Drugs & Pharmaceutical Technology Handbook

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Drugs and pharmaceutical industry plays a vital role in the economic development of a nation. It is one of the largest and most advanced sectors in the world, acting as a source for various drugs, medicines and their intermediates as well as other pharmaceutical formulations. India has come a long way in this field, from a country importing more than 95% of its requirement of drugs and pharmaceuticals; India now is exporting it even to developed countries. Being the intense knowledge driven industry, it offers innumerable business opportunities for the investors/ corporate the world over. The existence of well defined and strong pharmaceutical industry is important for promoting and sustaining research and developmental efforts and initiatives in an economy as well as making available the quality medicines to all at affordable prices. That is, it is essential to improve the health status of the individuals as well as the society as a whole, so that positive contributions could be made to the economic growth and regional development of a country. On the global platform, India holds fourth position in terms of volume and thirteenth position in terms of value of production in pharmaceuticals. The pharmaceutical industry has been producing bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing processes as well as a wide range of pharmaceutical machinery and equipments. The modern Indian Pharmaceutical Industry is recent and its foundation was laid in the beginning of the current century. The pharmaceutical industry can be broadly categorised as bulk drugs, formulations, IV fluids and pharmaceutical aids (such as medical equipment, hospital disposables, capsules, etc.). Special feature of the pharmaceutical industry is a large number of manufacturers in the small scale sector. The government is also encouraging the SSI sector providing some incentives. The recent developments in the technology and R & D work in this field have led to the increased growth rate of industries and have established Indian Pharmaceutical industries in the international market.

The content of the book includes information about properties, general methods of analysis, methods of manufacture, of different types of drugs and pharmaceuticals. Some of the fundamentals of the book are polymeric materials used in drug delivery systems, theoretical aspects of friction and lubrication, a convenient method for conversion of quinine to quinidine, formulation and evaluation of bio-available enteric-coated erythromycin and metronidazole tablets, extraction of virginiamycin, antipyretics and analgesics, column chromatographic assay of aspirin tablets, differentiating titration of phenacetin and caffeine, infrared spectra of some compounds of pharmaceutical interest etc.

This book covers an intensive study on manufacturing, production, formulation and quality control of drugs and pharmaceuticals with technology involved in it. This book is an invaluable resource for technologists, professionals and those who want to venture in this field.

1. INTRODUCTION Manufacturing Production Formulation Quality Control

2. POLYMERIC MATERIALS USED IN DRUG DELIVERY SYSTEMS

Preparation of polymers Addition (chain reaction) polymerization Condensation (step-growth) polymerization Crosslinked polymers Copolymerization More complex co-polymer systems

3. PROPERTIES OF FATTY ALCOHOL MIXED EMULSIFIERS AND EMULSIFYING WAXES Mixed emulsifier components Fatty alcohols Surfactants Mixed emulsifiers and emulsifying waxes

4. TABLET LUBRICANTS Theoretical aspects of friction and lubrication Mechanisms of friction **Boundary lubrication** Applications to tableting Chemical composition of lubricants Metallic salts of fatty acids (soaps) Fatty acids, hydrocarbons and fatty alcohols Fatty acid esters Alkyl sulphates Polymers Inorganic materials Miscellaneous materials Effects of lubricants on the manufacture and properties of tablets Batch variation of lubricants Processing **Tablet properties** Magnesium stearate Commercial materials and batch variation Pure grade materials Selection of Lubricants

5. PARACETAMOL-AN ANALYSIS OF TECHNOLOGIES FOR CLEANER PRODUCTION

6. A MODIFIED PROCESS FOR CONVERSION OF - PICOLINE TO NOCOTINIC ACID Experimental Procedure Experimental Data

7. A CONVENIENT METHOD FOR CONVERSION OF QUININE TO QUINIDINE Experimental Procedure Reduction of quinidinone with alane 8. SUSTAINED RELEASE SALBUTAMOL TABLETS - THEORETICAL CONSIDERATIONS Theoretical considerations Calculation of Sustained Release Parameters for Salbutamol Sulphate

9. SUSTAINED RELEASE SALBUTAMOL TABLETS - FOR MULATION ENGINEERING AND EVALUATION USE OF FAT AND WAX MATRIX Materials and methods Discussion

 SUSTAINED RLEASE SALBUTAMOL TABLETS - FORMULATION ENGINEERING AND EVALUATION COMPOSITE WAX MATRIX AND INFLUENCE OF ADDITIVES Materials and methods Results and Discussion
FEASIBILITY OF PRODUCTION OF CHOLERA VACCINE IN FERMENTOR Materials and methods Media Results and Discussion

12. MODIFICATION OF BEESWAX FOR ITS APPLICATION IN TABLET COATING Materials and methods Results and discussion

13. FORMULATION AND EVALUATION OF BIO-AVAILABLE ENTERIC-COATED ERYTHROMYCIN AND METRONIDAZOLE TABLETS Materials and Methods Coating formulations Coating process Dissolution rate studies Methods of analysis Results and discussion Conclusion

