A R DIGITECH
International Journal Of Engineering, Education And Technology (ARDIJEET)
www.ardigitech.in *ISSN 2320-883X,VOLUME 11 ISSUE 04 22/12/2023*

Good Practices in Production Facilities in India and Us as Per Gmp

Rakesh Kumar Charora, Research Scholar Sunrise University, Alwar, Rajasthan, India
Yatendra Kumar Gupta, Research Guide Sunrise University, Alwar, Rajasthan, India

Abstract:

The factory building(s) for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any factory which produce disagreeable or obnoxious odour or fumes, excessive soot, dust, smoke, chemical or biological emissions.

Current study is aimed at requirements of Facilities and Equipment as per the different regulatory guidelines Schedule M of D and C Act and USFDA

Key words: Schedule M of D and C Act, USFDA, Production, Good Practice.

Introduction:

Both the selected guidelines describe the requirement of Facilities and Equipment under the different chapters as below.

Schedule M describes about the Production in PART **1 Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products - 3. Production area**

USFDA describes about the Production in PART 211— Current Good Manufacturing Practice for Finished Pharmaceuticals-CFR Title 21 Chapter I Subchapter C Part 211 Subpart F**— Production and process control**

Table 1: Comparison of regulatory guidelines for Production in pharmaceutical industry

Schedule M	**USFDA**
Schedule M describes about the Production in **PART 1** **Good Manufacturing Practices For Premises And Materials of Good Manufacturing Practices And Requirements Of Premises, Plant And Equipment For Pharmaceutical Products**[2]	**USFDA** describes about the Production in **PART 211— Current Good Manufacturing Practice for Finished Pharmaceuticals** **e-CFR Title 21** **Chapter I Subchapter C** **Part 211 Subpart F** **— Production and process control**[3]
3. Production area: **3.1.** The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations. **3.2.** In order to avoid the risk of corss-contamination, separate dedicated and self-contained facilities shall be made available	**Production and process control** **211.100 Written procedures; deviations.** (a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the

Schedule M	USFDA
for the production of sensitive pharmaceutical products like penicillin or biological preparations with live micro-organisms. Separate dedicated facilities shall be provided for the manufacture of contamination causing and potent products such as Beta-Lactum, Sex Hormones and Cytotoxic substances. **3.3.** Working and in-process space shall be adequate to permit orderly and logical positioning of equipment and materials and movement of personnel to avoid cross-contamination and to minimize risk of omission or wrong application of any manufacturing and control measures. **3.4.** Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid. Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.	appropriate organizational units and reviewed and approved by the quality control unit. (b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified. **211.101 Charge-in of components.** Written production and control procedures shall include the following, which are designed to assure that the drug products produced have the identity, strength, quality, and purity they purport or are represented to possess: (a) The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient. (b) Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information: (1) Component name or item code; (2) Receiving or control number; (3) Weight or measure in new container; (4) Batch for which component was dispensed, including its product name, strength, and lot number. (c) Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that: (1) The component was released by the quality control unit; (2) The weight or measure is correct as stated in the batch production records; (3) The containers are properly identified. If the weighing, measuring, or subdividing operations are performed by automated equipment under §211.68, only one person is needed to assure paragraphs (c)(1), (c)(2), and (c)(3) of this section. (d) Each component shall either be added to the batch by one person or verified by a second person or, if the components are added by automated equipment under §211.68, only verified by

Schedule M	USFDA
	one person. **211.103 Calculation of yield.** Actualyields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person or independently verified by a second person, or, if the yield is calculated by automated equipment under §211.68, be independently verified by one person. **211.105 Equipment identification.** (a) All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch. (b) Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code. **211.110 Sampling and testing of in-process materials and drug products**. (a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate: (1) Tablet or capsule weight variation; (2) Disintegration time; (3) Adequacy of mixing to assure uniformity and homogeneity; (4) Dissolution time and rate;

Schedule M	USFDA
	(5) Clarity, completeness, or pH of solutions. (6) Bio burden testing. (b) Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications. (c) In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods. (d) Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable. **211.113 Control of microbiological contamination.** (a) Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed. (b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes. **211.115 Reprocessing.** (a) Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics. (b) Reprocessing shall not be performed without the review and approval of the quality control unit.

Discussion:

Based on the above comparative study of production controls in the pharmaceutical industry as per Schedule M of D and C act and USFDA. Good Manufacturing practice guidelines below are the discussion outcomes. Discussion is carried out under different heading for better understanding purpose.

