ISSN: 2231-3656

International Journal of Pharmacy and Industrial Research (IJPIR)

IJPIR |Vol. 16 | Issue 3 | Jul – Sep 2026

www.ijpir.com

DOI: https://doi.org/10.61096/ijpir.v16.iss3.2026.1356-1373

Beyond Final Testing: Building Quality Through in-Process Quality Control In Pharmaceutical Manufacturing

B.Rakesh*, Dr.L.V.Vigneshwaran, Dinesh.S, Abu Bakker.A, Madhu.P

Department of pharmaceutics, RKP College of Pharmacy, Krishnagiri, Tamilnadu

Corresponding author: **B. Rakesh***
Gmail Id:jbrakesh1234@gmail.com

Published on: 17.08.2026
Published by: Futuristic Publications

Abstract: The pharmaceutical industry is responsible for ensuring that medicinal products are consistently manufactured to meet the highest standards of quality, safety, and efficacy. In-Process Quality Control (IPQC) is an integral part of pharmaceutical quality assurance that involves continuous monitoring and testing of materials, manufacturing processes, and finished dosage forms throughout production. The primary objective of IPQC is to detect process variations at an early stage, implement timely corrective actions, and maintain batch-to-batch consistency while ensuring compliance with regulatory requirements and Good Manufacturing Practices (GMP). This review provides a comprehensive overview of the principles, objectives, and major stages of IPQC, including in-process checks, manufacturing operations, sampling, in-process testing, and packaging controls. It also summarizes the critical in-process quality control tests performed for solid, semisolid, liquid, and sterile dosage forms, such as hardness, friability, weight variation, content uniformity, disintegration, pH, viscosity, sterility, particulate matter, and leakage tests. Furthermore, the review discusses the importance of pharmaceutical documentation, including Standard Operating Procedures (SOPs), Batch Manufacturing Records (BMRs), Master Formula Records (MFRs), Drug Master Files (DMFs), Common Technical Documents (CTDs), and audit trails, in maintaining data integrity, traceability, and regulatory compliance. The effective implementation of IPQC enhances manufacturing efficiency, minimizes product rejection, reduces process deviations, and ensures the consistent production of safe, effective, and high-quality pharmaceutical products that comply with pharmacopeial standards and global regulatory expectations.

Key Words: In-Process Quality Control (IPQC), Pharmaceutical Manufacturing, BMR, MFR, Pharmaceutical Documentation.

INTRODUCTION

The pharmaceutical industry plays a vital role in the healthcare system by developing, manufacturing, and supplying medicines for the prevention, diagnosis, and treatment of diseases. The development of a pharmaceutical product is a systematic process involving drug discovery, preclinical studies, clinical trials, formulation development, manufacturing, and regulatory approval. Throughout these stages, maintaining product quality is essential to ensure patient safety, therapeutic effectiveness, and regulatory compliance. Regulatory authorities such as the United States Food and Drug Administration (US FDA), European

Medicines Agency (EMA), Therapeutic Goods Administration (TGA), and the World Health Organization (WHO) require pharmaceutical products to meet established standards of identity, strength, quality, purity, and stability before they are released for public use [1].

Quality is a fundamental principle in pharmaceutical manufacturing and refers to the ability of a product to consistently meet predetermined specifications and perform its intended function. High-quality pharmaceutical products are achieved through the careful selection of raw materials, validated manufacturing processes, qualified equipment, trained personnel, environmental control, and continuous quality monitoring. Good Manufacturing Practices (GMP) provide a framework to ensure that pharmaceutical products are consistently produced and controlled according to established quality standards.

In-Process Quality Control (IPQC) is an important component of pharmaceutical quality assurance. It involves monitoring and testing materials and manufacturing operations before, during, and after production to ensure that each stage of the process complies with predefined quality requirements [2]. IPQC helps identify process deviations at an early stage, allowing timely corrective actions to prevent defects and maintain process consistency. It also minimizes manufacturing losses, reduces product rejection, and improves batch-to-batch uniformity.

During manufacturing, in-process materials are evaluated for critical quality attributes such as identity, strength, purity, moisture content, weight variation, hardness, viscosity, pH, sterility, and other parameters depending on the dosage form. Only materials that satisfy the specified acceptance criteria are permitted to proceed to the next stage of production.

The implementation of an effective In-Process Quality Control (IPQC) system not only ensures compliance with regulatory requirements but also enhances manufacturing efficiency and product reliability[3]. Continuous monitoring of critical process parameters enables manufacturers to identify deviations promptly, implement corrective actions, and maintain consistent product quality throughout the production cycle

A Finished Pharmaceutical Product (FPP) is a medicinal product that has completed all manufacturing stages, including final packaging and labelling. Every manufacturing operation, from raw material receipt to processing, packaging, labelling, and product release, is performed according to Standard Operating Procedures (SOPs). These written procedures ensure consistency, support regulatory compliance, and facilitate accurate documentation. Therefore, an effective IPQC system, combined with GMP and proper documentation, is essential for producing safe, effective, and high-quality pharmaceutical products [4].

MAJOR STAGES OF IN-PROCESS CONTROL

Fig 1: Major Stages of In-Process Control

1. In-Process Checks Shall Include The Following Process Controls [5]

- Verify the cleanliness of the manufacturing area and ensure proper line clearance before starting production.
- Confirm that all area and process container status labels are accurate and up to date.
- Ensure that equipment and instruments are calibrated, verified, and appropriately labelled before use.

- Verify the identity of raw materials by checking details such as material name, material code, control number, or analytical reference (A.R.) number.
- Monitor and maintain the specified time limits at each stage of the manufacturing process.
- Check the integrity of sieves and filters before and during processing.
- Ensure that all incoming materials are received only from approved vendors.
- Review batch manufacturing records continuously throughout the production process.
- Monitor critical product attributes such as weight, hardness, or other relevant quality parameters.
- Verify product yield at different stages of manufacturing to ensure process consistency.
- Perform periodic examination of retained or control samples as per established procedures.
- Record and monitor environmental conditions, including temperature and relative humidity, throughout the manufacturing process.

