



3678 తెలంగాణ తేలంగానా TELANGANA  
07/05/2015 100/-  
SL. No. .... Dt. ....  
SOLD TO: RAMCHANDAR RAO  
S/o. MADHUSODAN RAO R/o HYD.  
FOR WHO:- Dr. Reddy's Laboratories Ltd. Hyd.

Sabiha B 235433  
Smt. SABIHA BEGUM  
LICENCED STAMP VENDOR  
Lic.No.15-23-014/2013  
H.No.13-5-139/2, V. Rama Rao Nara  
Mothi Nagar, Borabanda,  
Balanagar (M), Ranga Reddy Dis  
Cell 9052777508

1<sup>st</sup> AMENDMENT TO THE MEMORANDUM OF UNDERSTANDING

THIS 1<sup>st</sup> AMENDMENT TO THE MEMORANDUM OF UNDERSTANDING  
("Amendment") is made as of 18<sup>th</sup> day of June 2015 by and between;

DR. REDDY'S LABORATORIES LIMITED, a company incorporated under Companies Act 1956,  
having its registered office at 8-2-337, Road No 3, Banjara Hills, Hyderabad – 500034, Telangana  
– India (hereinafter referred to as "Dr. Reddy's") of FIRST PART

And

Dr. B R AMBEDKAR OPEN UNIVERSITY, a university established under an act of Andhra  
Pradesh legislature having its campus at Road No 46, Jubilee Hills, Hyderabad – 500033,  
Telangana, India (hereinafter referred to as "BRAOU") of the SECOND PART.

For the purpose of this MOU , Dr. Reddy's and BRAOU shall be collectively referred to as  
"parties" and the term "party" refers to either of them as the context permits.



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REGISTRAR  
Dr. B.R. AMBEDKAR OPEN UNIVERSITY  
JUBILEE HILLS, HYDERABAD



**WHEREAS**

1. Parties have entered into a Memorandum of Understanding on 7<sup>th</sup> day of March 2013 (the "MOU") pursuant to which BRAOU is offering a program at under graduate level called Bachelor of Science with Subjects Chemistry, Pharmaceutical Chemistry and Pharmaceutical Technology for Dr. Reddy's.
2. Parties have agreed to amend clause 1.3, 1.4.9 and 2.2 of the MOU by executing this Amendment which shall form an integral part of the MOU.

**NOW THEREFORE, IN CONSIDERATION TO THE MUTUAL COVENANTS AGREED HEREIN AND THE OTHER GOOD AND VALUABLE CONSIDERATION AGREED HEREIN, THE SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED THE PARTIES HEREBY AGREE TO THE AGREEMENT AND AGREE TO BE LEGALLY BOUND BY THE FOLLOWING TERMS;**

- a) Parties hereby agree to amend clause 1.3 of the MOU which shall hereafter stand amended and replaced and read as follows –
  - 1.3 *This MOU is applicable to the Programme conducted by BRAOU for Dr. Reddy's for the following academic years :*  
2013 to 2016  
2014 to 2017  
2015 to 2018,  
2016 to 2019.  
*In the event Parties intend to extend this MOU to other academic years, the same shall be agreed expressly by both the Parties in writing.*
- b) Parties hereby agree to amend clause 1.4.9 of the MOU which shall hereafter stand amended and replaced and read as follows –
  - 1.4.9 *BRAOU will permit enrollment of employees of Dr. Reddy's for the Programme in the month of June and July. The examinations will be conducted accordingly at the end of one (1) year from the date of commencement of the Programme.*
- c) Parties hereby agree to amend clause 2.2 of the MOU which shall hereafter stand amended and replaced and read as follows –
  - 2.2 *Full Programme fee shall be payable at the commencement of the respective academic year.*



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18/6/15  
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- d) This Amendment is executed to incorporate the terms of amendment. Except as expressly provided for in this Amendment, the MOU will remain unchanged and in full force and effect. The term "MOU", as used in the MOU and all other instruments and agreements executed there under, shall for all purposes refer to the Agreement as amended by this Amendment.
- e) Except as provided in this Amendment, all terms used in this Amendment that are not otherwise defined shall have the respective meanings ascribed to such terms in the Agreement.
- f) Except as specifically modified and amended herein, all of the terms, provisions, requirements and specifications contained in the MOU remain in full force and effect. Except as otherwise expressly provided herein, Parties do not intend to, and the execution of this Amendment shall not, in any manner impair the MOU, the purpose of this Amendment is being simply to amend clause 1.3, 1.4.9 and 2.2 of the MOU.
- g) This Amendment may be executed in one or more original counterparts, all of which together shall constitute one agreement.

