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Commentary

Pharmaceutical Analysis: Development of Drugs

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DESCRIPTION

Pharmaceutical analysis occupies a vital role in statutory certification of drugs and their formulations either by the industry or by the regulatory authorities. The complexity of problems encountered in pharmaceutical analysis coupled with the importance of achieving the selectivity, speed, cost, simplicity, sensitivity, precision and accuracy result in new methods of analysis being quickly adopted by the pharmaceutical industry. Formulations containing combinations of drugs for potentiating or complementing another in therapy are on the increase. In some cases, no precise analytical methods are reported and quite often the reported procedures need improvements or changes keeping in view of the advances. Among several instrumental techniques [HPLC, GLC, fluorimetry, NMR, mass spectroscopy, spectrophotometry covering IR, UV and visible regions] available for the assay of drugs, visible spectrophotometric methods depend only on the nature of chemical reaction utilised for colour development and not on sophistication of the equipment. Keeping these points in view, analytical methods have been developed for some of the widely used pharmacodynamic agents namely Nimodipine (NDP) {2-methoxyethyl-1,4-dihydro-5-(isopropoxycarbonyl)-2,6-dimethyl-4-(3-nitrophenyl)-3-pyridine carboxylate→antihypertensive and vasodilator}, Nitrendipine (NTD) etc.

The chemistry of the chromogenic reagents and reactions used in the investigations and general methodology for developing new visible spectrophotometric method [spectral characteristics of the coloured species : optimisation of experimental conditions (effect of pH , reagent concentration and order of addition, keeping time and temperature during each addition, effect of solvent, rate of colour formation and stability), optical characteristics (Beer's law limits, sandell's sensitivity, optimum photometric range and molar absorptivity), precision (standard deviation, percent range of error, testing of significance by F-test) and accuracy (comparison of the proposed and reference methods for pharmaceutical formulations, percent recovery studies with proposed methods, testing of significance by t-test)]. The reagents employed and the methods adopted in the present investigations are furnished. The introduction giving a brief account of chemical name, structure, analytically useful functional groups and details on important analytical methods reported for the concerned drugs. The details of systematic investigation (optimisation of procedures, sensitivity, selectivity, precision, accuracy, adequacy of calibration mode and nature of the coloured species formed) carried out in developing new visible spectrophotometric methods for the assay of each drug with different reagents are incorporated.

CONCLUSION

Manufacturing industries require both qualitative and quantitative analysis to warrant that their raw materials meet certain specifications, and to check the quality of final product. Raw materials are to be checked to ensure that the crucial components are present within the predetermined range of composition and there are not any unusual substances present which might disappoint the manufacturing process or it may appear as a harmful impurity in the final product. In the development of new products which contains mixtures other than the pure material, it is obligatory to ascertain composition of mixture which shows the optimum characteristics for which the material has been developed. Geographical surveys entail analysis to determine the composition of soil sample and numerous rock samples collected from the field. Most of the industrial processes give rise to pollutants which may cause health related problems. So quantitative analysis of air, water and soil sample should be carried out to determine the level of pollution and to establish the safe limits for pollutants.