system that is mandatory to avoid contamination and also to improve the quality of the products.

4. DISCUSSION

This survey research reveals the high gap and noncompliance practice of the pharmaceutical manufacturing system. This will be a good chance for all the stakeholders and pharmaceutical companies concerned with the production of active pharmaceutical ingredients to evaluate and improve their quality management systems. The study has also been carried out using a small sample. A researcher can also extend to a larger group in case they wish to. Such survey-based research should be encouraged all over the world, and the regulatory bodies should emphasize more such kinds of investigations to make sure that the safety of patients is maintained.

5. CONCLUSION

The therapeutic efficacy of any pharmaceutical product lies in the Active Pharmaceutical Ingredient (API). This particular issue of foreign particulate contamination of APIs is quite dangerous to the health of the patients, and the effects of the problem are effectively unknown. Although it is technically impossible to achieve complete removal of such foreign particles, there is the need to reduce their occurrence. Although a zero-defect standard that APIs should meet is not supported by regulatory bodies, such as the FDA and EMA, they do give a list of effective ways to manage contamination. Patient safety against contaminated pharmaceuticals is also a necessity, and this has resulted in the undertaking of a gap analysis study involving 6 pharmaceutical quality systems.

This was followed by a set of questionnaires, which were distributed to the experts in the pharmaceutical industry concerning logistical, technical, and good manufacturing practices (GMP), where an estimated number of 160 responses were received using Google Forms. The aim of the evaluation is to determine that the acceptance of quality and safety among the participants is at least 80 percent under the set standards. The results indicate that critical management systems, which are the Pharmaceutical Quality System and the Pharmaceutical Production System, are important in the contamination issues related to APIs.

It was analyzed that 42 of the 98 survey questions did not pass the acceptance criteria, and the failure rate was 42.85. The results of research have recognized Pharmaceutical Quality Systems, Pharmaceutical Laboratory Control Systems, and Pharmaceutical Production Systems, amongst other poorly controlled systems. The questionnaire has brought into the limelight a number of relevant issues in regard to good manufacturing practices (GMP). The knowledge contained in this report is expected to help all the concerned parties improve their practices and systems to meet the current GMP standards.

The GMP questionnaire survey has been conducted successfully as per protocol to detect the gaps in the six pharmaceutical quality systems and prevent the occurrence of the foreign particulate contamination in active pharmaceutical ingredients. As a preventive measure, the pharmaceutical industries should also upgrade the automated system in the manufacturing and analysis of active pharmaceutical ingredients in order to reduce the interference of human beings.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DISCLAIMER

Authors of this publication bear full responsibility, and this research does not aim at targeting and acquiring any information about a company. This research study is aimed at enhancing the whole pharmaceutical company. With this, the sole aim is to minimize the pollution of the foreign particles in the products manufactured by the pharmaceutical company. Only the purpose of the research is connected with the concept of patient safety.

ABBREVIATIONS

APIs: Active Pharmaceutical Ingredients

USFDA: United State Food and Drug Administration

QMS: Quality Management System

QR code: Quick Response Code

GMP: Good Manufacturing Practices

SOP: Standard Operating Procedure

APIC: Active Pharmaceutical Ingredients Committee

PPE: Personal Protective Equipment

IR: Infrared

USP: United State Pharmacopoeia

EP: European Pharmacopoeia

EMA: European Medicines Agency

APPENDIX

Survey report

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