2. Manufacturing Operation Stage

During the manufacturing operation, active pharmaceutical ingredients (APIs), excipients, diluents, and vehicles should be accurately weighed or measured under controlled environmental conditions to maintain their quality and suitability for use. Only calibrated and qualified equipment or instruments should be used to ensure measurement accuracy.

All weighing, measuring, and dispensing activities should be performed under the supervision of authorized production and Quality Assurance (QA) personnel. Before initiating the manufacturing process, production and In-Process Quality Control (IPQC) personnel should verify all raw materials against the Batch Manufacturing Record (BMR) to confirm their identity and suitability. Materials should be properly identified, stored, and controlled to prevent unauthorized use or mix-ups.

Each material container should be appropriately labelled with essential information, including:

- Material name
- Material code
- Control number or A.R. number
- Weight or volume of the material in the container
- Re-test date, where applicable

Whenever a product is transferred from one manufacturing stage to the next, the process yield should be compared with the predetermined target values. Any deviation or unexpected variation should be investigated, documented, and justified. Manufacturing activities should continue only after obtaining approval from the Quality Assurance (QA) or Quality Control (QC) department if the deviation exceeds the acceptable limits. All observations, approvals, and corrective actions should be properly documented using computerized systems or other approved recording methods [6].

3. Sampling Stage

Sampling activities should be planned and performed according to approved Standard Operating Procedures (SOPs) that clearly define the sampling methods and requirements. An adequate quantity of representative samples should be collected to perform all required quality control tests. The sampling plan should be designed based on the type of material, such as in-process materials, intermediates, bulk products, or finished dosage forms, and should consider the specific testing requirements for each product category [7].

Established sampling procedures should ensure that the integrity and quality of the collected samples are maintained throughout handling, storage, and transportation. After collection, the samples should be analysed by qualified Quality Control (QC) personnel to verify compliance with predetermined specifications before further manufacturing or product release.

4. In-Process Test Stage

In-process testing is performed on representative samples collected during different stages of manufacturing to evaluate product quality and process performance. The Quality Control (QC) department

is responsible for conducting these tests and ensuring that the results comply with the predefined acceptance criteria. The primary objective of in-process testing is to monitor the manufacturing process, detect process variations, and maintain product consistency.

The acceptance limits for in-process tests are established by the manufacturing facility based on product development studies, process validation data, stability studies, pharmacopeial requirements, and regulatory guidelines. These limits are intended for routine process monitoring and process adjustment rather than final product release specifications.

Typical in-process tests include the evaluation of parameters such as tablet hardness, friability, weight variation, pH, moisture content, and other dosage form-specific quality attributes. The results obtained during manufacturing are used to make necessary process adjustments to ensure consistent product quality. Since in-process limits are designed for process control, results falling outside these limits are generally managed through process investigation and corrective actions rather than formal Out-of-Specification (OOS) investigations [5].

Table 1. Examples of In-Process Quality Control Parameters

Manufacturing Stage / Dosage Form	In-Process Quality Control Parameters
Granulation	Moisture content, blend uniformity, bulk density, tapped density, particle size distribution
Solid Oral Dosage Forms	Appearance, average weight, weight variation, hardness, thickness, friability, disintegration time
Semi-solid Dosage Forms	Appearance, homogeneity, pH, viscosity
Liquid Oral Dosage Forms	Appearance, clarity, pH, specific gravity, viscosity, fill volume
Sterile Injectable Products	Appearance, clarity, fill volume, filter integrity, particulate matter, container integrity, sterility, bacterial endotoxin test
Dry Powder Injectable Products	Appearance, clarity after reconstitution, average weight, weight variation, particulate matter, container integrity, leak test
Transdermal Drug Delivery Systems	Drug content, adhesive properties, weight per unit area, backing layer integrity
Metered Dose Inhalers (MDI)	Fill weight, fill volume, leak test, valve performance
Dry Powder Inhalers (DPI)	Blend uniformity, API assay, moisture content, dose uniformity

5. Packing Stage

Before the commencement of packaging operations, the Quality Assurance (QA) department should provide authorization for the finished dosage forms at all critical stages according to approved written procedures. Packaging activities should be performed systematically to ensure product quality, accuracy, and regulatory compliance [8].

The following in-process checks should be carried out during the packing stage:

- Monitor environmental conditions and maintain appropriate records throughout the packaging process.
- Verify that the packaging area is clean and free from materials or residues of previous batches.
- Inspect blister packs and strips for defects such as misalignment, damaged pockets, or sealing imperfections.
- Ensure that all packaging materials are obtained from approved suppliers and released by the Quality Control (QC) department.
- Confirm the status labels of packaging materials, equipment, manufacturing areas, and in-process containers.
- Verify that printed packaging materials contain the correct product name, strength, dosage form, volume, and composition.

- Examine the printing quality of both primary and secondary packaging materials.
- Check the accuracy of batch details, including batch number, manufacturing date, expiry date, maximum retail price (MRP), barcode, and other coding information.
- Review all printed information on labels, foils, cartons, and shipping containers for correctness and legibility.
- Ensure that packaging materials comply with applicable pharmacopeial and regulatory requirements.
- Verify that the manufacturer's license number and all mandatory statutory information are correctly printed.
- Confirm that appropriate storage conditions and product-specific handling instructions are clearly displayed on all packaging components.
- Ensure that directions for use, warnings, and precautionary statements are included to promote safe product administration.
- Verify that packaging personnel perform all activities according to approved procedures.
- Review and maintain all electronic and manual packaging records.
- Collect packaging samples in accordance with approved Standard Operating Procedures (SOPs) for quality evaluation.