IN WITNESS WHEREOF, THE PARTIES HERETO HAVE HEREUNTO AFFIXED THEIR RESPECTIVE CORPORATE SEALS, ATTESTED BY THE HANDS OF THEIR RESPECTIVE OFFICERS, DULY AUTHORIZED IN THAT BEHALF AND DELIVERED THE SAME ON THE DAY AND YEAR FIRST ABOVE WRITTEN.

For and on behalf of

DR.REDDY'S LABORATORIES LIMITED

Name: Atul Dhavle

Designation: Vice President

*[Signature]*

*B. Krishna Sai  
Director HR & TO*

In the Presence of

Name:

Title:

*[Signature]*  
*R. Srikanta*  
*Associate Director - HR*

For and on behalf of

Dr. B R AMBEDKAR OPEN UNIVERSITY

Name:

Designation:

**REGISTRAR**  
**Dr. B.R. AMBEDKAR OPEN UNIVERSITY**  
**JUBILEE HILLS, HYDERABAD, A.P.**

*[Signature]* 18.6.2015

In the Presence of

Name:

Title:

*[Signature]*  
*N. Venkata Narayana*  
*Director (Academic)*



DRL IRN - 100002399



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S LAXMI NARAYANA  
S.V.L.NO. 02/2006  
H.NO.6-3-392,R.L.NO.....  
BEHIND PURDAGUTTA POLICE STATION  
HYDERABAD  
LICENCE NO. 12/2006

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**MEMORANDUM OF UNDERSTANDING**

This Memorandum of Understanding (hereinafter referred to as "MOU") is made on this .....<sup>7/5</sup> day of March 2013 by and between:

**DR. REDDY'S LABORATORIES LIMITED**, a company incorporated under Companies Act 1956, having its registered office at 8-2-337, Road No 3, Banjara Hills, Hyderabad - 500034, Andhra Pradesh - India (hereinafter referred to as "Dr. Reddy's") of **FIRST PART**

And

**Dr. B R AMBEDKAR OPEN UNIVERSITY**, a university established under an act of Andhra Pradesh legislature ( the "APOU Act, 1982" ) having its campus at Road No 46, Jubilee Hills, Hyderabad - 500033, Andhra Pradesh, India (hereinafter referred to as "BRAOU") of the **SECOND PART**.

For the purpose of this MOU, Dr. Reddy's and BRAOU shall be collectively referred to as "parties" and the term "party" refers to either of them as the context permits.

**WHEREAS**

- (a) Dr. Reddy's is engaged inter-alia in the business of manufacturing and marketing of pharmaceutical products for which it has factories at different locations in Andhra Pradesh and in other parts of the country / world.
- (b) BRAOU is a university with a primary mandate of catering to the educational needs of the state of Andhra Pradesh with a objective of democratizing higher education, providing opportunities to employed persons for continuing education, skill up gradation, delivering education and training at the pace and convenience of learners through open and distance education methodologies through a network of study centers or by partnering with institutions.
- (c) BRAOU currently offers a program at under graduate level called Bachelor of Science (Drug Science). Dr. Reddy's has perused the contents of the program and have suggested modification in course content / syllabus to suit its business needs.
- (d) BRAOU has agreed to the modifications suggested by Dr. Reddy's and agreed to create a customized program called Bachelor of Science (Pharmaceutical Chemistry) the syllabus of which is enclosed a annexure -1 to this MOU and forms part of it.
- (e) Dr. Reddy's has desired to enroll its employees to the Bachelor of-Science (Pharmaceutical Chemistry) programme offered by BRAOU with an aim to impart necessary education through distance mode.

