



**INTERNATIONAL JOURNAL OF
PHARMACEUTICAL SCIENCES**
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: <https://www.ijpsjournal.com>



Review Article

Revised Schedule M 2023 & Pharmaceutical GMP in India: Regulatory Evolution, Compliance Challenges, Digital Transformation and Future Perspective

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ARTICLE INFO

Published: 26 Oct 2026

Keywords:

Revised Schedule M, Good Manufacturing Practices (GMP), Quality Risk Management, Data Integrity, Pharma 4.0, Coldrif

DOI:

10.5281/zenodo.23658864

ABSTRACT

The new update to Schedule M under the Drugs and Cosmetics Rules is dated December 28, 2023. The update represents one of the most significant changes in India's Good Manufacturing Practices (GMP) since they were introduced in 1988. In the course of this article, I will discuss the evolution of regulations. They were amended in 2001 and 2005, and now there is another revision of the GMP. This update aligns India's regulations with those of the World Health Organization (WHO) and the International Council for Harmonisation (ICH). In this article, we will analyze different aspects of the schedule such as pharmaceutical quality system, quality risk management, qualification and validation, change control, record-keeping, computerized systems use and specific requirements for various products that are presented in Parts 2-13. The article will pay attention to the challenges of implementing the new rules, particularly in the case of MSMEs. These companies usually face financial and human resource limitations, which may influence not only product quality but also integrity of data. The integration of digitalization, Industry 4.0, AI/ML technologies and continuous manufacturing into GMP requirements will also be discussed in this paper. The article will also provide an overview on the impact of the Coldrif cough syrup incident that occurred in India. This tragedy serves as an example of what can happen when GMP rules are not followed, and we'll look ahead at the future of Pharma 4.0.

INTRODUCTION:

Background & Evolution of GMP in India

Drug and Cosmetic Act, 1940 is act before independence during the British rule, passed by the British assembly under the Government of India Act, 1935 as the Drug Act, 1940. In later year 1962, word

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



“Cosmetics” was also been added in the Drug Act, 1940 from then on the Act renamed as the Drug and Cosmetics Act, 1940.^[1]

The part of good manufacturing in Drug and Cosmetics Act 1940 was mentioned firstly in Schedule M of Drug and Cosmetics Act 1940 & Rules 1945, in the year 1988 the further amendments came in year 2001, 2005 and recent amendment came in 2023 that handles good manufacturing practices for pharmaceutical industries in India. The Schedule M provides the roadmap on Good Manufacturing Practices regarding company premises, quality control system, quality check laboratories, production, cleaning of equipment, housekeeping, cross-contamination, and other related topics.^[2]

The Good Manufacturing Practices are designed to ensure the use of the raw materials in the process of manufacturing are original as well as of good quality and most importantly free from contamination. The process of manufacturing the pharmaceutical products should be documented and properly maintained for the audits and inspection purposes.^[3]

Key Regulatory Changes under Revised Schedule M

The revised Schedule M 2023 describes an important government notice which introduces the changes in the Good Manufacturing Practices. The notice include the following major changes:-

1. There is change in requirements for designing the facility, validation of the equipments used in the pharmaceutical industry as well as monitoring of the environment.
2. The revised Schedule M has increased focus on the documentation, maintaining the batch records and promoting the electronic data management.
3. Compulsory risk based quality management systems and time to time re-validation of the processes used in the pharmaceutical industry.
4. Guidelines to integrate the Indian standards with WHO-GMP and International Council for Harmonization (ICH) principles.^[4]

The World Health Assembly a governing body of the WHO has adopted many regulatory decision to form global standards, instructions and instruments to help maintain the quality of the medicinal products whether

they are manufactured and being marketed or traded globally.^[5]

Detail Architecture of Revised Schedule M

In 1988 the Schedule M was officially added in Drugs and Cosmetics Act 1940 and Rules 1945 forming the limited standards for manufacturing and practices in the pharmaceutical industries. It included basic regulations for Good Manufacturing Practices. In 2001 the modification in Schedule M came to align with the global Good Manufacturing Practices (GMP) as the pharmaceutical sector grew in India. The modification that came in 2001 focused on the improvement of the infrastructure of facilities as well as sanitation, documentation and record maintenance. Later in 2005 another modification was introduced in the Schedule M that gave greater importance to enhancing standards for plant design. The major weightage was given to the cleanliness, plant layout and training of personnel working in the pharmaceutical industries. The recent major modification was notified on 28 December, 2023 that aims at moving towards global regulatory alignment. The revised Schedule M includes key addition of advanced equipments, improved guidelines for risk management, data integrity and validation instructions.^[6]

The revised Schedule M, primarily aims towards quality management process of the pharmaceutical products. The Schedule M provides direction on Good Manufacturing Practices in relation to company premises, quality control system, quality check laboratories, production, cleaning of equipment, housekeeping, cross-contamination, and other related topics.