IN-PROCESS QUALITY CONTROL TESTS FOR SOLID DOSAGE FORM

1. General Appearance
2. Tablet Hardness
3. Friability Test
4. Uniformity of Weight (Weight Variation)
5. Uniformity of Content (Content Uniformity)
6. Disintegration Test

1. GENERAL APPEARANCE

Size and Shape:

The size and shape of compressed tablets are determined by the design of the punches and dies used during the compression process. Tablet crown thickness is measured using a micrometer, while the overall tablet thickness is determined with a Vernier caliper. During manufacturing, the tablet thickness should be maintained within ±5% of the specified standard value to ensure product uniformity and quality [9].

Color:

The colour of tablets should be uniform and free from mottling or discoloration. Quantitative evaluation of tablet colour is performed using reflectance spectrophotometry and tristimulus colorimetry to ensure consistency in appearance.

2. HARDNESS

Tablet hardness is an important quality control parameter that influences friability, disintegration, and dissolution. It ensures tablets can withstand handling, packaging, and transportation. Hardness mainly depends on the compression force applied during manufacturing and is measured using instruments such as the Pfizer, Monsanto, Erweka, or Schleuniger hardness tester [10].

Fig 2: Monsanto Hardness Tester

3. FRIABILITY

Friability is an important in-process quality control test used to assess the mechanical strength and durability of uncoated tablets. It determines the ability of tablets to resist abrasion, chipping, and breakage during manufacturing, packaging, transportation, and handling. The test is commonly performed using a Roche friabilator, in which a specified number of tablets are weighed, dedusted, and rotated for 100 revolutions. After the test, the tablets are reweighed, and the percentage weight loss is calculated from the initial and final weights. A tablet batch passes the friability test if the weight loss is not more than 1.0% and the tablets remain free from cracks, chips, or breakage [11].

Fig 3: Friability tester

4. UNIFORMITY OF WEIGHT (WEIGHT VARIATION)

The uniformity of weight test is performed to ensure that each tablet contains a consistent amount of formulation. In this test, 20 tablets are individually weighed, and the average tablet weight is calculated. The weight of each tablet is then compared with the average weight to determine any variation. The batch complies with pharmacopeial standards if the number of tablets exceeding the specified weight variation limits is within the acceptable range. This test helps ensure dose uniformity and consistent product quality [12].

Table 2: USP limits for weight variation test for uncoated tablets

Average weight (mg)	Percentage Deviation (%)
130 or less	10
130-324	7.5
More than 324	5

5. CONTENT UNIFORMITY

The content uniformity test is performed to ensure that each tablet contains the intended amount of active pharmaceutical ingredient (API) within the specified limits. According to USP and BP, 10 tablets are randomly selected and individually analysed for drug content. A batch is considered acceptable when the drug content of each tablet falls within the prescribed pharmacopeial limits, ensuring consistent dose delivery and product quality. If one or more tablets fall outside the acceptable range, additional tablets are tested according to the pharmacopeial acceptance criteria [13].

Acceptance Criteria (BP):

- The drug content of each tablet should generally be within 85–115% of the average content.
- If one tablet falls between 75–125% but outside 85–115%, an additional 20 tablets should be tested.
- No tablet should contain less than 75% or more than 125% of the average content.

6. DISINTEGRATION TEST

The disintegration test is performed to determine the time required for a tablet to break down into smaller particles under specified conditions. Tablets are placed in the disintegration test apparatus containing a suitable medium maintained at 37 ± 2°C. The apparatus moves the tablets up and down until they completely disintegrate. The tablets should disintegrate within the pharmacopeial time limit, ensuring proper drug release and subsequent dissolution [14].

Table 3: IP Limit for Disintegration Time of Different Categories of Tablets

Categories of tablets	**Disintegration Time (min) for IP limit**
Uncoated tablets	15
Coated tablets	60
Enteric coated tablets	60
Film coated tablets	30
Effervescent tablets	5
Soluble tablets	3
Dispersible tablets	3

Fig 4: Disintegration apparatus

IN-PROCESS QUALITY CONTROL TESTS FOR SEMISOLID DOSAGE FORMS

1. APPEARANCE TEST

The appearance test is performed to evaluate the physical characteristics of semisolid formulations, including colour, odour, texture, homogeneity, and phase separation. The product should be smooth, uniform, and free from visible particles or signs of instability. This test is generally carried out by visual inspection [15].

2. P^H DETERMINATION

The pH of semisolid formulations is measured to ensure product stability and skin compatibility. A small quantity of the formulation is dispersed in distilled water, and the pH is determined using a calibrated pH meter. The pH should be within the specified range to avoid skin irritation [16].

Fig 5: pH Meter

3. SPREADABILITY TEST

Spreadability evaluates the ease with which a semisolid formulation spreads on the skin. A fixed amount of the formulation is placed between two glass plates, and a standard weight is applied. The diameter of spreading is measured to assess the formulation's spreadability. Good spreadability ensures uniform drug distribution and patient convenience[17].

4. VISCOSITY (RHEOLOGY) TEST

The viscosity test determines the resistance of the formulation to flow and ensures uniform consistency. It is commonly measured using a Brookfield viscometer under controlled conditions. Proper viscosity improves product stability, spreadability, and ease of application[18].

IN-PROCESS QUALITY CONTROL TESTS FOR LIQUID DOSAGE FORMS

1. LEAKAGE TEST

The leakage test is performed to evaluate the integrity of the container–closure system and ensure that the package effectively protects the product from contamination, moisture, and leakage during storage and transportation. A defective package may allow the entry of microorganisms or the escape of the product, thereby affecting its quality and stability.

One of the most commonly used methods is the dye bath test. In this method, the filled container is immersed in a coloured dye solution and subjected to vacuum or pressure for a specified period. The container is then removed, cleaned, and examined visually or by UV spectrophotometry for the presence of dye inside the package. The detection of dye indicates leakage in the container. Low-viscosity dye solutions are often used to

improve penetration through small pores. The dye bath test is simple, economical, and widely accepted in the pharmaceutical industry, particularly for ampoules and vials, as it does not require specialized equipment [19].

