# Scheme of Instruction and Evaluation for M. Pharmacy
## (Pharmaceutics)

### I – Semester – Revised-2009

<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>
</thead>
<tbody>
<tr>
<td>M PCT.T. 1.101</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M PCT.T. 1.102</td>
<td>Industrial pharmacy-I (pharmaceutical production technology)</td>
<td>Theory</td>
<td>4</td>
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<tr>
<td>M PCT.T. 1.103</td>
<td>Pharmaceutical Product Development</td>
<td>Theory</td>
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<tr>
<td>M PCT.T. 1.104</td>
<td>Quality Assurance</td>
<td>Theory</td>
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<tr>
<td>M PCT.P. 1.105</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Practical</td>
<td>6</td>
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<tr>
<td>M PCT.P. 1.106</td>
<td>Pharmaceutical Product Development</td>
<td>Practical</td>
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<td>30</td>
<td>70</td>
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<tr>
<td>M PCT.T. 1.107</td>
<td>Scientific and Technical Writing (SAIL)</td>
<td>Tutorial</td>
<td>2</td>
<td>A/B/C/D</td>
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<tr>
<td>M PCT.1.108</td>
<td>Seminar</td>
<td>Theory</td>
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### Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutics)

## II– Semester – Revised-2009

<table>
<thead>
<tr>
<th>Subject Code</th>
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<th>Duration of External Examination</th>
</tr>
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<tbody>
<tr>
<td>M PCT.T. 1.201</td>
<td>IPR &amp; Regulatory Affairs</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
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<tr>
<td>M PCT.T. 1.202</td>
<td>Industrial pharmacy – II (scale up and validation)</td>
<td>Theory</td>
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<tr>
<td>M PCT.T. 1.203</td>
<td>Biopharmaceutics and Pharmacokinetics</td>
<td>Theory</td>
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<tr>
<td>M PCT.T. 1.204</td>
<td>Advances in drug delivery system</td>
<td>Theory</td>
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<tr>
<td>M PCT.P. 1.205</td>
<td>Advances in drug delivery system</td>
<td>Practical</td>
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<tr>
<td>M PCT.P. 1.206</td>
<td>Biopharmaceutics and Pharmacokinetics</td>
<td>Practical</td>
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<tr>
<td>M PCT.T. 1.207</td>
<td>Entrepreneurship Management (SAIL)</td>
<td>Tutorial</td>
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<td>M PC. 1.208</td>
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SAIL: Self assess Instrumentation Learning
Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmaceutics)

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 Grade A/B/C/D/F
Dissertation report Grade A/B/C/D/F

A. Excellent B. Very good C. Good D. Fair F. Fail
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:

UNIT -1

**Improved Tablet Production:** Tablet production process, unit operation improvements, granulation and pelleting equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

**Coating Technology:** Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT – 2

**Parenteral Production:** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

**Lyophilization Technology:** Principles, process, freeze-drying equipments.

UNIT -3

**Capsule Production:** Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

**Disperse Systems Production:** Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

UNIT -4

**Packaging Technology:** Types of packaging materials, machinery, labeling, package printing for different dosage forms.

UNIT -5

**Air Handling Systems:** Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.

**Water Treatment Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI.

**Recommended books:**

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.
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 – 1
Quality Assurance Systems: Basic concept of quality control & quality assurance, functions, sources of variation, quality assurance for raw materials, APIs, packing materials & finished products (specifications, receipt, testing, sampling and certificate of analysis), production (change control, aseptic process control, temperature, pressure & humidity control tests, tests for air flow pattern, microbiological monitoring) buildings & facilities (design and construction features, construction materials, lighting, air handling systems, sanitation & maintenance) equipments (construction, cleaning and maintenance, calibration & handling).

UNIT - 2
In-process quality control: Importance, inspection, IPQC tests for tablets (weight variation, hardness, thickness, friability, disintegration tests and content uniformity), suspensions and emulsions (appearance and feel, volume check, viscosity, particle size distribution, electrical conductivity and content uniformity) and parenterals (pH, volume check, clarity, content uniformity, integrity of seals and particulate matter). Problems encountered and trouble shooting.

UNIT - 3
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 – 4

UNIT – 5
Statistical Quality Control: Scope, sampling – importance, sampling plans, sample size, statistical consideration - probability, frequency distribution. Sampling procedures, handling, labeling & preservation. Analysis of data, Control charts – X charts, R charts, applications.
Recommended books:

4. Statistical design and analysis in pharmaceutical sciences, Marcel Dekker, NY.
5. Statistical Methodology in Pharmaceutical Science, D.A. Berry, Marcel Dekker, NY.
8. Good Laboratory Practice Regulations, S.Weinberg, Vol 69, Marcel Dekker, NY.
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.
ENTREPRENEURSHIP MANAGEMENT

Subject Code : M PCT .T 1.107 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 FRAME WORK
- 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
    Toronto.
    Managing a New Enterprise, Richard D., Inwin, INC, USA.
    Ahmedabad EDII.
UNIT – 1
Patents and Intellectual Property Rights (IPR): Definition, scope, objectives, sources of patent information, patent processing & application, Patents, copyrights, trademarks, salient features, trade related aspects (TRIPS), international & regional agreements.