**IN CONSIDERATION TO THE MUTUAL COVENANT AGREED TO BETWEEN THE PARTIES HEREBY AGREE TO BE LEGALLY BOUND BY FOLLOWING TERMS WHICH HEREAFTER GOVERN THE TERMS OF THIS MOU.**



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Dr. B. R. AMBEDKAR OPEN UNIVERSITY  
JUBILEE HILLS, HYDERABAD, A.P.



## 2. PROGRAMME FEE:

- 2.1 The fees for the first year Programme will be Rs. 1100/- (Rupees Eleven Hundred Only) and for the Second and Third Year of the Program is Rs. 8000/- (Rupees Eight Thousand Only) for each student inclusive of all taxes. The same is subject to revision from time to time as per university norms.
- 2.2 The fee shall be payable in two equal installments one in the month of September and another in the month of March every year and for the first time, the first installment shall be payable at the time of enrollment.
- 2.3 The Programme fee shall include the cost of courseware, prospectus, and student hand book which will be developed by both the parties for the said Programme.
- 2.4 As part of course delivery process, BRAOU will extend its computer lab facility to the employees of Dr. Reddy's who enroll to this Programme.
- 2.5 BRAOU will charge examination fee from the student as per university rules.
- 2.6 Save as above BRAOU will not charge any other expenses except which shall be mutually agreed upon in writing.

## 3. TAXES AND DUTIES:

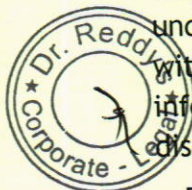
The parties hereby agree to comply with the relevant provisions of taxation laws including but not limited to income tax, service tax etc., as applicable and amended from time to time.

## 4. INTELLECTUAL PROPERTY:

- 4.1 Where Dr. Reddy's and BRAOU share sensitive information and material which are classified / patented / copy righted / marked as confidential by either parties, the same would neither be shared nor be used for any other programme other than for the Programme for which this MOU is entered, without express permission from the other party in writing. Whereas material and information with rights of the third party are used, the same can only be used by either party with express permission from the right holder.
- 4.2 BRAOU shall neither disclose the details set out herein in any journal, magazine or publication or other medium nor otherwise use Dr Reddy's name in any of its advertising material without Dr. Reddy's prior written consent which may be given or withheld at Dr. Reddy's sole discretion. Such obligation of BRAOU not to disclose Dr. Reddy's confidential information shall survive termination of this MOU

## 5. CONFIDENTIALITY :

The parties acknowledge that during the term it may be necessary for Dr. Reddy's to disclose to BRAOU, orally, in writing or in any other tangible or intangible form, technical information including but not limited to business information regarding recruitment procedure or any other 'Confidential Information' of Dr. Reddy's. All information derived from the Dr. Reddy's is to be considered Dr. Reddy's information for the purposes of this MOU. All Dr. Reddy's information is deemed to be highly confidential by the Dr. Reddy's. BRAOU agrees not to disclose any Dr. Reddy's information to any third party (except to its employees, its affiliates and sister companies, on a strictly need to know basis and underwritten terms of confidentiality at least as protective as those in this clause) without the prior express written consent of the Dr. Reddy's and not to use Dr. Reddy's information other than strictly in the performance of this MOU. These restrictions upon disclosure and use of Dr. Reddy's information including information pertaining to Dr.





- a) Both the parties shall reconcile their accounts and determine the amounts to be settled. The party owing any amount shall pay the undisputed amount promptly to the other party upon receipt of the in un-disputed invoice.
- b) Upon termination, BRAOU shall cease to use all the information material ( if any) in its possession and shall forthwith promptly return all materials, information and data to Dr. Reddy's, including any material, access cards, devices, information, documentation etc., and all other properties within seven (7) days and if necessary certify the same in writing.
- c) Upon the termination of the MOU, the BRAOU shall deliver and transfer to Dr. Reddy's or its representative or such person, firm or company as Dr. Reddy's direct, all material, monies collected by the BRAOU in excess or for breach of performance of duties hereunder (whether held in cash or otherwise in any other form).

