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Regulatory Landscape change in India Revised Schedule M

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Abstract: *A significant component of the Drugs and Cosmetics Act 1940, Rules 1945, is Schedule M. Maintaining or adhering to schedule M's requirements is essential for producing a product that is both of appropriate quality and beneficial for humans. The rules that primarily discuss Good Manufacturing Practices are included in Schedule M. When Schedule M was initially created in 2001, it was separated into Parts 1 and 2. Then, in 2018, it was more carefully divided into 12 parts than the initial one, which was created in 2001. Then, in 2024, it became more specific and was broken down into 13 parts, including the modifications made to Schedule M. These included the introduction a Pharmaceutical Quality System (PQS), Quality Risk Management (QRM), a Product Quality Review (PQR), and the Qualification and Validation of Equipment. The product will be more appropriate and useful for people thanks to these updated Schedule M. The updated Schedule M makes it simple to identify risks and determine if the product is upholding the quality system. The documentation will be recorded for future use in the updated Schedule M. Schedule M is an essential component of every manufactured product that humans utilize. Prior Schedule M provides little description of each subject, which frequently leads to issues. It is preferable to be revised.*

Keywords: *Drugs and Cosmetics Act*

I. INTRODUCTION

The collection of rules known as Schedule M primarily addresses good manufacturing standards for pharmaceutical products. It is covered by the 1940 Drugs and Cosmetics Act and the 1945 Regulations. All manufacturers adhere to it in order to create high-quality therapeutic products for people. Effective goods are those that are produced in accordance with regulations or norms.

It is a component of the quality assurance system, which verifies that the goods are regularly produced to standards suitable for their intended use. There are 13 segments in the updated schedule M. The updated schedule M places a specific emphasis on the buildings, plants, and equipment with the additional GMP criteria, whereas the current schedule M exclusively addresses good manufacturing practices. (Mainville J 2025)

Product quality review (PQR), pharmaceutical quality system (PQS), quality risk management (QRM), equipment qualification and validation, and computerized storage systems for all goods are further areas of emphasis. It also emphasizes self-inspection and risk control. This will contribute to the drug's efficacy, safety, and quality. The updated timetable is more topic-specific and aids in producing an efficient and high-quality result. As is well known, schedule M is crucial, and manufacturers closely adhere to it. (World Health Organization 2024; 31)

1. Regulatory Framework in India

The Indian pharmaceutical industry is widely acknowledged as one of the biggest manufacturers of generic medications, providing more than 200 nations with reasonably priced, high-quality medications. India's regulatory system has consistently changed to conform to international norms to preserve its reputation abroad and guarantee patient safety. Schedule M of the Drugs and Cosmetics Rules, 1945, which establishes standards for Good

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Manufacturing Practices (GMP) and facilities for pharmaceutical manufacturing, controls a large portion of this regulatory environment. (Madanayake SN 2024)

Since its initial notification in 1988 and subsequent significant revision in 2001, Schedule M has served as the benchmark for manufacturing procedures in India. However, the Central Drugs Standard Control Organization (CDSCO) and the Government of India realized that the framework needed to be updated to better align with WHO-GMP, PIC/S (Pharmaceutical Inspection Co-operation Scheme), and ICH (International Council for Harmonization) guidelines due to the rapid advancements in science, the need for global harmonization, and the growing demand for exports. (Madanayake SN 2024)

With the release of the Revised Schedule M by the Ministry of Health and Family Welfare in August 2023, India's regulatory environment underwent a dramatic change. To improve the quality culture, compliance, and global acceptance of Indian pharmaceutical products, this change is seen as a transformative reform.

The laws, regulations, guidelines, and procedures set up by national and international authorities to guarantee that medications are safe, effective, and of the highest caliber before they are administered to patients are referred to as regulatory in the pharmaceutical sector.

Pharmaceutical businesses must adhere to this set of rules and compliance specifications at every stage of the medication lifecycle, from development to marketing and post-marketing monitoring. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

II. WHY IS REGULATION NEEDED IN PHARMA?

- Patient Safety - to guarantee the safety of medications.
- Drug Efficacy - To confirm medicines work as intended.
- Quality Assurance – To maintain consistency in manufacturing and prevent contamination.
- Market Authorization – To approve only those drugs that meet required standards.
- Global Trade – To harmonize practices for export and international acceptance.

