### Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmaceutical Analysis and Quality Assurance)

#### I – Semester

<table>
<thead>
<tr>
<th>Subject Code</th>
<th>Subject / Paper</th>
<th>Theory / Practical</th>
<th>Instruction Hours per week</th>
<th>Evaluation</th>
<th>Duration of External Examination</th>
</tr>
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<tbody>
<tr>
<td>M PAQ.T. 1.101</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
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<tr>
<td>M PAQ.T. 1.102</td>
<td>Instrumental Methods of Analysis</td>
<td>Theory</td>
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<td>M PAQ.T. 1.103</td>
<td>Pharmaceutical Product Development</td>
<td>Theory</td>
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<tr>
<td>M PAQ.T. 1.104</td>
<td>Quality Control of Health Related Products</td>
<td>Theory</td>
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<tr>
<td>M PAQ.P. 1.105</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Practical</td>
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<tr>
<td>M PAQ.P. 1.106</td>
<td>Pharmaceutical Product Development</td>
<td>Practical</td>
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<tr>
<td>M PAQ.T. 1.107</td>
<td>Scientific and Technical Writing (SAIL)</td>
<td>Tutorial</td>
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<td>-</td>
<td>A/B/C/D</td>
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<tr>
<td>M PAQ. 1.108</td>
<td>Seminar</td>
<td>Theory</td>
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### Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmaceutical Analysis and Quality Assurance)

#### II – Semester

<table>
<thead>
<tr>
<th>Subject Code</th>
<th>Subject / Paper</th>
<th>Theory / Practical</th>
<th>Instruction Hours per week</th>
<th>Evaluation</th>
<th>Duration of External Examination</th>
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<tbody>
<tr>
<td>M P Q.T. 1.201</td>
<td>IPR &amp; Regulatory Affairs</td>
<td>Theory</td>
<td>4</td>
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<tr>
<td>M PAQ.T. 1.202</td>
<td>Quality Control of Raw Materials (RM) and Finished Pharmaceutical Products (FPP)</td>
<td>Theory</td>
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<tr>
<td>M PAQ.T. 1.203</td>
<td>Analytical Method Validation</td>
<td>Theory</td>
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<tr>
<td>M PAQ.T. 1.204</td>
<td>Quality Assurance and Management</td>
<td>Theory</td>
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<tr>
<td>M PAQ.P. 1.205</td>
<td>Quality Control of Raw Materials (RM) and Finished Pharmaceutical Products (FPP)</td>
<td>Practical</td>
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<tr>
<td>M PAQ.P. 1.206</td>
<td>Analytical Method Validation</td>
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<td>M PAQ.T. 1.207</td>
<td>Entrepreneurship Management (SAIL)</td>
<td>Tutorial</td>
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SAIL: Self Assess Interactive Learning
Scheme of Instruction and Evaluation for M. Pharmacy  
(Pharmaceutical Analysis and Quality Assurance)

Semester III and IV

**DISSERTATION** – Original research work carried out by the candidate under the guidance of regular teaching faculty/visiting faculty of the department should be submitted in a bound form.

Evaluation of the dissertation shall be done by external and internal examiners appointed by the university.

Dissertation viva-voce  
Dissertation report

<table>
<thead>
<tr>
<th>Grade</th>
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<tbody>
<tr>
<td>A. Excellent</td>
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<tr>
<td>B. Very good</td>
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<tr>
<td>C. Good</td>
</tr>
<tr>
<td>D. Fair</td>
</tr>
<tr>
<td>F. Fail</td>
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</tbody>
</table>

Grade A/B/C/D/F
UNIT – I


UNIT – II

UNIT – III
Mass Spectrometry: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT – IV
Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation and their basic principles. Gas chromatography: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis. Liquid chromatography: Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

UNIT – V
Electrophoresis: Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.
Radio immunoassay and ELISA: Principle, instrumentation, applications and limitations.
Recommended books:


INSTRUMENTAL METHODS OF ANALYSIS

UNIT – I
Microscopy: General aspects, hot stage microscopy, scanning electron microscopy (SEM), transmission electron microscopy (TEM): principle, instrumentation and applications.
Particles size analysis: Zetameter, Photon correlation spectroscopy, counter-counter apparatus, atomic force microscopy and confocal.

UNIT – II
Emission Spectrophotometry: Principles, instrumentation and applications of Raman, laser, plasma emission, ESR, atomic absorption spectrophotometer and flame photometry.
Spectrofluorimetry: fluorescence, phosphorescence, chemiluminiscence: theory, instrumentation and applications.