## 9. REPRESENTATIONS AND WARRANTIES

- 9.1 Each party hereby represents to the other that they have been duly incorporated /organized/registered under the applicable laws and has full legal right and authority to be engaged in the business and it has full corporate power and authority and is duly authorized to execute this MOU and perform its obligations as herein contemplated; and that neither the performance of the obligations or execution of this MOU will violate or in violation of any applicable laws for the time being in force.
- 9.2 Each party represent that there are no litigations pending or threatened (judicial, regulatory or otherwise) that would or might prevent or adversely interfere with the performance of obligations under this MOU and BRAOU hereby agrees to promptly notify the other in writing of any threatened or proposed action it may file or be filed against it.
- 9.3 BRAOU hereby represents and warrants that it has requisite skills and manpower to perform its obligations under this MOU and while rendering services on continuous basis under this MOU it will maintain the necessary academic standards of the industry.
- 9.4 BRAOU shall fulfill all statutory requirements pertaining to the manpower etc., and indemnify Dr. Reddy's from all the claims whatsoever.

## 10. GOVERNING LAW AND DISPUTE RESOLUTION:

- 10.1 This MOU is governed by the laws of India. The parties hereby explicitly agree to submit all the disputes, differences and other claims arising from the MOU to the exclusive jurisdiction of courts of Hyderabad, India and waive its rights to challenge or defend any claim on the choice of jurisdiction.
- 10.2 All disputes, controversies or claims arising out of or relating to this MOU including existence or interpretation of any clause hereof, shall be referred to arbitration by a sole arbitrator appointed through mutual consent by the parties in writing. The place of arbitration shall be Hyderabad (India) and the arbitration shall be governed by the Arbitration & Conciliation Act, 1996 as amended from time to time. The language of the arbitration proceedings shall be English. The cost of arbitration proceedings shall be initially born equally by parties and the prevailing party shall be entitled to recover the same from the other.



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## ANNEXURE – 1

### B. Sc (Pharmaceutical Chemistry), Course details

#### 1<sup>st</sup> Year

1. Social Sciences
2. Science & Technology
3. English
4. Functional English

#### 2<sup>nd</sup> Year

1. Chemistry – 1
2. Chemistry – 2
3. Chemical Analysis
4. Microbiology
5. Unit Operations
6. \*Pharmaceutical Technology – Pharmaceutics 1

#### 3<sup>rd</sup> Year

1. \*Pharmaceutical Technology – Pharmaceutics 2
2. \*Basics of Electrical and Mechanical Engineering
3. Instrumental Analysis
4. \*QA in Pharmaceuticals
5. \*Forensic pharmacy - Drug and Cosmetics Act and Pharmacopeia – IP, BP, USP and EP
6. \*Operations Management & Industrial Safety

Note: The subjects marked in \* are the changes in the existing B.Sc (Drug Science) Syllabus.



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**Subject 3: ENGLISH**

(A FOUNDATION COURSE)

**Block – I                      Reading Skills I**

- Unit 1 - Reading and Understanding Short Texts
- Unit 2 - Locating Information
- Unit 3 - Using the Dictionary
- Unit 4 - Reading for Specific Information
- Unit 5 - Reading for General Ideas
- Unit 6 - Reading Between the Lines

**Block – II                      Reading Skills: II**

- Unit 7 - Reading Instructions
- Unit 8 - Reading a Text Using a Map/ Chart/ Diagram / Table
- Unit 9 - Reading Descriptions of Processes & Procedures
- Unit 10 - Reading Instructions of People
- Unit 11 - Reading Dialogues
- Unit 12 - Critical and Interpretative Reading

**Block – III                      Writing Skills**

- Unit 13 - Writing Short Messages
- Unit 14 - Writing Notices / Announcements
- Unit 15 - Filling up Forms
- Unit 16 - Using Telegraphic Language
- Unit 17 - Writing Directions and Instructions
- Unit 18 - Writing a Paragraph

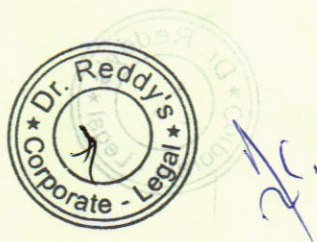
**Block – IV                      Writing Skills - II**

- Unit 19 - Writing notes from Academic Texts
- Unit 20 - Writing a Summary
- Unit 21 - Writing Business Letters
- Unit 22 - Report Writing
- Unit 23 - Essay Writing
- Unit 24 - Creative Writing

**Subject 4: FUNCTIONAL ENGLISH**

(A FOUNDATION COURSE)