New Schedule M

GMP Standards and Requirements for Pharmaceutical Premises, Plants and Equipment.

Part 1

- Pharmaceutical Quality System (PQS)
- Quality Risk Management (QRM)
- GMP for the pharmaceutical products
- Sanitation and Hygiene Practices
- Qualification and Validation



- Product Recall
- Change Control
- Equipment's material
- Waste materials
- Documentation
- Computerised System

Part 2 to Part 12

Part 2 - Specific requirements for manufacture of Sterile Products, Small & Large Volume Parenterals, Ophthalmic Preparations.

Part 3 - Specific requirements for manufacture of Hazardous substances such as Sex Hormones, Steroids or Cytotoxic substances.

Part 4 - Specific requirements for manufacture of Biological Products.

Part 5 - Specific requirements for manufacture of Radiopharmaceutical Products.

Part 6 - Specific requirements for manufacture of Phytopharmaceutical Products.

Part 7 - Specific requirements for manufacture of Investigational Pharmaceutical Products for Clinical Trials in Human.

Part 8 - Specific requirements for manufacture of Oral Solid Dosage Forms.

Part 9 - Specific requirements for manufacture of Oral Liquids.

Part 10 - Specific requirements for manufacture of external Preparations.

Part 11 - Specific requirements for manufacture of Metered Dose-Inhalers.

Part 12 - Specific requirements for manufacture of Active Pharmaceutical Ingredient.

Part 13

Plant and Equipment requirements for different Pharmaceutical Products.^[7]

Implementation Challenges for Indian Manufacturers

The revised Schedule segregated the manufacturers of pharmaceutical products into different sections on the

basis of their revenue, the companies with the annual income more than 250 crore had to meet the requirements within 6 months and the companies who have less than 250 crore had 12 months. For the micro, small and medium enterprises financial barriers are the major obstacles for compliance with the operational facilities, machinery, documentation system because it requires substantial investment. Human resource limitation create more difficulties for compliance, the revised schedule M need well trained personnel in staff for operating the new systems and techniques.^[8]

The revised Schedule M which was notified on 28 December 2023 under the Drug and Cosmetic Act 1940 and Rules 1945, which was published in early January 2024 included various essential aspects such as: pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, computerised storage and control of drug records. The revised Schedule M has given greater importance to pharmaceutical facilities, worksite and machinery. The amendment intended to optimise adherence to quality standards concurrently aligning the Indian industrial production with the global standards. The upgradation means not only meeting the basic regulations of the government but follow the regulations and properly document, monitor, control as well as improve the quality of the manufacturing processes.^[9]

Impact of Revised Schedule on Pharmaceutical Quality

Good Manufacturing Practices simultaneously manages production and quality control in order to eliminate flaws at every step of production, quality control, skilled person examine the quality in all areas of production as an crucial part of the Good Manufacturing Practice. By controlling and eliminating errors at every step of production of pharmaceutical products while the quality control focuses on generating consistent final product. The modernisation of the revised Schedule by the Central Drug Standard Control Organization (CDSCO) improves mechanism of quality control to make sure that the pharmaceutical products persistently comply with the standards for ensuring the quality, safety and efficacy during the entire period of manufacturing process.^[7]



The existing clause of the Drug and Cosmetics Act 1940 and Rules 1945 needed upgradation to deal with new technological advancement, upgraded production processes and international quality standards.^[10] The specified requirements for quality, safety and efficacy of certain products and procedures that may raise risk to the consumer. Therefore the Quality Risk Management (QRM) system is incorporated in the Good Manufacturing Practices regulations of the New Schedule M. The process of analyzing the manageable risk and the scientific evidence of this assessment needed to be transparently available.^[11]

Data Integrity and Computerized System as per Revised Schedule M

Data integrity basically means to prevent the inaccuracies, to maintain integrity and uniformity of information across all stages of lifecycle. In the pharmaceutical industries the results developed during the production of the pharmaceutical product and distribution straightaway result in patient safety and treatment beneficial effects. The pharmaceutical industries works within tightly regulated surrounding where each conclusion must be supported by the reliable results. From the beginning of the drug discovery till the post marketing monitoring the pharmaceutical companies produces enormous about data that should be meticulously handled and stored. This data is used as framework for the regulatory submission, for making production choices, quality control measures and safety analysis. As the new technological advancement coming in the industry managing the data integrity has become more difficult. The automated system handles everything from the test result to production information producing both positive outcomes as well as potential risk. The pharmaceutical companies should assure that all the information digital or mentioned on the paper are correct, consistent and maintained in the there generated form.^[12]