Fig 6: Leak test apparatus

2. HOMOGENEITY TEST

The homogeneity test is performed to ensure that creams and gels have a uniform texture and drug distribution. A small quantity of the formulation is pressed between the thumb and index finger to check for smoothness and the absence of lumps or coarse particles. A suitable homogenizer is used during manufacturing to achieve uniform mixing.

3. PARTICULATE MATTER TEST

The particulate matter test is performed to detect the presence of visible and sub-visible particles in liquid formulations, especially parenteral preparations. Injectable products should be clear and free from foreign particles to ensure patient safety and product quality. Initially, the filled containers are visually inspected under suitable lighting conditions for visible particulate matter. According to USP, Large Volume Parenterals (LVPs) are evaluated using the microscopic examination method, while Small Volume Parenterals (SVPs) are tested using a light obscuration particle counting system. The formulation must comply with pharmacopeial limits for particulate matter to ensure safety, efficacy, and regulatory compliance [20].

Table 4: IP, BP, EP and JP Limits for Particulate Matter in Parenteral Preparations

Volume of Solution	≥ 10 µm Particle Size	≥ 25 µm Particle Size
Small Volume Injections (≤ 100 mL)	3000 per container	300 per container
Large Volume Injections (> 100 mL)	12 per ml	2 per ml

4. VISCOSITY AND SPECIFIC GRAVITY TEST

- Ensures proper consistency, stability, and flow properties of semisolid formulations.
- Freshly prepared emulsions should be allowed to stand for 24–48 hours before viscosity measurement.
- Emulsion viscosity is directly related to the viscosity of the continuous phase.
- Higher internal phase volume increases the apparent viscosity.
- Viscosity depends on the composition and interaction of formulation components.
- Reducing the particle size of the dispersed phase increases viscosity in both o/w and w/o emulsions.
- Smaller particle size also improves emulsion stability.

5. CONSISTENCY TEST

- Evaluates the texture and homogeneity of the formulation.
- Ensures uniform consistency and freedom from lumps or grittiness [21].

IN-PROCESS QUALITY CONTROL TESTS FOR STERILE DOSAGE FORM

1. CLARITY TEST

The clarity test is carried out to determine whether a sterile formulation is free from visible particulate matter, turbidity, or foreign contaminants. The sample is visually inspected against both black and white backgrounds under suitable illumination. White or transparent particles are more easily observed against a black background, whereas dark particles are detected against a white background. The formulation should appear clear and free from suspended particles to ensure product quality, patient safety, and compliance with pharmacopeial standards [22].

2. PYROGEN TEST

(Limulus Amebocyte Lysate Test)

The Limulus Amoebocyte Lysate (LAL) test is an in vitro method used to detect bacterial endotoxins in sterile pharmaceutical preparations. Endotoxins are pyrogenic substances derived from the cell walls of Gram-negative bacteria and may cause fever or severe adverse reactions when introduced into the body [23]. The test is based on the clotting or gel-forming reaction of lysate obtained from the blood cells of the horseshoe crab (*Limulus polyphemus*) in the presence of bacterial endotoxins. The degree of gel formation is directly proportional to the endotoxin concentration and can be measured using appropriate analytical instruments. Compared with the rabbit pyrogen test, the LAL test is more sensitive, rapid, reliable, and suitable for the quantitative detection of endotoxins, making it the preferred method for quality control of sterile pharmaceutical products.

3. STERILITY TEST

The sterility test is an essential quality control test performed to confirm that sterile pharmaceutical products are completely free from viable microorganisms. It is applicable to products such as injectables, ophthalmic preparations, infusions, implants, and other sterile dosage forms. The test is based on the principle that if microorganisms are present in the sample, they will multiply when incubated in a suitable culture medium under optimal conditions of nutrients, temperature, moisture, pH, and aeration. The presence of microbial growth is indicated by turbidity or visible growth in the culture medium. Sterility testing is generally carried out using either the Membrane Filtration Method or the Direct Inoculation Method, depending on the nature of the product.

A. Membrane Filtration Method

The membrane filtration method is the preferred technique for testing filterable sterile products such as aqueous solutions and injections. A sterile membrane filter with a pore size of 0.45 µm or smaller is used to retain microorganisms present in the sample. After filtration, the membrane is aseptically removed and divided into two equal portions. One portion is transferred to a culture medium suitable for bacterial growth and incubated at 30–35°C, while the other portion is transferred to a fungal culture medium and incubated at 20–25°C. Both media are incubated for at least 7 days and examined periodically for turbidity or microbial growth. The absence of growth indicates that the product complies with sterility requirements.

B. Direct Inoculation Method

The direct inoculation method is used for products that cannot be filtered, including viscous, oily, or non-filterable formulations. In this method, a measured quantity of the sample is aseptically transferred directly into sterile culture media suitable for the growth of bacteria and fungi. The inoculated media are incubated under appropriate temperature conditions for not less than 14 days. During the incubation period, the media are examined at regular intervals for signs of microbial growth, such as turbidity or visible colonies. If no microbial growth is observed throughout the incubation period, the product is considered sterile and complies with pharmacopeial standards. This method is simple, reliable, and widely used for the sterility testing of products that are unsuitable for membrane filtration[24].

LIST OF DOCUMENTS USED IN PHARMACEUTICAL INDUSTRY

Documentation is a vital part of the pharmaceutical industry, ensuring effective communication, regulatory compliance, product quality, and patient safety. It supports all stages of drug development, manufacturing, quality control, and distribution through accurate, traceable, and well-maintained records. Good documentation practices (GDP) also ensure data integrity, facilitate audits, validation, and batch release, while helping organizations comply with FDA, EMA, WHO, and GMP requirements [25].