The regulatory system in the pharmaceutical sector refers to the set of laws and organizations that make sure medications are created, produced, tested, and distributed in a way that ensures patient safety, effectiveness, and quality. It serves as a link between patients, government, and industry, ensuring that innovation is promoted while public health is safeguarded. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

III. WHAT IS SCHEDULE M

Under the 1940 Drugs & Cosmetics Act, Schedule M is a part of the 1945 Drugs & Cosmetics Rules. It specifies the facilities, machinery, and equipment needed for the Indian pharmaceutical business as well as the Good Manufacturing Practices (GMP) standards. To put it simply, it establishes the minimal requirements for quality that all pharmaceutical producers must meet in order to guarantee that their products are safe, efficient, and of constant caliber. (Mishra L and Kurmi BD 2023)

3.1 Objective of Schedule M

- To guarantee consistent quality standards in India's pharmaceutical manufacturing industry.
- To bring Indian manufacturing into compliance with global GMP standards.
- To establish policies regarding personnel, facilities, equipment, paperwork, and quality control.
- To reduce the possibility of contamination, misunderstandings, and mistakes in order to protect public health. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

3.2 Importance of Schedule M

- Provides the legal framework for GMP in India.
- Ensures uniform standards across states, avoiding quality variations.
- Increases acceptability of Indian drugs in global markets.

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- Protects patients from substandard/spurious medicines.

Encourages quality culture and risk-based compliance within the industry. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

IV. DETAILED ANALYSIS OF REVISED SCHEDULE M

A. Objectives of the Revision

- Using a risk-based approach, manufacturing may now implement Quality Risk Management (QRM).
- Culture of Quality: Shifting from a compliance-based approach to ongoing quality enhancement.
- Ensuring the dependability, security, and effectiveness of medications is known as patient safety.
- Export Competitiveness: Increasing credibility and lowering global warnings.
- Putting Indian GMP on par with WHO and PIC/S GMP is known as global alignment. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

B. Major Changes in Revised Schedule M Quality Management System (QMS)

- Creation of an ICH Q10-aligned Pharmaceutical Quality System (PQS).
- Combining the duties of management, production, QA, and QC.
- Increased emphasis on continuous improvement, CAPA (Corrective and Preventive Action), and management reviews. (Dey S, Dutta S and Ray J 2025)
- Risk-Based GMP
- Acceptance of the concepts of quality risk management, or QRM.
- Risks to the quality of the product are identified, assessed, and controlled.
- Use of risk-based decision-making in change control, validation, and addressing deviations. (Dey S, Dutta S and Ray J 2025)

C. Facility & Equipment Requirements

- Dedicated Facilities mandatory for high-risk products such as:
- Penicillin’s, Beta-lactams
- Cytotoxic drugs
- Hormones
- Sex hormones and immunosuppressant’s

Stricter norms for:

- HVAC systems (Heating, Ventilation, Air Conditioning)
- Cleanroom classification (like EU GMP standards).
- Contamination Control Strategy (CCS).
- Equipment qualification (IQ, OQ, PQ) is now mandatory. (Dey S, Dutta S and Ray J 2025)

D. Validation & Qualification

- Process validation is compulsory for all critical processes.
- Cleaning validation to prevent cross-contamination.
- Analytical method validation in QC labs.
- Re-validation required periodically and after major changes. (Dey S, Dutta S and Ray J 2025)

E. Documentation & Data Integrity

- Strengthened requirements following ALCOA+ principles:
- Attributable, Legible, Contemporaneous, Original, Accurate (+ Complete, Consistent, Enduring, Available).
- More detailed SOPs, logbooks, and electronic data management.

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- Emphasis on data security, traceability, and audit trails. (Zothanpuii F, Rajesh R 2020)

F. Personnel & Training

- Outlined duties for the heads of production, quality assurance, and quality control.
- Regular, structured training sessions for employees at all levels.
- Records of training must be kept up to date and examined during inspections. (Zothanpuii F, Rajesh R 2020)

G. Quality Control & Microbiology Labs

- Separate spaces for chemical, instrumental, and microbiological testing are required in QC labs.
- Improved standards for microbiological and sterility testing.
- Documentation of source material, in-process, and final product testing is required. (Zothanpuii F, Rajesh R 2020)

H. Product Lifecycle & Distribution

- Procedures for recall must be followed and evaluated on a regular basis.
- System for managing complaints that incorporates CAPA and root cause analysis.
- Better conditions for storing APIs, excipients, and final goods.
- Emphasis on traceability and serialization. (Zothanpuii F, Rajesh R 2020)

I. Environmental & Safety Measures

- ETPs, or effluent treatment facilities, must be established by manufacturers.
- Appropriate disposal of discarded, rejected, and expired goods.
- Safe management of biologicals and dangerous substances.
- Integrated sustainability concepts. (Zothanpuii F, Rajesh R 2020)

V. OLD SCHEDULE M: SCHEDULE M WAS FIRST DIVIDED INTO 2 PARTS

Part I:

Proper manufacturing procedures for the materials and facilities.
Additionally, it had a section that ran from 1A to 1F.