- Unit 1 - Asking for Information
- Unit 2 - Making Requests
- Unit 3 - Seeking permission
- Unit 4 - Offering Help
- Unit 5 - Asking for and giving Directions



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**Block – III                      Carbon Compounds – I**

Unit 12 - Nomenclatures, Introduction and Isomerism of Carbon Compounds

Unit 13 - Structure and Reactivity of Carbon Compounds

Unit 14 - Alkenes

Unit 15 - Cyclo Alkenes

Unit 16 - Alkenes and Alkadienes

**Block – IV                      Physical Chemistry**

Unit 17 - Atomic Structure – I

Unit 18 - Atomic Structures – II

Unit 19 - Gases

Unit 20 - Solutions

**Subject 2: CHEMISTRY – 2**

**CARBON COMPOUNDS – II  
SOLIDS**

**Block – I                              Chemistry of Elements**

Unit 1 - d – block Elements

Unit 2 - f – Block Elements

Unit 3 - Bonding in Metals

Unit 4 - principles of Metallurgy

**Block – II                              Chemistry of Carbon Compounds -2**

Unit 5 - Alkynes

Unit 6 - Benzene – Aromatic Character

Unit 7 - Arenes

Unit 8 - Halogen Derivatives

Unit 9 - Hydrogen Compounds

Unit 10 - Ethers

Unit 11 - Aldehydes and Ketones

Unit 12 - Mono carboxylic acid

Unit 13 - Carboxylic acid derivatives

Unit 14 - Carbanions as intermediates in Synthesis

Unit 15 - Nitro Compounds

**Block – III                              Physical Chemistry**

Unit 16 - Solid State

Unit 17 - Phase Rule

Unit 18 - Colloids & Emulsions

Unit 19 - Adsorption



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**Block III                      Drug**

Unit 6 - Definition of Drug: Concept of dosage form and formulation

Unit 7 - Scope of Pharmaceutics, Routes of administration and physiological considerations

Classification of dosage forms and their applications.

**Block IV                      Drug Administration**

Unit 8 - Drug administration: Introduction to bioavailability and biopharmaceutics.

Unit 9 - Concepts of drug efficiency and dose response.

Unit 10 - Introduction to Absorption, Distribution and fate of drug.

**Block V                      Pharmaceuticals Calculations**

Unit 11 - Pharmaceutical Calculations: Reduction and enlargement of formula, Formula by weight (w/v, w/w, v /v); in parts.

**Block VI                      Delivery systems**

Unit 12 - Delivery systems: Non – sterile monophasic liquids.

Unit 13 - Unit operation of Filtration and clarification (Theory and equipment for filtration of solid from liquids) and mixing

**Block VII                      Rheology**

Unit 14 - Rheology: Definition and concepts,

Unit 15 - Types of flow, thixotropy and measurement of flow properties

**Block VIII                      Introduction to per formulation studies w.r.t monophasics**

Unit 16 – Introduction to per formulation studies w.r.t monophasics:

- Organoleptic properties
- Purity
- Solubility and techniques of solubilization
- Partition coefficient and dissociation constant, Salt formation
- Polymorphism and crystal habit
- Stability and Interaction with excipients.

**Block IX                      Complexion**

Unit 22 – Types of complexions-non sterile in brief monophasic liquids:

- Solutions
- Aromatic waters
- Syrups



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## **Block II                      Capsules**

Unit 7 - Hard capsules – Raw materials, gelatin manufacturing (brief), manufacturing of hard capsule shells, size, sealing, storage, Mention of gelatin substitute – vegetarian capsules, Hard capsule fill formulation aspects, Large scale manufacturing filling of hard capsule shells, filling equipments with examples (stress or principle of equipments), Packaging – strip & Blister packaging equipments. Q. C. tests, Layout of capsule section.

Unit 8 - Soft Gelatin Capsules Raw material Gelatin desirable properties, Soft Capsule properties, nature of shell & contents, Large scale manufacturing Rotary Die Process Packaging Q.C. tests.