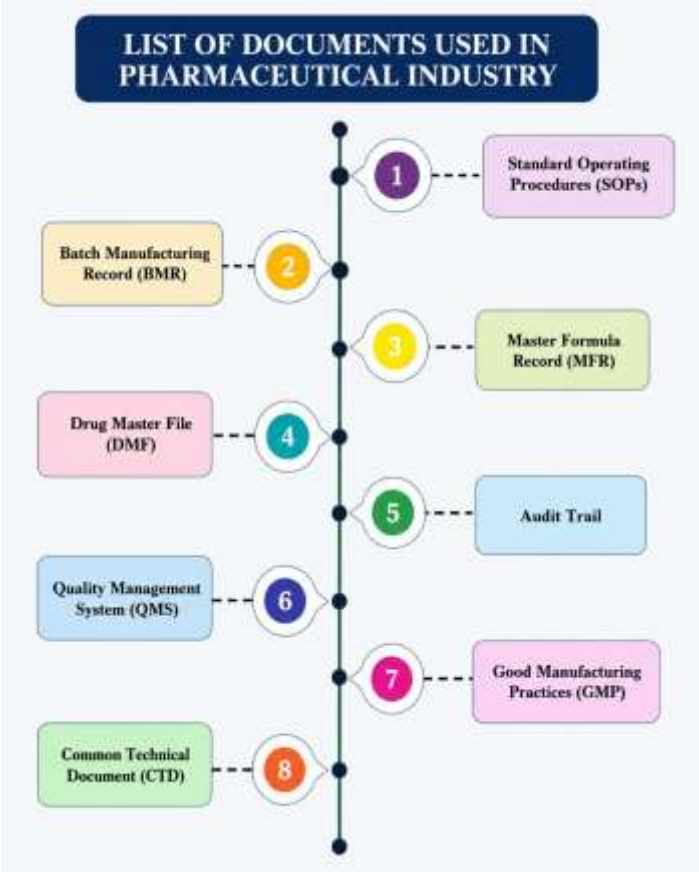


Fig 7: list of documents used in pharmaceutical industry

1. Standard Operating Procedures (SOPs)

A Standard Operating Procedure (SOP) is a written document that provides clear, step-by-step instructions for performing routine tasks consistently and correctly within an organization. It helps maintain quality, safety, and regulatory compliance [26].

Purpose of SOPs

- Ensures uniform and standardized work procedures.
- Maintains product quality and regulatory compliance.
- Reduces operational errors through clear instructions.
- Ensures accurate documentation and data integrity.
- Improves efficiency, consistency, and accountability.