UNIT – III
Thermal Methods of Analysis: Principles, instrumentation and applications of thermogravimetric analysis (TGA), differential thermal analysis (DTA), differential scanning calorimetry (DSC), and thermo mechanical analysis (TMA).
X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT – IV
Potentiometry and pH metry: Principles and theoretical aspects – electrodes, representation of electrodes and cells, measurement of cell potential, measurement of pH, end point evaluation methods, null point Potentiometry and applications.
Conductometry: Principles and theoretical aspects – conductance, equivalent and molar conductance, instrumentation, measurement of conductivity, wheatstone bridge principle and conductometric applications.
Optical Rotatory Dispersion (ORD) and Circular Dichroism (CD): Principles and theoretical aspects – instrumentation, sample handling and applications.
Polarography: Principle and theoretical aspects – instrumentation, factors effecting limiting current, cells, form of waves, half wave potentials and applications.

UNIT – V
Hyphenated Techniques: LC-MS, GC-MS, MS-MS and LC-NMR, interpretation and applications in pharmacy.
Recommended books:

UNIT – I
Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT – II
Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

UNIT – III
Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

UNIT – IV

UNIT – V

Recommended books:


UNIT – I
Quality Control of Cosmeceuticals: Hair care products (shampoo and hair dyes), baby care products (oils, creams, powders and shampoos), personal hygiene products (shaving creams, after shave lotions and soaps), eye care products (eye shadows, eye liners, and eye brow pencils)

UNIT – II
Quality Control of Herbal Products: WHO guidelines for the quality control of raw materials used in herbal formulations. Quality control of crude drugs: proximate analysis, including ash and extractive values, crude fiber content, UV and fluorescence analysis of powdered drugs, quantitative microscopy and micro-chemical tests. Analysis of official formulations derived from crude drugs including some herbal preparations, alkaloids (ephedrine, reserpine and ergotamine).

UNIT – III
Quality Assurance of Biological Products: Biological assays of the following.
1. Vaccines: diphtheria, tetanus, rabies.
2. Enzymes: streptokinase, urokinase.
3. Antitoxins: diphtheria, tetanus.

UNIT – IV
Quality Control of Nutraceuticals: Vitamins (A, B₁, B₂, B₁₂, C, D, E and K), micro nutrients and health supplements including free radical scavengers.

UNIT – V
Quality Control of Food Constituents: Carbohydrates, proteins and fats with special emphasis in the determination of moisture, ash, nitrogen and physical constituents. General analytical methods for milk and milk constituents (milk powder and margarine).

Recommended books:

List of Experiments

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.

2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).

3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).

4. Experiments based on the application of derivative spectroscopy. (2 experiments).

5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).

6. Interpretation of drugs by IR spectra.

7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).


9. Any other relevant experiments based on theory.
1. Effect of surfactants on the solubility of drugs.
2. Effect of pH on the solubility of drugs.
3. Dissolution methods of transdermal drug delivery systems.
4. Dissolution studies of drug in three different biorelevant dissolution media (2 experiments).
5. Effect of solid dispersion and hydrotropy on the dissolution.
6. Test for degradation of compounds using TLC for any two drugs.
7. Stability testing of solution and solid dosage forms for photo degradation. (2 experiments).
8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
9. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
10. Compatibility evaluation of drugs and excipients.
11. Product development and protocol preparation using preformulation data for tablets and capsules.
12. Dissolution of drugs in different pH media for comparison of performance with innovator.
Course Objectives: To be able to appreciate and understand importance of writing scientifically.
- To Develop competence in writing and abstracting skills.
- To write either a draft research proposal or a chapter of dissertation.

UNIT – I: COLLECTION AND EVALUATION OF INFORMATION
Identification, sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

UNIT – II: WRITING AS A MEANS OF COMMUNICATION
- Different forms of scientific and technical writing.
- Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.
How to formulate outlines: The reasons for preparing outlines
- as a guide for plan of writing
- as skeleton for the manuscript
Kinds of outline: topic outlines, conceptual outline, sentence outlines and combination of topic and sentence outlines

UNIT – III: DRAFTING TITLES, SUB TITLES, TABLES, ILLUSTRATIONS
- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
- Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
- Appendices: use and guidelines
The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading
Checking: Organization, Headings, Content, Clarity and Grammar
Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

UNIT - IV: PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE
Introduction, Review of Literature, Methodology, Results and Discussion
Ask questions related to: content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

UNIT – V: WRITING FOR GRANTS
- Clearly state the question to be addressed
- Rationale and importance of the question being addressed
- Empirical and theoretical conceptualization
- Presenting pilot study/data
- Research proposal of method
- Clarity, specificity of method.
- Clear organization
- Outcome of study and its implications
- Budgeting
- Available infra-structure and recourses
- Executive summary

References

UNIT – I
Patents and intellectual property rights (IPR): definition, scope, objectives, source of patient information, patent processing and application. Patents, copyrights, trademarks, silent features, trade related aspects (TRIPS), international and regional agreements.