The individual batch manufacturing records should be electronically saved and shall be secured by the appropriate back-up. While the duration of continuation, all the related information should be easily accessible.^[13]

Digitalization and Industry 4.0 for GMP Compliance

Digital transition has emerge as a major influencing factor in changing the production industry scenario including the highly stringent and quality focused pharmaceutical field. The utilization of the digital advancement involves more than an operational tool but the major context of planning is optimising the compliance with Good Manufacturing Practices (GMP) objectives and enhancing the manufacturing process reliability. The incorporation of the advance technologies like Artificial Intelligence (AI), Internet of Things (IoT), provides an opportunities for real time monitoring of manufacturing processes and information based on that determining appropriate actions. Many pharmaceutical manufacturers are facing the difficulty to coordinate the older systems with new technological upgradation and to match the GMP regulation.^[14]

The pharmaceutical industry 4.0 describes the harmonization of the Internet of Things (IoT), computer integrated physical system into the pharmaceutical production surrounding. In pharmaceutical industry, this systems helps for the real time monitoring, automated operations and important decision process. Key technological advancement include AI, IoT, machine learning and robotics. These systems collaboratively increases the process efficiency and decrease variability in pharmaceutical manufacturing mechanism.^[15]

AI/ML in GMP Compliance

The pharmaceutical industries are in the understanding and development phase the way to demonstrate the application of the various systemic advancement like Artificial Intelligence in the GMP guidelines manufacturing environment.^[16] The Artificial Intelligence (AI) and Machine Learning (ML) technologies are rapidly advancing area, including the healthcare and pharmaceutical production. In the pharmaceutical industry the Good Manufacturing Practices can enhance the batch manufacturing, quality control, and improving the real time monitoring of the quality by the help of AI/ML. Despite the beneficial outcome of the AI/ML the pharmaceutical regulatory remain alert due to undefined algorithms and increase in the risk due better understanding of the system. The AI/ML helps in the continuous learning and as better decision making ability.^[17]



The practical implementation of the Artificial Intelligence (AI) and Machine Learning (ML) evolved rapidly in the recent years. Large amount of the information from the quality system, digital devices and PAT system provides the new insights that is not possible by the conventional analytical techniques.^[18] Good Manufacturing Practices are made mandatory for ensuring that guidelines met the manufacturing process. However, the AI can help automation for compliance with real time monitoring and documentation.^[19]

Continuous Manufacturing and GMP Compliance

Continuous Manufacturing is a newly developed and innovative concept, as it reduce the middle unnecessary stages. The entire manufacturing process of the pharmaceutical products are performed systematically in single unit of instruments and facilities, with not a single product moved from one manufacturing location to another location or unit of instruments to another. In simpler words the raw material enters in the instrument used in the production of the pharmaceutical products and exits as the fully finished product in the specified duration. In Continuous Manufacturing the process of manufacturing the products never pause or comes to end. The continuous manufacturing is an innovative concept to the production of pharmaceutical products that is entirely opposite to the conventional method of manufacturing the drug products.^[20]

The Good Manufacturing Practices is an integral part of the quality management assure the quality of the pharmaceutical products regulate it according to the suitability requirements for use. It needs all the production processes to be clearly mentioned, checked on daily basis and show defined production in order to assure the quality. It is achieved through trained and responsible personnel, suitable equipment and facilities, proper documentation, well-controlled manufacturing processes, and timely investigation and correction of quality defects and deviations.^[21] The introduction of the continuous manufacturing under the principle of the International Council for Harmonization (ICH) Q13 that need all the pharmaceutical manufacturing plant to primarily illustrate higher level of method understanding in reference to the conventional batch manufacturing concept, completely integrating

Quality by Design principle. This understanding should not be limited to traditional batch processes. It should also consider process behaviour during startup and shutdown and how process disturbances can affect the entire continuous manufacturing system.^[22]

Case Study of the GMP Compliance

The cough and cold syrup known as Coldrif became the main concerning topic due major health tragedy in India, due to occurrence of several number of deaths in the children below specific age group roughly below 5-6 years old. After this tragedy, came into notice the reason of such severe tragedy, how it occurred, the actual reason for it, severity of the event and how we can avoid such tragic events. The Coldrif was a paediatric cough syrup that was in use from a very long time across some regions of India to cure symptoms like cough, nasal congestion, allergic rhinitis and fever. From the available sources the Coldrif is cough/flu paediatric syrup. The manufacturers of this Coldrif cough assure that all the ingredients used such as excipients was of standard quality but when the investigation by the regulatory officers was carried out they found out contamination of Diethylene Glycol (DEG) above the acceptable limit range.