Part II:

Requirements of Plant and Equipment:

✔ External Preparations.
✔ Oral Liquid Preparations
✔ Tablets
✔ Powders
✔ Capsules
✔ Surgical Dressing
✔ Ophthalmic Preparation
✔ Pressurizes and suppositories
✔ Inhalers and Vitalie
✔ Repacking of Drugs and Pharmaceutical Chemicals
✔ Parenteral Preparation

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VI. PROPOSED SCHEDULE M: SCHEDULE M WAS DIVIDED INTO 12 PARTS

Part I: Good Manufacturing Practices for Pharmaceutical Products.

✔ Part I is completely different.

✔ It is required to adhere to Part I, which is referred to as the "Main Principles," regardless of the product type under consideration.

✔ A section of the Appendix I that addresses the
Requirements for the Site Master File. (Souto EB, Silva GF 2020)

Part II to Part XII:

✔ Specifications for the production process, considering the various product types. E.g. Sterile products.

✔ Oral Solid dosage Forms etc.

✔ In comparison to the old Schedule M, there are five new categories that have been introduced.

Part XIII:

✔ Requirements of plant and equipment for manufacture of 11 kinds of Pharma goods.

✔ This portion is comparable to the earlier M 2001 schedule. (Souto EB, Silva GF 2020)

VII. NEW SCHEDULE M: GOOD MANUFACTURING PRACTICES AND PHARMACEUTICAL PRODUCT REQUIREMENTS FOR FACILITIES, PLANTS, AND EQUIPMENT

Part I:

✔ Pharmaceutical Quality system

✔ Quality Risk Management

✔ Good Manufacturing practices for pharmaceutical products.

✔ Sanitation and Hygiene

✔ Qualification and Validation

✔ Complaints and Adverse Reaction

✔ Product Recall

✔ Change Control

✔ Contract analysis and production under loan license or contract, among other things.

✔ Self-examination, supplier audits and approval, and quality audits

✔ Personnel

✔ Premises

✔ Equipment's

✔ Materials

✔ Reference Standard

✔ Waste materials

✔ Documentation

✔ Good Practices in Production

✔ Good Practices in Quality Control

✔ Computerized system

✔ Appendix – 1: Site Master File

Part II: Particular specifications for the production of ophthalmic preparations, small and large volume parental, and sterile products. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

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Part III: Particular specifications for the
Production of dangerous chemicals, including steroids, cytotoxic compounds, and sex hormones (recently added). (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Part IV: Particular specifications for the
Production of biological products (just added). (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Part V: Particular specifications for the production of radiopharmaceutical products (just added). (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Part VI: Particular specifications for the
Production of phytopharmaceutical products (just added). (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Part VII: Particular specifications for
Producing pharmaceutical products for human clinical trials (recently added).
Specific specifications for the production of
Oral solid dosage forms are outlined in Part VII.
Part IX: Particular specifications for oral
Liquid production. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Part X: Particular specifications for the production of external preparations.

Part XI: Particular specifications for the
Production of metered dose inhalers.

Part XII: Particular specifications for the production of active pharmaceutical ingredients. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Part XIII:
1. Equipment and Plant Needed for External Preparations.
2. Requirements of Plant and Equipment for Oral Liquid Preparations.
3. Requirements of Plant and Equipment for Tablets
4. Requirements of Plant and Equipment for Powders
5. Requirements of Plant and Equipment for Capsules
6. Requirements of Plant and Equipment for Surgical Dressing
7. Requirements of Plant and Equipment for Ophthalmic Preparation
8. Requirements of Plant and Equipment for Pessaries and Suppositories
9. Requirements of Plant and Equipment for Inhalers and Vitalie
10. Requirements of Plant and Equipment for Repacking of Drug and Pharmaceutical Chemicals. Requirements of Plant and Equipment for Parenteral Preparation. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)
8. Revised Schedule M Principles: Pharmaceutical Quality System (PQS):
It is a component of the pharmaceutical industries
Management system. A pharmaceutical quality system ought to be implemented for the product from the time of manufacture until it is shipped to the market. Every industrial company's top executive to detect the risk, there should also be high-quality risk management. Any flaws, variations, or other issues must be noted, investigated, and documented. Every phase should include a self-inspection or audit in order to identify and fix any mistakes.