UNIT – II

UNIT – III
Regulatory affairs: Indian context – requirements and guidelines of GMP, understanding of drugs and cosmetics act 1940 and rules 1945 with reference to schedule M, U and Y.

UNIT – IV
Related quality systems: objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.

UNIT – V
Documentation types related to pharmaceutical industry, protocols, harmonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended books:

6. Hussain. Law of drugs in India.
QUALITY CONTROL OF RAW MATERIALS (RM) AND FINISHED PHARMACEUTICAL PRODUCTS (FPP)

UNIT – I
Reagent Based and Functional Group Based Analysis of APIs: Analytical principles, procedures and applications involved in the use of the following reagents.

a) MBTH (3-methyl-2-benzothiazoline hydrazone).

b) Folin – Ciocalteu (FC) reagent.

c) 2,6- Dichloroquinone chlorimide.

d) 2,3,5- Triphenyl tetrazolium salt.

e) 1,2- Naptho quininone -4- sulfonate.

f) Bratton-Marshall reagent.

g) p-Dimethyl amino cinnamaldehyde (PDAC) reagent.

Principles and procedures involved in quantitative determination of the following functional groups:

A) Hydroxy  B) Aldehyde  C) Ketone  D) Amine  
E) Methoxyl  F) Ester  G) Carboxyl

UNIT – II
Quality Control of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest, disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT – III

UNIT – IV
Impurity Profile: Sources of impurities, their effect on drug stability and therapeutic action. Determination of impurities in bulk drugs - Isolation, characterization, and analytical methods. Formulation related impurities - Isolation, characterization, and analytical methods. ICH and WHO guidelines for impurity and related substances in the drugs.

UNIT – V
Analysis of Drugs in Dosage Forms: Principles and procedures involved in the analysis of drugs in dosage forms: A) Antibacterials (penicillins, erythromycin) and fluoroquinolones) B) steroids (cholesterol, progesterone, and androsterone); C) Anti-inflammatory drugs (nimusuline, diclofenac. Ibuprofen and indomethacin); D) Antihypertensive drugs (propranolol, levodopa); and E) antidiarrhoeals (metronidazole, tinidazole).
Recommended books:

UNIT – I
**Analytical Method Development:** Introduction, qualification and calibration of various analytical instruments for drug analysis and maintenance of instruments.

UNIT – II
**Development of Analytical Methods and Validation:** The instruments include UV-visible spectrophotometer, FT-IR spectrometer, HPLC and GC-MS.

UNIT – III
**Analytical Procedures Validation:** Needs, types, accuracy, precision, linearity, sources of errors, use of significant figures and their correct usage, robustness system, sensitivity, specificity, ruggedness, system suitability parameters, revalidation, LOQ, and LOD.

UNIT – IV
**Drug Analysis in Biological Matrices:** Selection of biological sample, extraction of drugs by various methods as LLE, SPE and membrane filtration, factors affecting extraction of drugs, bio analytical method validation.

UNIT – V
**Validation Methods:** Methods of validation for the following – pharmaceutical water systems, cleaning validation, HVAC system – vendor qualification – validation of computer system and software, validation master plan and validation protocol. EQ (DQ, IQ, OQ & PQ).

Recommended books:

7. Mehra ML. Good manufacturing practices (GMP), University Book Agency.
QUALITY ASSURANCE AND MANAGEMENT

<table>
<thead>
<tr>
<th>M PAQ. T.1.204</th>
<th>Period/week: 4</th>
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<tr>
<td>Sessional: 30</td>
<td>Duration of Exam: 3 hrs</td>
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<tr>
<td>Examination: 70</td>
<td>Nature of Exam: Theory</td>
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UNIT – I
**Basic Concepts of Quality Assurance:** Quality control and quality assurance, definition, concept, philosophy, concept of total quality management, functions, sources of variation, change control program. NABL certification and accreditation procedure, quality audits, EQ (DQ, IQ, OQ & PQ), process validation (PV) (prospective, retrospective and concurrent).

UNIT – II
**Good Laboratory Practices:** Scope, Organization, personnel- technical competence, desirable qualities of analyst, analyst validation, QBD (quality by design) responsibilities of key personnel in the QC laboratories. Routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities, raw data maintenance.