Every active pharmaceutical ingredient used in the formulation of Coldrif cough syrup has individual mode of action for example H1 antihistamine inhibit H1 receptor which decreases rhinorrhea and sneezing, decongestant produces the vasoconstriction of nasal mucosa, the analgesic and antipyretic effect lower pain and fever. The therapy like combination therapy majorly focuses on the therapeutic relief. The general side effects of the accepted level cough syrup contains drowsiness, irritability, nausea, dry mouth and palpitations. There are some more potentially harmful effects when the formulation over-dose occurs or misuse is done, the effects like seizures, tachycardia, hypertension, impaired breathing they may be life threatening. Precise dosing is essential in children due to smaller safety margins.

The health crisis reached to peak level in October, 2025 the death of 20-25 children around the age group of 5 died in Chhindwara district of Madhya Pradesh after the consumption of Coldrif cough syrup. After that the



sample was tested in the laboratory so, the laboratory result exposed the contaminated batch of the syrup contained Diethylene Glycol above the approved limits (500 times more amount). Due to consumption of DEG which is harmful and toxic chemical used in the industry children lead to problems like damage to the kidney, multiple organ failures, damage to brain and even death. The main factor behind occurrence of this tragedy is lacking of Good Manufacturing Practices, inappropriate testing of the raw material used in the manufacturing, lack of effective regulatory control.

Reacting to the health crisis in India, Indian State Government officially prohibited Coldrif and commissioned recall of syrup as well as the Central Drug Standard Control Organization informed World Health Organization (WHO) and published medical product alert for the contaminated oral liquid preparation in India. The revised manufacturing and testing regulation regarding the DEG and strict GMP compliance was mandate.^[23]

Future Direction and Pharma 4.0

Numerous advancements are coming in the technologies and their role in the pharmaceutical industry is increasing rapidly. Upcoming innovations of Artificial Intelligence, IoT and other systems may enhance the precision and accuracy of the processes of pharmaceutical industry. Evolving digital technologies like Quantum computing, advanced machine learning algorithms and more technologically advanced systems may strengthen the process of drug discovery, manufacturing procedure and supply chain management. The transition towards the automated systems in the field of pharmaceutical industry indicate the important future path for the pharmaceutical industry. The collaboration of different digital system will be required and regulatory structure will be needed for the assuring the efficacy and safety of the pharmaceutical products.^[24]

Pharma 4.0 represents a digital operating model for pharmaceutical organizations that integrates advanced technologies, including Big Data, interconnectivity, collaborative robotics, virtual and augmented reality, 3D printing, blockchain, and cloud-based systems to support modern pharmaceutical operations. Pharma 4.0

is bringing changes to the way pharmaceutical companies operate, compete, and respond to market needs. Since every organization has different requirements, the approach to digitization may also vary between companies, supply chains, regions, and markets. It provides better visibility of operations and supports faster decision-making by making important information available when needed. It also helps companies monitor processes and maintain product quality more effectively. The use of data analysis can further improve process reliability, product quality, productivity, and overall performance. These improvements can ultimately support safer and more efficient pharmaceutical manufacturing.^[25]

CONCLUSION:

The Revised Schedule M 2023 represents a shift from the minimum requirements of pharmaceutical manufacturing in India towards a risk-based, well-documented, and high-quality controlled process following global regulations. The key areas of focus for the revised schedule are pharmaceutical quality system, quality risk management, validation, and data integrity to ensure complete control over the production processes. Yet, the implementation of these changes faces risks, especially for small and medium-sized companies, due to the high costs and lack of knowledge about the new standards.

The case of Coldrif proves that the inadequate testing of raw materials, poor compliance with GMP, and weak regulation result in tragic outcomes for the health of the population, especially children. Therefore, it is necessary to adhere to the requirements of the revised schedule in order to guarantee the safety of the patients and prevent similar problems. Technologies that involve artificial intelligence and machine learning, the Internet of Things, and continuous manufacturing processes, as part of the Pharma 4.0, may be helpful for this purpose. Nevertheless such tools will be effective only when the pharmaceutical companies invest in equipment and education meeting the high standards of Schedule M 2023.

In general, the updated regulations are a great opportunity to increase the quality and international reputation of the Indian generics market. Yet, it will require



strict adherence to the new standards and sufficient investment into employees' training and machinery upgrades.

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HOW TO CITE: Sarwadnya Ambadkar, Abhijeet Welankiwar, Revised Schedule M 2023 & Pharmaceutical GMP in India: Regulatory Evolution, Compliance Challenges, Digital Transformation and Future Perspective, *Int. J. of Pharm. Sci.*, 2026, Vol 4, Issue 10, 3938-3945. <https://doi.org/10.5281/zenodo.23658864>