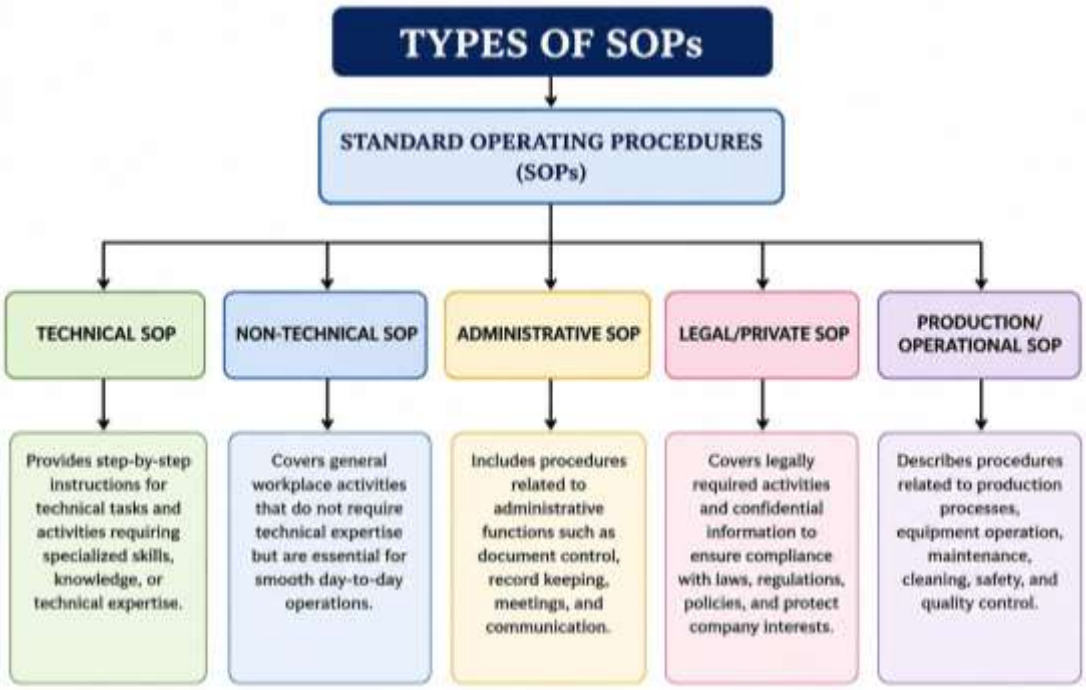


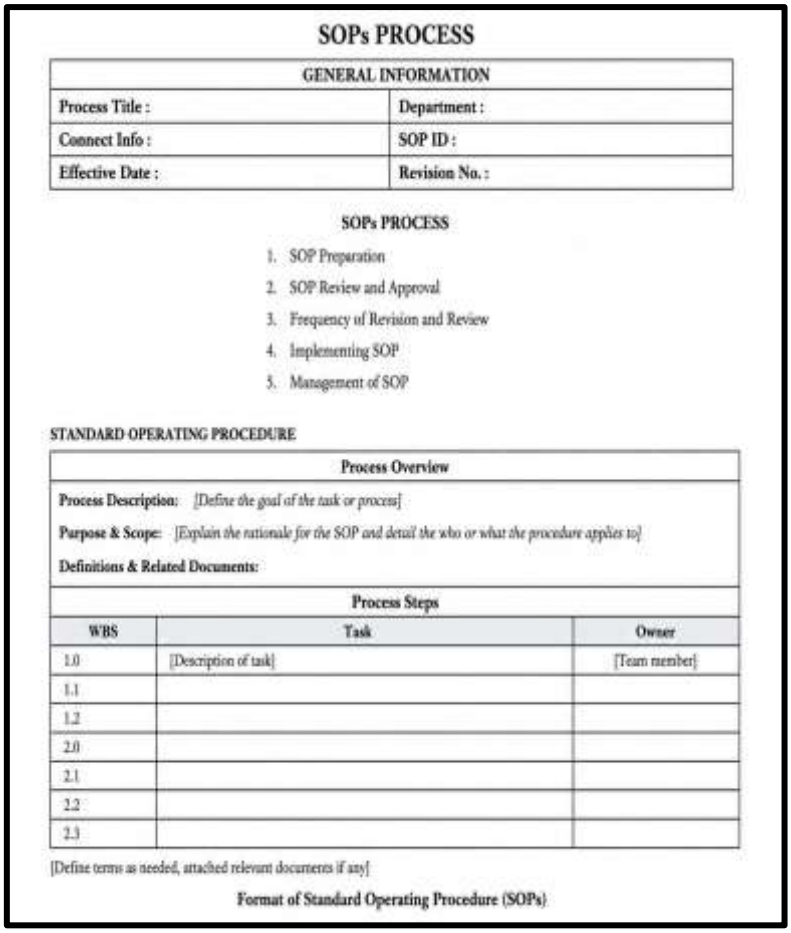
Fig 8: Types of SOPs

SOP Writing Style

- Written in a clear, step-by-step format.
- Uses simple and easy-to-understand language.
- Written in the present tense and active voice.
- Brief, accurate, and unambiguous.

2. Batch Manufacturing Record (BMR)

A Batch Manufacturing Record (BMR) is a detailed document used in pharmaceutical manufacturing to record every stage of batch production. It provides evidence that the product was manufactured according to approved procedures and quality standards. A separate BMR is prepared for each batch and includes complete manufacturing, processing, packaging, and quality control information [27]. Before production begins, the document is verified for accuracy and the production area, equipment, and instruments are checked for cleanliness and readiness. Each BMR carries a unique batch number, signatures of authorized personnel, and is maintained as an official record for traceability and regulatory compliance.



SOPs PROCESS

GENERAL INFORMATION	
Process Title :	Department :
Connect Info :	SOP ID :
Effective Date :	Revision No. :

SOPs PROCESS

1. SOP Preparation
2. SOP Review and Approval
3. Frequency of Revision and Review
4. Implementing SOP
5. Management of SOP

STANDARD OPERATING PROCEDURE

Process Overview
Process Description: *[Define the goal of the task or process]*
Purpose & Scope: *[Explain the rationale for the SOP and detail the who or what the procedure applies to]*
Definitions & Related Documents:

Process Steps		
WBS	Task	Owner
1.0	[Description of task]	[Team member]
1.1		
1.2		
2.0		
2.1		
2.2		
2.3		

[Define terms as needed, attached relevant documents if any]

Format of Standard Operating Procedure (SOPs)

Fig 9: Standard Operating Procedure (SOP) Process and Format

A Batch Manufacturing Record (BMR) includes:

- Date and time of each manufacturing step.
- Batch number, batch size, and product identification.
- Details of equipment used during manufacturing.
- Information on raw materials, intermediates, and reprocessed materials.
- Critical process parameters and actual manufacturing data.
- Sampling details and in-process quality control records.
- Laboratory test results and final quality evaluation.
- Signatures of operators, supervisors, and quality personnel.
- Actual yield and reconciliation details.
- Packaging, labelling, and storage information.

Company Logo	BATCH MANUFACTURING RECORD (BMR)		Page No. : ___ of ___
Product	:	B.M.R. No.	: XX/XXX/XXX
Batch Size	:	B.M.R. Revision No./ Date	: ___/___/___
Batch No.	:	M.F.R. No.	: XX/XXX/XXX
		M.F.R. Revision No. & Date	: ___/___/___

1. BATCH DETAILS			
Batch Quantity	:	Date of Manufacturing	:
Manufacturing Date	:	Time	:
Expiry Date	:	Retest Date	:

2. RAW MATERIALS / COMPONENTS USED

S. No.	Material Name	Batch No.	Qty. Used	Unit	Manufacturing Date	Expiry Date
1						
2						
3						
4						
5						

3. MANUFACTURING PROCESS DETAILS

S. No.	Step / Operation	Equipment Used	Process Parameters (Temp., Time, Speed, etc.)	Actual Data / Observation	Performed By (Sign & Date)
1.					
2.					
3.					
4.					
5.					

4. IN-PROCESS CHECKS & SAMPLING

S. No.	Sampling Point	Test / Parameter	Specification	Observed Result	Remarks	Analysed By (Sign & Date)
1.						
2.						
3.						

5. YIELD & RECONCILIATION

Theoretical Yield	:	_____ _____	Unit	:
Actual Yield Obtained	:	_____ _____	Unit	:
% Yield	:	_____%	Loss / Gain	: _____

6. PACKING & LABELLING DETAILS

Packing Material Used	:	Labelling Status	:
Pack Size / Batch Quantity	:	Date of Packing	:
Batch No. on Label	:	Packed By (Sign & Date)	:

7. DOCUMENTATION & REVIEW

Manufacturing Completed By (Sign & Date)	:
Checked By (Production) (Sign & Date)	:
Checked By (QA) (Sign & Date)	:
Approved By (QA Head) (Sign & Date)	:

8. REMARKS

Note: This record is to be completed in ink and all entries must be dated and signed.

Fig 10: Format of Batch Manufacturing Record (BMR)

3. Master Formula Record (MFR)

A Master Formula Record (MFR) is an authorized document that provides complete instructions for manufacturing a pharmaceutical product. It contains details of raw materials, packaging materials, manufacturing procedures, equipment, in-process controls, and quality requirements needed to produce a specific batch size. The MFR is prepared and approved by the Research and Development (R&D), Production, and Quality Assurance (QA) departments. It serves as the master reference document for preparing Batch Manufacturing Records (BMRs) and ensures consistency, quality, and regulatory compliance in every production batch [28].