## **Block III                      Introduction to sterile dosage forms Parental products**

Unit 9 - Various routes of parental administration, pyogens, vehicle, WFI preparation, purity, storage and distribution, vehicles other than WFI, additives in parental products, types of formulations, freeze drying, containers glass and plastics types and evaluation, concept of FFS, rubber closures and testing, personnel, facilities layout, environmental control cleanliness classes, air handling (HVAC systems), HEPA filters, laminar flow, production procedures, QA & Qcsterility test, pyrogen/ endotoxin test, particulate evaluation, leaker test.

## **Block IV                      Ophthalmic products**

Unit 10 - Types of ophthalmic products solutions, suspension, ophthalmic ointments and gels, preservatives and efficacy test, additives, QA and QC sterility test, clarity, particle size for suspension, tests on ointments and collapsible tubes, packaging.

## **Block V                      Oral sustained and controlled release systems**

Unit 11 - Advantages of SR systems, biopharmaceutical consideration and dose calculation of drug, properties of drug with reference to the design of oral SR systems, matrix and reservoir type of systems, dissolution controlled systems, diffusion controlled systems, ion exchange controlled systems.

## **Block VI                      Stability studies**

Unit 12 - Kinetic principles, Arrhenius equation and derivation of shelf life based on Arrhenius equation, limitations and advantages equation, degradation pathways hydrolysis, oxidation , photolytic degradation, methods to enhance stability studies, introduction to ICH guidelines.



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Unit 9 - Concept & Importance of Welding of metals, brazing, resistance welding. Concept of Furnaces using electrical energy.

## Block II Mechanical Engineering:

Unit 10 - Scalars and Vectors, Velocity & acceleration, Equations of motion, Newton's law of motion, Force & its derivation from Newton's laws of motion, Composition and resolution of forces. Centripetal acceleration, centripetal and centrifugal forces, Concept of friction and its application. Application to banking of roads

Unit 11 - Temperature and its measurement: Concept of heat and temperature on the basis of K.E. of molecules. Unit of heat, Basic Principles of measurement of temperature, Thermocouple, Bimetallic and resistance, Pyrometers and Thermometers, Criteria for the selection of thermometers. Three modes of transfer of heat, Coefficient of thermal conductivity, Conduction through compound media, Heat radiation, Characteristic of heat radiations.

Unit 12 - Water: Hard and soft water, removal of hardness by a. Soda lime process. b. Ion exchange method. Disadvantages of hard water in industrial use, boiler scales, priming, foaming corrosion and caustic embrittlement. Expressing the degree of hardness of water in (with simple problems) Water for drinking purposes.

Unit 13 - Solutions & Colloids: Solute, solvent, solution & colloids. Particle size and colloidal state Tyndell effect, Brownian movement, coagulation.

Unit 14 - Free Hand Sketching and Lettering: Different types of lines in engineering drawing as per ISI specifications. Practice of free hand sketching of vertical, horizontal and inclined lines, geometrical figures such as triangles, rectangles and circles.

Unit 15 - Dimensioning Technique: Necessity of dimensioning , method and principles of dimensioning (mainly theoretical instructions). Dimensioning of Overall sizes, circles, threaded holes, chamfered surfaces, angles, tapered surfaces, holes, equally spaced on P.C.D., counter sink holes, counter bored holes, cylindrical parts, narrow spaces and gaps, radii, curves and arches.

Unit 16 - Friction, Concept of friction, laws of friction, limiting friction and coefficient of friction, sliding friction.

Unit 17 - Centre of Gravity, Concept of gravity, gravitational force, centroid and center of gravity, centroid for regular lamina and center of gravity for regular solids. Position of center of gravity of compound bodies and centroid of composition area. CG of bodies with portions removed.

Unit 18 - Laws of Motion, Concept of momentum, Newton's laws of motion, their application, derivation of force equation from second law of motion, numerical problems on second law of motion, piles, lifts, bodies tied with string. Newton's third law of motion and numerical problems based on it, conservation of momentum, impulsive force



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### **Block III Potentiometry and Conductometry**

- Unit 10 - Principle and Techniques of pH Meter
- Unit 11 - Principles and Techniques of Potentiometry
- Unit 12 - Principles and Techniques of Conductometry

### **Block IV Separation Techniques**

- Unit 13 - Separation techniques by Solvent Extraction
- Unit 14 - Introduction and Principles of Chromatography
- Unit 15 - Principles and techniques of Paper Chromatography
- Unit 16 - Principles and techniques of Thin Layer Chromatography
- Unit 17 - Principles and techniques of Column Chromatography
- Unit 18 - Introduction to GC and HPLC

### **Block V Miscellaneous Instrumentation Techniques**

- Unit 19 - Principles and techniques of Polarimetry
- Unit 20 - Principles and techniques of Refractometry
- Unit 21 - Principles and techniques of Turbidimetry and Nephelometry

### **Block VI GLP and Validation**

- Unit 22 - Calibrations of Analytical Instruments
- Unit 23 - Validation of Analytical Procedure
- Unit 24 - Good Laboratory Practices (GLP).