Guidelines Chapters

Schedule M: Schedule M describes about the Productionin PART **1 Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products**

USFDA: USFDA **describes about the Production in** PART 211— Current Good Manufacturing Practice for Finished Pharmaceuticals **e-CFR Title 21Chapter I Subchapter C Part 211 Subpart F— Production and process control**

Principle

Production and process controls in pharmaceutical industry works on the principle "Production operations must follow clearly defined procedures; they must comply with the principles of Good Manufacturing Practice in order to obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorisations"

Production Area and Construction features

The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations. Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid. Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

Schedule M of D and C act describe this requirement under 3.1 and 3.4

Requirement of production area and construction features is not covered under subpart F – Production and process control of USFDA however same is covered under subpart C building and facilities.

Access to production area

All the selected guidelines details about the access to production area, as per the guidelines, access to production area is restricted and only authorized personnel shall have the access.

Schedule M of D and C act describes this requirement under different chapters of the act.

USFDA describe this requirement under 211.28 (c) of USFDA, this section is covered under requirement of personnel in pharmaceutical industry

Written procedures; deviations

All the activities related to production shall be as per the written procedures, requirement of written procedures are described under the different clauses of selected guidelines as follows

Schedule M of Drugs and Cosmetic Act does not detail the requirement of written procedures under the chapter 3. Production area, however this requirement is detailed under the different chapters of the act.

USFDA describes this requirement under 211.100 written procedures; deviations.

Equipment

All the selected guidelines describe the requirement of equipment for production of drug products. The equipments should be installed, qualified and maintained in such a way to fulfil the requirement of product, all the equipment should be cleaned properly to avoid any cross contamination before start of manufacturing activity, same shall be verified and confirmed. The equipment shall be identified properly for its usage, calibration status, content along with date and sign of the personnel identified. If any defective equipment is identified same shall be isolated from the area with proper means or shall be labelled appropriately to avoid usage of such equipments.

Starting and packing materials

The detailed requirement of raw materials or starting materials are given under different chapters of the selected guidelines, however all the selected guidelines are not described this requirement under production and process control accordingly schedule M of D and C act describe this in chapter 10 Raw materials. USFDA describe the requirement of starting materials under 211.101 Charge-in of components.

Weighing and measurement

As per the guidelines selected for study all the materials used in the production of drug products should be weighed accurately before charging in for production, the measuring, weighing, recording and control equipment and instruments should be serviced and calibrated at pre specified intervals and records of the same shall be maintained. To ensure satisfactory functioning, instruments should be checked daily or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due should be clearly indicated on a label attached to the instrument.

Prevention of cross contamination

The GMP guidelines selected for study describe the prevention of cross contamination by suitable means. All the guidelines emphasise on the subject under different sections as described below:

Schedule M of D and C act describe this requirement under 3.2

USFDA guidelines details about the prevention of microbial contamination under 211.113 Control of microbiological contamination.

In-process testing

All the guidelines selected for study describe the requirement of in-process testing to confirm that the product is conforming to predetermined specification.

USFDA describes this requirement under 211.110 Sampling and testing of in-process materials and drug products.

Schedule M of D and C act describe this under 22.4 testing.

Calculation of yield

Yield calculation is essential to understand the loss during production and to take measures to minimize the loss. Calculation of yield is given under 211.103 of USFDA, Schedule M of D and C act describe this requirement under section 12.1 documentation, however schedule M does not specify this requirement under production.

Packing operations

Schedule M of D and C act describe the packing labelling and storage under different category of dosage forms in the act

USFDA details the packing operations under subpart G packing and labelling control.

Results

Development of Theory for Production and process control in pharmaceutical industry

Based on the above comparative analysis and discussion on production and process control in pharmaceutical industry as per the different regulatory guidelines below is the theory developed which is common for all the regulatory requirement. Following of the below common theory shall suffice the requirements of all the regulatory guidelines with respect to Production and process control.

Production Area

The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations.

Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid cross contaminations. Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

Accessto production area

Access to production premises should be restricted to authorized personnel.

Written procedure

There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality unit.

Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

Equipment

The Equipment used in the production of pharmaceutical products should be of required quality and size. Equipment should not affect the product adversely and it should be designed in such a way that the equipment should be user friendly, safe and cleaning should be easy. Material of construction should not affect the quality of the product.

Normally, non-medicinal products should not be produced in areas or with equipment destined for the production of pharmaceutical products

Before any processing operation is started, steps should be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels or documents not required for the current operation.

All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch.

Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.

Starting and packing materials

The purchase of starting materials is an important operation which should involve staff who have a particular and thorough knowledge of the suppliers and manufacturers.