A Master Formula Record (MFR) includes:

- Product name, dosage form, strength, and batch size.
- List and quantity of all raw materials and packaging materials.
- Manufacturing formula and detailed processing instructions.
- Equipment and machinery required for production.
- In-process quality control tests and acceptance criteria.
- Packaging, labelling, storage conditions, and shelf life.
- Product specifications and quality requirements.
- Approval signatures of Production, Quality Control (QC), and Quality Assurance (QA) personnel.
- Document number, version number, and revision date.
- Safety precautions and special manufacturing instructions.

Form Number MF-001-V1
Date Original Issue: JULY 2021
Date Revised:
Page 1 of 1

MASTER FORMULA

PRODUCT NAME:			
FORMULA REFERENCE:			
FORM PREPARED BY:			
		LOT NUMBER:	
		THEORETICAL YIELD:	
START DATE:		FINISHED PRODUCT SIZE:	
MIX TANK:		BATCH SIZE IN LBS:	

PRODUCT DESCRIPTION:
Example: Anhydrous emollient skin balm, white in color. Bulk product is manufactured by xxx and packaged in white stick with orange cap. Then sent to third party for label and tag application and shipped to client from there.

RESPONSIBILITY:
The person in charge of making products is responsible for making this product. This formula is confidential, and should not be shared with others outside the company.

MATERIALS/EQUIPMENT/SUPPLIES:
1. Mix tank 3
2. Scale X
3. Bowls
4. Blender
5. Measuring cups/beakers
6. Thermometer

INGREDIENTS:		
Phase A		%
Phase B		%
Ingred #		
Ingred #		
Ingred #		
Ingred #		
Ingred #		
Ingred #		
TOTAL		100.00

Fig 11: Format of Master Formula Record (MFR)

4. Drug Master File (DMF)

A Drug Master File (DMF) is a confidential document submitted by a pharmaceutical manufacturer to regulatory authorities. It contains information on the manufacturing process, facilities, packaging, quality control, stability, and cGMP compliance of a drug or excipient. Although DMF submission is voluntary, it supports regulatory approval while protecting confidential manufacturing information.

Parts of DMF:

- **Applicant Part:** Non-confidential information.
- **Restricted Part:** Confidential manufacturing information

Types of DMF:

1. **Type I:** Manufacturing site and facilities *(obsolete)*.
2. **Type II:** Drug substances and drug products.
3. **Type III:** Packaging materials.
4. **Type IV:** Excipients, colourants, flavours, and essences.
5. **Type V:** FDA-accepted reference information [29].

5. Common Technical Document (CTD)

The Common Technical Document (CTD) is a standardized format developed by the International Council for Harmonisation (ICH) for submitting pharmaceutical registration dossiers to regulatory authorities. It simplifies the drug approval process by providing a common structure for regulatory submissions across different countries, reducing duplication of work and enabling simultaneous submissions.

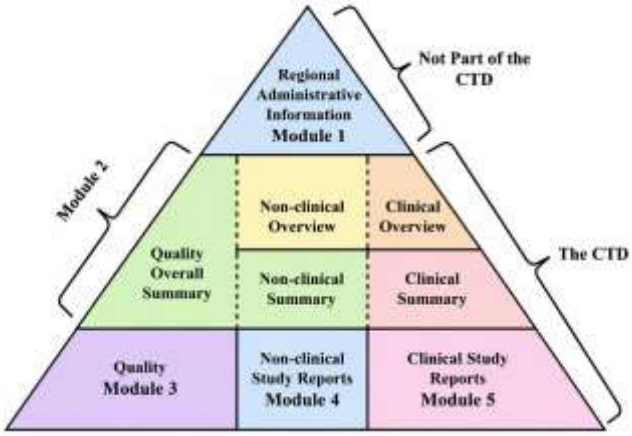


Fig 12: Common Technical Document (CTD)

CTD Modules

- Module 1: Regional administrative information (application forms, labelling, legal documents, risk management plans).
- Module 2: Summaries of Quality (CMC), Nonclinical, and Clinical information.
- Module 3: Quality information, including manufacturing, specifications, and stability data.
- Module 4: Nonclinical study reports (pharmacology and toxicology studies in animals).
- Module 5: Clinical study reports demonstrating the safety and efficacy of the drug in humans [30].

6. Audit Trails

An audit trail is a secure electronic record that tracks all changes made to pharmaceutical data throughout the product lifecycle. It helps ensure data integrity, traceability, regulatory compliance, and product quality by recording who performed an action, what was changed, when it was changed, and why. Audit trails support batch release decisions, investigations, and regulatory inspections.

Types of Quality Audits

- **Adequacy (Document) Audit:** Evaluates whether quality documents and procedures meet regulatory requirements.
- **Compliance (On-site) Audit:** Verifies that procedures are correctly implemented and followed.
- **External Audit:** Conducted by customers or regulatory authorities to assess suppliers or manufacturers.
- **Internal Audit:** Performed within the organization to evaluate compliance and identify areas for improvement.
- **Product/Process Audit:** Assesses whether products and manufacturing processes meet quality specifications and performance standards [31].

CONCLUSION

In-Process Quality Control (IPQC) is an essential component of pharmaceutical manufacturing that ensures the consistent production of safe, effective, and high-quality medicines. By continuously monitoring critical process parameters and performing appropriate quality control tests at different stages of manufacturing, IPQC helps identify and correct process deviations before they affect the final product. The implementation of IPQC, together with Good Manufacturing Practices (GMP), Quality Assurance (QA), and comprehensive documentation such as SOPs, BMRs, MFRs, DMFs, CTDs, and audit trails, strengthens regulatory compliance, maintains data integrity, and improves manufacturing efficiency. Furthermore, dosage form-specific in-process testing supports product consistency, minimizes batch rejection, and enhances patient safety. Overall, a robust IPQC system plays a vital role in ensuring pharmaceutical product quality, supporting regulatory requirements, and promoting continuous improvement in pharmaceutical manufacturing processes.