### **Subject 4: QA in Pharmaceuticals**

- Unit 1 - Concept of Total quality management philosophy and GMPs, GLPs, ISO 9000.
- Unit 2 - Introduction to ICH process, organization and personnel, responsibilities, training, hygiene, personnel, records.
- Unit 3 - Manufacturing Premises: Location, Design, plant layout, construction maintenance, and sanitation, environmental control, utility services like gas, water, maintenance of non sterile areas & control of contamination.
- Unit 4 - Equipment, selection, purchase specifications, maintenance, clean-in place and sterilize- in place methods (TP and STP). Raw materials; purchase, specifications, stores, selection of vendors & control of raw materials.
- Unit 5 - Manufacture and quality control of dosage forms; manufacturing documents, master formula, batch formula records, standard operating procedure.
- Unit 6 - Quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; non-sterile standard operating procedure for various operations like cleaning, disinfection, fumigation, sterilization, membrane filtration etc.
- Unit 7 - Quality control in laboratory, responsibilities, good laboratory practice, routine controls, instruments, reagents, sampling plans, standard test procedure, protocols, non-clinical testing, control on animal house.





## Unit 6 - Factories Act 1954

- Definitions and Provisions

## Unit 7 - Indian Penal Code and Code of Criminal Procedures

- Provisions pertaining to different Courts, jurisdiction and power
- Provisions governing entry, search, arrest, bailable and non-bailable offences, Cognizable and non-cognizable offences

### **Subject 6: OPERATIONS MANAGEMENT & INDUSTRIAL SAFETY**

#### **Block I OPERATIONS MANAGEMENT**

Unit 1 - Operations management: concept, functions. transformation process model: inputs, process and outputs; classification of operations; responsibilities of operations manager, contribution of henryford, deming, crossby, taguchi. Process selection- project, job, batch, mass and process types of production systems.

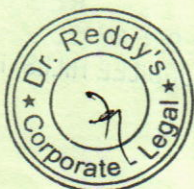
Unit 2 - Quality Management: Introduction, Meaning, Quality Characteristics of Goods and Services, Juran's Quality Trilogy, Deming's 14 principles, Tools and Techniques for Quality Improvement, Statistical Process Control Chart, Quality Assurance, Total Quality Management (TQM) Model Concept of Six Sigma and its Application. Acceptance Sampling – Meaning, Objectives, Single Sample, Double Sample and Multiple Sample Plans with sated risk, Control charts for variables – Averages and Ranges, Control Charts for Defectives – Fraction Defective and Numbers Defective.

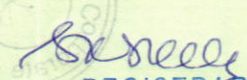
Unit 3 - JIT and Lean Production System: JIT Approach, Implementation requirements, Services, Kanban System. Inventory Management: Concepts, Classification, Objectives, Factors Affecting Inventory Control Policy, Inventory Costs, Basic EOQ Model, Re-order level, ABC analysis. Logistics and Franchising. Purchasing Management – Objectives, Functions, Methods, Procedure, and Value Analysis: Concepts, Stock Control Systems, Virtual Factory Concept and Production Worksheets.

#### **Block II INDUSTRIAL SAFETY**

Unit 1 - Industrial Safety and Environment - Personal Basics and Chemical Safety, PPE, Compatibility Matrices, MSDS, Waste Management, Storage Concerns, Safety measures in handling and storage of chemicals, Fire chemistry and its control, Safety color codes of chemicals.

Unit 2 - Hazard Classification - Hazard Classification chemical, physical, mechanical, ergonomics, biological and noise hazards, Hazards from utilities like air, water, steam



  
REGISTRAR  
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