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Through a comprehensive collection of rules, procedures, and practices, the Pharmaceutical Quality Management System (QMS) seeks to ensure and maintain consistent and excellent quality in the production of pharmaceutical goods. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Quality Risk Management:

It is a specialized instrument for evaluating the risk or flaws related to the production of the product and medication ingredients. We can deliver a high-quality product if we are able to mitigate the risks involved. The manufacturing and usage of pharmaceuticals, including component elements, are always fraught with risk. The danger to its quality is only one aspect of the whole risk.

It's important to understand that making sound risk- based decisions over the course of a product's lifecycle guarantees that the characteristics that are essential to the medical Product's) quality are maintained, and that the product remains safe and effective.

Implementing a successful PQS inside the organization is the duty. Only once the final product has been examined and verified can it be shipped. Corrective action and preventative action, or CAPA, should be upheld so that any issues with the product may be found via root cause analysis and prevented from happening again. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

FLOW CHART OF RISK IDENTIFICATION PROCESS

(Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Product Quality Review:

All pharmaceutical products must undergo rolling, periodic, or regular quality evaluations. Verify the consistency of the product process and quality parameters. The manufacturer should decide whether re-validation or the appropriate CAPA is necessary based on the quality evaluation report. CAPAs must be completed on schedule and incorporate a continuous assessment of their effectiveness.

Apart from ensuring the data is correct, the person responsible for product release should also ensure that the quality review is completed within the allocated time. Reviews of the quality of the products must be conducted and documented annually.

All previous evaluations must also be considered in each yearly review report.

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Some, but not all, of the following subjects should be covered in the report:

✔ Examination of the product's packaging and raw supplies.

✔ Analyzing the supply chain's traceability of active substances.

✔ Analyzing important process controls and final
product results, as well as researching and questioning each batch that didn't meet the required standards.

✔ An analysis of every change made to the methods or methods of analysis.

✔ An examination of the filed, approved, or rejected dossier variations.

✔ A review of the results of the stability monitoring program, including any negative trends. (Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

Sanitation and Hygiene:

Every step of the pharmaceutical production process must adhere to strict hygienic and sanitation regulations. Employees, facilities, containers, production materials, equipment, and cleaning and disinfecting products should all be included in the scope of sanitation and hygiene. Anything that has touch with the goods. Any possible sources of contamination must be eliminated. A program for hygiene and sanitization ought to be in place. Use soap and water to wash your hands. In order to prevent cross-contamination of the product, the garment must be clean. Employees working in the industrial sector must be free from any illnesses. (Shinde AA, Gurav AS, Chaudhari BP and at all 2024)

The Qualification and Validation:

More specific requirements are listed in the revised schedule M than in the prior one. It is important to determine the tools, processes, equipment, and procedures the business wants certified and validated. The key elements of the validation and qualification program should be outlined in a validation master plan. The design qualification (DQ), installation qualification, operations qualification (OQ), performance qualification (PQ) / process, and qualification (IQ) verification (PV) are really established and proofed using it. Requirements for re- validation and re-qualification must be clearly stated. Clearly defined who is responsible for doing validation tasks is necessary. Particular attention needs to be paid to cleaning techniques, analytical test procedures, and automated system validation. It also has a significant impact on the product's manufacture. (Mainville J 2024)

Production under Loan License or Contract and Contract Analysis and Other Activities:

The most important additions to Schedule M. Activities conducted under a certain arrangement and covered by GMP should be carefully specified, agreed upon, and critically regulated in order to prevent quality issues. A quality contract or agreement should include the following tasks: supply chain, tech transfer, subcontracting validation, batch releasing authority, changes or changes resulting from incidents or errors, quality control, in-process controls, etc.