Starting materials should only be purchased from approved supplier named in the relevant specification and, where possible, directly from the producer. It is recommended that the specifications established by the manufacturer for the starting materials be discussed with the suppliers. It is of benefit that all aspects of the production and control of the starting material in question, including handling, labelling and packaging

requirements, as well as complaints and rejection procedures are discussed with the manufacturer and the supplier.

For each delivery, the containers should be checked for integrity of package and seal and for correspondence between the delivery note and the supplier's labels.

If one material delivery is made up of different batches, each batch must be considered as separate for sampling, testing and release.

Starting materials in the storage area should be appropriately labelled. Labels should bear at least the following information:

The designated name of the product and the internal code reference where applicable;

Batch number given at receipt; Where appropriate, the status of the contents (e.g. in quarantine, on test, released, rejected); Where appropriate, an expiry date or a date beyond which retesting is necessary. There should be appropriate procedures or measures to assure the identity of the contents of each container of starting material. Bulk containers from which samples have been drawn should be identified. Only starting materials which have been released by the Quality Control Department and which are within their shelf life should be used. Starting materials should only be dispensed by designated persons, following a written procedure, to ensure that the correct materials are accurately weighed or measured into clean and properly labelled containers. Each dispensed material and its weight or volume should be independently checked and the check recorded. Materials dispensed for each batch should be kept together and conspicuously labelled as such.

Packaging Materials

The purchase, handling and control of primary and printed packaging materials shall be accorded attention similar to that given to starting materials.

Particular attention should be paid to printed materials. They should be stored in adequately secure conditions such as to exclude unauthorised access. Cut labels and other loose printed materials should be stored and transported in separate closed containers so as to avoid mix-ups. Packaging materials should be issued for use only by authorised personnel following an approved and documented procedure. Each delivery or batch of printed or primary packaging material should be given a specific reference number or identification mark. Outdated or obsolete primary packaging material or printed packaging material should be destroyed and this disposal recorded.

Weighing and measurement

Measuring, weighing, recording, and control equipment and instruments should be serviced and calibrated at prespecified intervals and records maintained. To ensure satisfactory functioning, instruments should be checked daily or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due should be clearly indicated on a label attached to the instrument. Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information:

Component name or item code; Receiving or control number; Weight or measure in new container; Batch for which component was dispensed, including its product name, strength, and lot number.

Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that: The component

was released by the quality control unit; The weight or measure is correct as stated in the batch production records; The containers are properly identified.

Each component shall either be added to the batch by one person and verified by a second person.

Prevention of cross contamination and Microbial contamination

Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes

When dry materials and products are used in production, special precautions should be taken to prevent the generation and dissemination of dust. Provision should be made for proper air control (e.g. supply and extraction of air of suitable quality).

Contamination of a starting material or of a product by another material or product must be avoided. This risk of accidental cross contamination arises from the uncontrolled release of dust, gases, particles, vapours, sprays or organisms from materials and products in process, from residues on equipment, from intruding insects, and from operators' clothing, skin, etc. The significance of this risk varies with the type of contaminant and of the product being contaminated. Among the most hazardous contaminants are highly sensitizing materials, biological preparations such as living organisms, certain hormones, cytotoxic substances, and other highly active materials. Products in which contamination is likely to be most significant are those administered by injection or applied to open wounds and those given in large doses and/or over a long time. Cross-contamination should be avoided by taking appropriate technical or organizational measures, for example:

Carrying out production in dedicated and self-contained areas (which may be required for products such as penicillins, live vaccines, live bacterial preparations and certain other biologicals); Conducting campaign production (separation in time) followed by appropriate cleaning in accordance with a validated cleaning procedure; Providing appropriately designed airlocks, pressure differentials, and air supply and extraction systems; Minimizing the risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air;

Wearing protective clothing where products or materials are handled;

Using cleaning and decontamination procedures of known effectiveness; Using a "closed system" in production; Testing for residues; Using cleanliness status labels on equipment.

Measures to prevent cross-contamination and their effectiveness should be checked periodically according to SOPs.

Production areas where susceptible products are processed should undergo periodic environmental monitoring (e.g. for microbiological monitoring and particulate matter where appropriate).

Sampling and testing of in-process materials and drug products

To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the

characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

Tablet or capsule weight variation; Disintegration time; Adequacy of mixing to assure uniformity and homogeneity; Dissolution time and rate; Clarity, completeness, or pH of solutions.

Bio burden testing.

Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications.

In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Processing operations

Before any processing operation is started, steps should be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels or documents not required for the current operation. Any necessary in-process controls and environmental controls should be carried out and recorded. Means should be instituted of indicating failures of equipment or of services (e.g. water, gas) to equipment. Defective equipment should be withdrawn from use until the defect has been rectified. After use, production equipment should be cleaned without delay according to detailed written procedures and stored under clean and dry conditions in a separate area or in a manner that will prevent contamination.