UNIT – 2

UNIT – 3
Regulatory Affairs: Indian context – Requirements and guidelines of GMP, understanding of Drugs and Cosmetic Act 1940 and Rules 1945, with reference to Schedule M, U and Y.

UNIT – 4

UNIT – 5
Documentation: Types related to pharmaceutical industry, protocols, ammonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended books:

2. Protection of Industrial Property Rights, P. Das and Gokul Das.
3. Law and Drugs, law publ. SN Katju.
4. Original laws published by Govt. of India.
5. Laws of drugs in India, Hussain.
UNIT – 1
**Pilot plant design:** Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenterals and semisolid preparations.

**Scale up:** Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenterals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

UNIT - 2
**Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

UNIT - 3
**Equipment Qualification:** Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

UNIT - 4
**Process validation:** Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT - 5
**Industrial safety:** Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

**Recommended books:**
1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.

8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

UNIT -1
Bioavailability and Bioequivalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.

UNIT -2
Drug Distribution: Factors affecting, protein & tissue binding, kinetics, determination of rate constants & different plots (direct, Scatchard, & reciprocal).

UNIT -3

UNIT - 4
Drug Disposition and Excretion: Biotransformation, factors affecting biotrasformation, Phase I & Phase-II reactions.
Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

UNIT – 5
Pharmacokinetics of Multiple Dosing: Various terminology, determination, adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.
Non-linear kinetics: Cause of non-linearity, estimation of various parameters, bioavailability of drugs that follow non-linear kinetics. Chronopharmacokinetics & pharmacokinetics of elderly and infants.
Recommended books:

3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
UNIT – 1  
**Concept & Models for NDDS:** Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.  
**Carriers for Drug Delivery:** Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT -2  
**Study of Various DDS:** Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary).

UNIT -3  
**Transdermal Drug Delivery Systems:** Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.  
**Advances in Drug Delivery:** Pulsatile, colon specific, liquid sustained release systems.

UNIT – 4  
**Targeted Drug Delivery Systems:** Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

UNIT - 5  
**Protein / Peptide Drug Delivery Systems:** Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.  
**Biotechnology in Drug Delivery Systems:** Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

**Recommended books:**

3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.  
Suggested experiments

1. Preparation and evaluation of different polymeric membranes.
2. Formulation and evaluation of sustained release oral matrix tablet.
3. Formulation and evaluation of sustained release oral reservoir system.
4. Formulation and evaluation of microspheres / microcapsules.
6. Formulation and evaluation of transdermal films.
7. Formulation and evaluation of mucoadhesive system.
Suggested experiments

1. Comparative dissolution studies on different dosage forms for drugs.
2. Effect of pH / particle size on dissolution studies.
3. Plasma protein binding studies on different drugs.
5. Estimation of creatinine clearance.
6. Estimation of pharmacokinetic parameters for the given urinary excretion data.
7. Estimation of pharmacokinetic parameters for the given oral absorption data.
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 address
- 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

The Handbook of Pharmaceutical Excipients has been point, moisture content, moisture-absorption isotherms, particle conceived as a systematic, comprehensive resource of information size distribution, rheology, specific surface area, and solubility, on all of these topics. Scanning electron microphotographs (SEMs) are also included for the first edition of the Handbook was published in 1986 and many of the excipients. This edition contains over 130 near-infrared contained 145 monographs. This was followed by the second (NIR) spectra specifically generated for the Handbook. Pharmaceuticals: basic principles and application to pharmacy practice. October 2013. In book: PHARMACEUTICS: BASIC PRINCIPLES AND APPLICATION TO PHARMACY PRACTICE. Chapter: Semi-solid dosage forms. AuthorsÂ Preparation and evaluation of double-phased mucoadhesive suppositories of lidocaine utilizing CarbopolÂ® and white beeswax. Article. Sep 1999. Log In. Mol. Pharmaceutics All Publications/Website. Or search citations. Molecular Pharmaceutics Accounts of Chemical Research Accounts of Materials Research ACS Agricultural Science & Technology ACS Applied Bio Materials ACSÂ Letters Journal of Proteome Research Journal of the American Society for Mass Spectrometry Langmuir Macromolecules Nano Letters News Edition, American Chemical Society Organic Letters Organic Process Research & Development Organometallics Product R&D SciMeetings The Journal of Physical and Colloid Chemistry. Molecular Pharmaceutics. My Activity. Recently Viewed. Pharmaceuticals can publish multimedia files in articles or as supplementary materials. Please contact the editorial office for further information. All Figures, Schemes and Tables should be inserted into the main text close to their first citation and must be numbered following their number of appearance (Figure 1, Scheme I, Figure 2, Scheme II, Table 1, etc.). All Figures, Schemes and Tables should have a short explanatory title and caption. All table columns should have an explanatory heading.