**Complaints and Recalls:** Evaluation of complaints, recall procedures, related records and documents, handling of OOS (out of specification), market complaint analysis.

UNIT – III
**Documentation:** Manufacturing documents, manufacturing formula, batch formula records, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

UNIT – IV
**In-process Quality Control:** Various dosage forms sterile, biological and non-sterile products. Packaging and labeling controls, line clearance and other packaging materials.

UNIT – V
**Environment Health and Safety (EHS):** Hazards- Fire, mechanical, chemical and pharmaceutical, monitoring and prevention systems, industrial effluents testing and treatment, control of environmental pollution.

**Recommended books:**

7. Harburn K. Quality control of packaging materials in pharmaceutical industry. ASQC
11. Mehra ML. Good manufacturing practices (GMP), University Book Agency.
QUALITY CONTROL OF RAW MATERIALS (RM) AND FINISHED PHARMACEUTICAL PRODUCTS (FPP) (PRACTICAL)

M PAQ. P.1.205
Period / Week: 6
Sessional: 30
Examination: 70
Duration of Exam: 6hrs
Nature of Exam: Practical

List of Experiments

1. Qualitative and quantitative analysis of some pharmaceutical dosage form using the following reagents and reactions:
   a. Oxidative coupling reactions using 3-methyl-2-benzothiazoline hydrazone (MBTH).
   b. Condensation reaction using the reagent.
   c. P-Dimethyl amino cinnamaldehyde (PDAC).
   d. Folin Ciocatecu reagent (FC) reagent.
   e. Diazotization followed by coupling reaction.
   f. Oxidation followed by complexation reaction.
2. Analysis of active pharmaceutical ingredients (API) (5 experiments).
3. Quality control tests of packaging materials (2 experiments).
4. Identification of impurities and related substances in API’s (Albendazole, metronidazole, diclofenac, paracetamol, aspirin, ibuprofen) (2 experiments).
5. Detection and quantitative determination of antioxidants and preservatives.
6. Effectiveness of antimicrobial preservatives (preservative challenge test).
7. Evaluation of congealing temperature, gelling temperature and swelling temperature of excipients (2 experiments).
8. Determination of viscosity of excipients using Brookfield viscometer (2 experiments).
9. Simultaneous estimation of drugs in fixed dose combinations (4 experiments).
10. Experiments based on gel doc system for protein based drugs.
List of experiments:

1. Calibration of instruments (UV, IR, HPLC etc).
2. Validation of (analytical) instruments. (IQ, OQ & PQ) (UV, IR, HPLC).
3. Validation of analytical methods.
4. Standard operating procedure (SOP) for analytical instrumentation.
5. Standard operating procedure (SOP) for cleaning validation.
6. Standard test procedure (STP) for monograph analysis including COA (certificate of analysis).
7. Comparison of methods available in the official methods mentioned in IP, BP, USP etc for various dosage forms.
8. Analytical method validation for evaluation of drugs from biological samples.
9. Analysis of drugs in biological fluids.
10. Cleaning validation method, swab and rinse sample, maximum allowable concentration calculations.
ENTREPRENEURSHIP MANAGEMENT

Subject Code : M PAQ. T. 1.207   Grade: A/B/C/D.
Periods/week : 2                 Examination : --
Nature of Exam : Tutorials       Exam Duration: --

Course Objectives:
- To provide conceptual inputs regarding entrepreneurship management.
- To sensitise and motivate the students towards entrepreneurship management.
- To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.
- To develop management skills for entrepreneurship management.

UNIT – I: CONCEPTUAL FRAMEWORK
- Concept need and process in entrepreneurship development.
- Role of enterprise in national and global economy
- Types of enterprise – Merits and Demerits
- Government policies and schemes for enterprise development
- Institutional support in enterprise development and management

UNIT – II: THE ENTREPRENEUR
- Entrepreneurial motivation – dynamics of motivation.
- Entrepreneurial competency – Concepts.
- Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT – III: LAUNCHING AND ORGANISING AN ENTERPRISE
- Environment scanning – Information, sources, schemes of assistance, problems.
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis.
- Resource mobilisation - finance, technology, raw material, site and manpower.
- Costing and marketing management and quality control.
- Feedback, monitoring and evaluation.

UNIT – IV: GROWTH STRATEGIES AND NETWORKING
- Performance appraisal and assessment
- Profitability and control measures, demands and challenges
- Need for diversification
- Future Growth – Techniques of expansion and diversification, vision strategies
- Concept and dynamics
- Methods, Joint venture, co-ordination and feasibility study

UNIT – V: PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE
- Project work – Feasibility report; Planning, resource mobilisation and implementation.
Reference