DISCUSSION

In-Process Quality Control (IPQC) is a vital part of pharmaceutical manufacturing that ensures product quality is maintained at every stage of production. It involves continuous monitoring of raw materials, manufacturing processes, sampling, in-process testing, and packaging to identify and correct deviations before they affect the final product. IPQC helps improve batch-to-batch consistency, minimizes manufacturing losses, reduces product rejection, and enhances overall process efficiency. Different dosage forms require specific in-process tests to evaluate critical quality attributes such as hardness, friability, weight variation, pH, viscosity, sterility, and particulate matter. In addition, proper documentation, including SOPs, BMRs, MFRs, DMFs, CTDs, and audit trails, ensures traceability, data integrity, and regulatory compliance. Overall, effective implementation of IPQC, together with Good Manufacturing Practices (GMP), supports the production of safe, effective, and high-quality pharmaceutical products while ensuring patient safety and regulatory compliance

REFERENCE

1. Verma A & Tyagi P, In Process Quality Control: A Review, International Journal of Industrial Pharmacy and Bio Sciences, 1: May-June 2014, 48-59.
2. Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices for Pharmaceutical Products. WHO Technical Report Seriesno.82.geneva: World Health Organization, 1992, 14-79.
3. WHO Technical Report Series, No. 970, 46th Report, Annex 3.
4. Mazumder B, Bhattacharya S, Yadav A, Total Quality Management in Pharmaceuticals: A Review. International Journal of PharmaTech Research, 2011, 3, 365-375.
5. Varsha kshirsagar, In-Process Quality Control: A Systematic Approach to Control Critical Steps in Finished Pharmaceutical Products, Indo American Journal of Pharmaceutical Research, 2017;7, 7369-7373.
6. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for human Use Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7A, 10 November 2000, 39.
7. WHO Technical Report Series, No. 970, 46th Report, Annex 4.
8. Drugs & Cosmetics Act, 1940 and Rules 1945 of India. Revised Schedule ‘M’, Schedule ’L’ and Schedule ‘U’.
9. Lachman L, Lieberman HA and Kanig JL. (1987). The Theory and Practice of Industrial Pharmacy, Third edition. Varghese Publishing House, Dadar Bombay, 296-300.
10. Jr. LVA and Ansel HC. (2014). Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems, Tenth edition, Baltimore, Philadelphia, 271.
11. United State Pharmacopoeia 40-National Formulary 35. (2017). Thirty Five edition. United State Pharmacopoeia Convention, Stationery Officer, USA.
12. 12 European Pharmacopoeia, 8th Edition, Council of Europe, Europe, 2013.Unites States Pharmacopoeia Convention. United States Pharmacopoeia 38-National Formulary 33, Stationery Office, USA, 2010.
13. British Pharmacopoeia Commision. (2020). British Pharmacopoeia. British Pharmacopoeia Commision, Stationery Office, Great Britain.
14. Indian Pharmacopoeia, Government of India, Ministry of Health and family Welfare. (2018). Eight edition. The Indian Pharmacopoeia Commision, Gaziabad, India.
15. Herbert A. Lieberman, Martin M. Riger and Gilbert S. Banker’ Pharmaceutical Dosage forms Volume-2.
16. Asif Shaikh et al. An updated review on pharmaceutical mini tablets: Formulation and it’s evaluation. 2019; 5(3): 5-7.

17. Sood R et al. Immediate release antihypertensive valsartan oral tablet: A Review. Journal of Scientific Research in Pharmacy.2012; 1(2): 20-26.
18. Chowdary KP et al. Formulation development of etoricoxib tablets by wet granulation and direct compression methods employing starch phosphate- A New modified starch" Der Pharmacia Lettre 2011; 3 (6): 163-172.
19. Dhakane K et al. Fast dissolving tablet: A Future prospective. Journal of Pharmacy Research. 2011; 4(11): 4176- 4180.
20. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig: The theory and Practice of Industrial Pharmacy, Varghese publication house, 3rd edition, 1990, 293-373.
21.]Vyas S P, Khar. Controlled drug delivery: concepts and advances In: Vyas S P, Khar, eds, Controlled oral administration, Delhi, India: Vallabh Prakashan, 2002, 155-195.
22. Jayasree M, Sowmya C, Divya L, Niranjan MB, RajasekharVR, Lavakumar V. Injectable Preparations-An Emerging Dosage Forms. Int J Advanced Pharm. 4(1), 2014, 36-41.
23. Japanese Pharmacopoeia. The Ministry of health, Labour and Welfare Ministerial Notification No. 14thed, 285, 2001, 112-19.
24. Chaudhari PD, Chaudhari SP, Lanke SD, Patel N.Formulation and in vitro evaluation of taste maskedorodispersible dosage form of Levocetirizine. Indian J Pharm Educ Res. 41, 2007, 319-28.
25. Chavan V, Chaudhari B, Redasani V. Documentation in pharmaceutical industry: review. J Emerg Technol Innov Res. 2024 May; 11(5). Available from: https://www.jetir.org
26. Escoe, Adrienne. Nimble Documentation. The Practical Guide for World-Class Organizations. Milwaukee, Wisconsin: American Society for Quality, Quality Press, 1997.
27. Taral DD, Kolhe SB, Jadhav YK, Kokane SP, Kondawar MS. Review of pharmaceutical documentation system. Int J Creat Res Thoughts (IJCRT). 2022 May; 10(5).
28. Documentation and Records: Website of GMP Online Consultancy Available from: http://www.gmp-online-consultancy.com/gmp/ Documentation-Records.htm Accessed: [Last cited on 2010 May 8.
29. Meghna D, Dedania R, Gandhi S, Juhi R, Gaurav K. Regulatory requirements for Drug master file in context to Canada and Australia. Int J Drug Regul Aff. 2018; 6(2):41–7.
30. Kiran CBM, Nagabhushanam MV, Reddy DP, Sai GY, Ramakrishna G, Sindhu YR, Bonthagarala B. Drug master files preparation and requirements for marketing authorization of API in European countries. World J Pharm Res. 2022; 11(12):275–84.
31. Juran JM, De Feo JA. Juran's Quality Handbook. 6th ed. New York: McGraw-Hill Education; 2010.