Time limits for storage of equipment after cleaning and before use should be stated and based on data.

Containers for filling should be cleaned before filling. Attention should be given to avoiding and removing any contaminants such as glass fragments and metal particles.

Any significant deviation from the expected yield should be recorded and investigated.

Checks should be carried out to ensure that pipelines and other pieces of equipment used for the transportation of products from one area to another are connected in a correct manner.

Pipes used for conveying distilled or deionized water and, where appropriate, other water pipes should be sanitized and stored according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.

Measuring, weighing, recording, and control equipment and instruments should be serviced and calibrated at prespecified intervals and records maintained. To ensure satisfactory functioning, instruments should be checked daily or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due should be clearly indicated on a label attached to the instrument.

Repair and maintenance operations should not present any hazard to the quality of the products.

Calculation of yield

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person.

Packing operations

When setting up a programme for the packaging operations, particular attention should be given to minimising the risk of cross-contamination, mix-ups or substitutions. Different products should not be packaged in close proximity unless there is physical segregation.

Before packaging operations are begun, steps should be taken to ensure that the work area, packaging lines, printing machines and other equipment are clean and free from any products, materials or documents previously used, if these are not required for the current operation. The line-clearance should be performed according to an appropriate check-list.

The name and batch number of the product being handled should be displayed at each packaging station or line.

All products and packaging materials to be used should be checked on delivery to the packaging department for quantity, identity and conformity with the Packaging Instructions.

Containers for filling should be clean before filling. Attention should be given to avoiding and removing any contaminants such as glass fragments and metal particles.

Normally, filling and sealing should be followed as quickly as possible by labelling. If it is not the case, appropriate procedures should be applied to ensure that no mix-ups or mislabelling can occur.

The correct performance of any printing operation (for example code numbers, expiry dates) to be done separately or in the course of the packaging should be checked and recorded. Attention should be paid to printing by hand which should be re-checked at regular intervals.

Special care should be taken when using cut-labels and when over-printing is carried out off-line. Roll-feed labels are normally preferable to cut-labels, in helping to avoid mix-ups.

Checks should be made to ensure that any electronic code readers, label counters or similar devices are operating correctly. Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing. On-line control of the product during packaging should include at least checking the following: General appearance of the packages; Whether the packages are complete; Whether the correct products and packaging materials are used; Whether any over-printing is correct; Correct functioning of line monitors. Samples taken away from the packaging line should not be returned. Products which have been involved in an unusual event should only be reintroduced into the process after special inspection, investigation and approval by authorised personnel. Detailed record should be kept of this operation.

Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced should be investigated and satisfactorily accounted for before release.

Upon completion of a packaging operation, any unused batch-coded packaging materials should be destroyed and the destruction recorded. A documented procedure should be followed if uncoded printed materials are returned to stock.

Finished Products

Finished products should be held in quarantine until their final release under conditions established by the manufacturer. The evaluation of finished products and documentation which is necessary before release of product for sale should be carried out.After release, finished products should be stored as usable stock under conditions established by the manufacturer.

References:

1. **Annex 3** - WHO good manufacturing practices for pharmaceutical products
2. **PART 1 – Schedule M -**Good Manufacturing Practices for Premises and Materials of Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.
3. **PART 211**— USFDA- Current Good Manufacturing Practice for Finished Pharmaceuticals -e-CFR data is current as of January 12, 2016, Title 21 → Chapter I → Subchapter C → Part 211 → Subpart B
4. **MHRA -Section II –** 2EU Guidance On Good Manufacturing Practice (GMP)-Production,
5. **TGA/PICS** describes about the Production in **CHAPTER 5 – Production**
6. Good Manufacturing practice in the pharmaceutical industry. (July 2007) working paper, prepared for workshop on tracing pharmaceuticals in South Asia, University of Edinburgh.
7. Reham M. Haleem a,*, Maissa Y. Salem b, Faten A. Fatahallah a, Laila E. Abdelfattah , Quality in the pharmaceutical industry – A literature review Saudi Pharmaceutical Journal , Vol 23, pg-463 to 469.
8. "The Great Quinine Fraud": (Fall 2007) Legality issues in the "Non-narcotic" drug Trade in British India 1: Patrica Barton: Social History of Alcohol and Drugs, Volume 22, No 1.
9. Government of India Ministry of Health and family Welfare (Department of Health). The Drugs and Cosmetics Act and Rules-1940 (23 of 1940) (as amended up to the 30th June, 2005).