The vendor's contract acceptor should regularly audit the site or sites and be aware of any risks associated with the work, product, or testing that might put people, property, equipment, etc. in danger. The technical provisions of the contract should be developed by qualified persons who possess the requisite knowledge of process technology, analysis, and good manufacturing practices. (Weaver E, O'Hagan C 2022)

Computerized System:

Important part on current regulatory bodies' approach. This section provides detailed information about computerized systems' qualifications, validation, review, and data management. The complexity, variety, and criticality of the system must all be considered while doing validation. The electronic system must be modified in accordance with a change procedure that upholds and approves each and every record. These documents will demonstrate that the system is verified and maintained current. In order to prevent records from being permanently lost due to system failure or collapse, a backup system must be in place. Adequate security measures must be in place to prevent unauthorized access or data alteration in computerized systems. (Weaver E, O'Hagan C 2022)

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Waste Materials:

A specific location must be used for the safe and appropriate storage of waste items. Separating waste items from one another is essential. Toxic and flammable goods must be kept in separate, closed cabinets that are properly built. Sewage and solid, liquid, and gaseous effluents are removed. The manufacturing sector needs to follow the Board for Environment Pollution Control's guidelines. The Biomedical Waste Products criteria must be followed when getting rid of any biomedical waste. It is prohibited for fumigating agents, insecticides, rodenticides, and sanitizing supplies to contaminate equipment, starting materials, packing materials, manufacturing processes, or finished items. It is best to dispose of waste stuff in the trashcan. (Patel KT and Chotai NP 2013)

IX. CONCLUSION

It is determined that the pharmaceutical business finds both the new and current schedule M to be highly beneficial when producing a product. Compared to the updated schedule M, the current schedule M is more thoroughly explained. The new schedule M is more exact and has 13 sections instead of the previous 12 parts. Schedule M primarily discusses excellent manufacturing procedures, as is well known. The requirements for radiopharmaceuticals, phytopharmaceutical, and experimental pharmaceutical items used in clinical studies are not covered by the current schedule M. Maintaining safety, effectiveness, and quality while creating a good pharmaceutical product is made easier with a proper timetable.

Comparison with Schedule M and revised Schedule M

Sr. No.	Content	Schedule M	Revised Schedule M
1	Sanitation	It solely covers employees and production facilities.	Employees, machinery, supplies, production space, containers, and closing systems are all covered.
2	Qualification/ Validation	It covers only manufacturing process, testing and cleaning	It covers premises, utilities and equipment.
3	Product Recall	There was no provision to inform the LA.	Should be informed to LA, Comprehensive system specifies for Prompt and effective Recall.
4	Compliance and Adverse drug reaction	LA should be notified, since the comprehensive system calls for efficient and timely recall.	This involves poor manufacturing, deteriorating products, and significant issues with quality.
5	Change Control	Only in case of significant change	This includes modifications to buildings, utilities, equipment, labeling, packaging, analytical techniques, and standards.
6	Production	This include changes to structures, utilities, machinery, packaging, labeling, standards, and analytical methods.	This covers the roles and responsibilities of contract giver, acceptor agreement.
7	Self-inspection/ quality audit/ supplier audit/ approval	Carried out both regularly and on special occasions, such as during recalls and third-party inspections.	Auditing and approving suppliers at least once a year
8	Materials	-	Digital storage system that has been verified. With the exception of specialized facilities, reworking rejected items into a new batch number, and repurposing portions of previous batches into a batch of the same product at a specified manufacturing stage, identify the test for

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			each container. Retest date extension
9	Reference standard	-	IP RS/IS was obtained For The working Standard From the IPC method.
10	Documentation	Master Formula Record (MFR), Standard Operating Procedure (SOP) in hard copy for verification	Audit trail to guarantee traceability, recorded proof, and MFR—the amount Of time allowed for intermediates and in-process materials to be held.
11	Sterile Products	Schedule M has the requirement, although it makes no mention of the most recent one.	distinct, thorough clauses pertaining to certain criteria
12	Hazardous materials, hormones, steroids, cytotoxic	Separated/isolated production regions within the building with differing AHU and pressure differential, but no explicit provision about the requirements for manufacturing such a product	Distinct comprehensive clauses pertaining to distinct criteria.
13	Biological-Radiopharmaceutical, clinical trials	No such explicit clause on the prerequisites for producing such a product	Distinct comprehensive clauses pertaining to distinct criteria.
14	Pharmaceutical Quality system (PQS)	No section in existing schedule M	Newly added. Specific requirements are mentioned separately
15	Quality Risk Management	No section in existing schedule M	Separate section for risk management systems

(Dey et al., IJPSR, 2025; Vol. 16(3): 663-669.)

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