**PHC 516: PHARMACOPEIAL METHODS OF ANALYSIS OF DRUGS AND DOSAGE FORMS (2 + 2)**

**Course Description**

The course will cover the official qualitative and quantitative tests and methods of assay compiled mainly in the British Pharmacopoeia and the United States Pharmacopoeia and National Formulary to drugs and their dosage forms. The course will deal with the following topics:

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|  |  | **No. of**  **Lectures** |
| **I.** | **Introduction and terminology**  A provision to the statements and terms used in the monographs and appendices. | **1** |
| **II.** | **Formulated preparations**  The definition, storage and labeling of the various types of pharmaceutical preparations. | **2** |
| **III.** | **Validation of official methods of analysis**  The requirements of test procedure of the quality levels of pharmaceutical products: precision, accuracy, specificity, limit of detection, limit of quantification, linearity and range, ruggedness and robustness. | **3** |
| **IV.** | **Uniformity of dosage units**  The uniformity of dosage unit is studied by both weight variation and content uniformity tests. | **2** |
| **V.** | **Chemical tests**  1- Identification of organic nitrogenous bases.  2- Identification of cations and anions.  3- Spectrophotometric identification tests.  4- Limit tests: | **5** |
|  |  | **No. of**  **Lectures** |
| **VI.** | **Analysis of fats and fixed oils**  1- Physical examination.  2- Chemical examination.  a) Acid value.  b) Ester value.  c) Iodine value.  d) Saponification value. | **4** |
| **VII.** | **Biological assays**  1- Design of biological assays.  2- Steps preceeding the calculation of potency.  3- Calculation of potency from a single assay.  4- Experimental error and tests of assay validity.  5- The confidence interval and limits of potency. | **4** |
| **VIII.** | **Miscellaneous determinations**  1- Iodometric assays of antibiotics.  2- Ziesel method for methoxyl group content.  3- Diazometric titration.  4- Oxygen-flask method.  5- Kjeldahl method.  6- Mercurimetric titrations. | **5** |
|  | **Exams.** | **2** |
|  | **Total** | **28** |

**PHC 516: PRACTICAL**

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|  | **No. of Labs** |
| **Validity tests of HPLC methods recommended by USP of some selected drugs and their preparations** | **2** |
| **Content uniformity tests for some selected tablets and capsules; assayed spectrophotometrically** | **2** |
| **Analysis of oils and fats**  Physical examination of oils and fats.  Chemical examination of oils and fats.  1- Acid value.  2- Seponification value.  3- Iodine value.  4- Ester value.  5- Unsaponifiable matter. | **2** |
| **Limit tests**  1- Arsenic.  2- Calcium, potassium and sodium.  3- Chloride and sulphate.  4- Heavy metals: iron, lead and mercury.  5- Residue on ignition.  6- Acid-neutralizing capacity. | **2** |
| **Biological assays**  1- Assay of dexpanthenol.  2- Assay of insulin. | **2** |
| **Miscellaneous determinations**  1- Iodometric assay of antibiotics e.g. amipicillin, benzyl penicillin … etc.  2- Diazometric assay of sulphonamides e.g. sulphacetamide, sulphafurazole.  3- Non-aqueous assay of some drugs (acidic and basic drugs).  4- Mercurimetric determination of some drugs, e.g. thiomersal. | **2** |
| **Exams.** | **2** |
| **Total** | **14** |