14. REDUCING - SUBSTANCES-FREE ACETIC ANHYDRIDE FOR PHARMACEUTICAL INDUSTRIES Experimental procedure Materials Procedure Results and discussion

15. ANTHRACYCLINE ANTIBIOTICS (DAUNORUBICIN AND ADRIAMYCIN) Biosynthesis

A. Origin of the Carbon Skeleton

B. Biosynthetic Interrelationships

Fermentation and Recovery

A. Inoculum Preparation and Production of Daunorubicin

B. Isolation and Purification of Daunorubicin

C. Inoculum Preparation and Production of Adriamycin

D. Isolation and Purification of Adriamycin

16. 6-APA

Production of 6-Apa using Penicillin Acylase

A. Enzymation of Penicillin G

B. Extraction of 6-APA

17. EXTRACTION OF VIRGINIAMYCIN Extraction

18. SAGAMICIN Fermentation Process

19. CHEMOTHERAPEUTICS, ANTIVIRAL Antiviral Agents Effective in Humans Thiosemicarbazones Amantadine Hydrochloride 5-lodo-2'-deoxyuridine Trifluorothymidine Arabinosylcytosine Arabinosyladenine Ribavirin Interferon Immunopotentiating Agents Future of Antiviral Chemotherapy

20. CHEMOTHERAPEUTICS, ANTIPROTOZOAL

Coccidiosis **Thiamine Competitors** Antifolates Antibiotics Nitrobenzamides and Nitrofurans Toxoplasmosis Anaplasmosis **Babesiasis** Theileriasis Trypanosomiasis African Trypanosomiasis Chagas' Disease Leishmaniasis Pneumocystosis **Trichomoniasis** Hexamitosis **Balantidial Dysentery** Giardiasis Amebiases **Intestinal Amebiasis** Primary Amebic Meningo-Encephalitis The Malarias **Drugs Acting on Asexual Blood Forms Drugs Affecting Tissue Forms Drugs Acting on Gametocytes** Action Spectra of Antiprotozoal Drugs Economic considerations

21. CHEMOTHERAPEUTICS, ANTIMYCOTIC AND ANTIRICKETTSIAL Mycotic Infections Superficial Mycoses Systemic and Generalized Mycoses

Antifungal Agents The Polyene Antibiotics Candicidin Pimaricin Nonpolyene Antifungal Antibiotics Griseofulvin Cycloheximide Other antifungal agents Synthetic Antifungal Agents Nonspecific Systemic Medications 5-Fluorocytosine Imidazole Compounds Tolnaftate Haloprogin Agricultural Use of Antifungal Agents **Rickettsial Infections** Treatment of Rickettsial Infections

22. CHEMOTHERAPEUTICIS, ANTIMITOTIC

Drug Classification Alkylating Agents Antimetabolites Antibiotics Plant alkaloids Miscellaneous Agents Hormones Combination therapy Multidrug Treatment Immunology Drug Toxicity Radiation Therapy

23. CHEMOTHERAPEUTICS, ANTHELMINTIC Treatment of Blood Fluke Disease (Schistosomiasis) Treatment of Fluke (Trematode) Infections in the Lungs, Intestines, and Liver Treatment of Tapeworm (Cestode) Infections Treatment of Intestinal Roundworm (Nematode) Infections Treatment of Tissue Roundworm (Nematode) Infections

24. ANTIPYRETICS AND ANALGESICS Salicylic Acid and its Derivatives Methods of Manufacture Sodium Salicylate Aspirin Salicylamide Salicylic Acid Sodium salicylate Aspirin Salicylamide Methods of Analysis Separation and Identification Extraction into Sodium Bicarbonate Solution Procedure

Separation by Column Chromatography Procedures Preparation of Chromatographic Column **Preparation of Samples** Separation of Components Separation by Gas Chromatography **Procedures** Preparation of Column **Preparation of Samples** Separation of Components Identification Procedures **Test with Ferric Chloride** Percipitation of Salicylic Acid Assay Methods Titrimetric Assay of Aspirin Capsules Procedure Column Chromatographic Assay of Aspirin Tablets Procedures Preparation of Column Preparation of Samples and Standard Analysis of Samples Assay by Gas Chromatography Procedures Preparation of Column Calibration Assay of sample for aspiring content **Determination of Impurities** Determination of free salicylic acid in aspirin Chromatographic Method Procedures Preparation of Reagent Preparation of Salicylic Acid Standard Preparation of Column Analysis of Aspirin and Aspiring Tablets **APC Tablets and Flavoured Tablets** Spectrophotometric Method Procedure Readily Carbonizable Substances in Aspirin Procedures **Preparation of Reagents Cobaltous Chloride Cupric Sulphate** Ferric Chloride Sulfuric Acid **Testing of Sample** Impurities in Salicylic Acid Ion Exchange Ultraviolet Method Procedures **Preparation of Apparatus** Preparation of Column Analysis of Samples Procedure

Procedures Preparation of Plates Preparation of Reagents & Standards Preparation of Sample **Qualitative Detection** Quantitative Determination Determination in mixtures Determination After Separation by Extraction Ultraviolet absorption method Procedures Calibration Calculations Heuermann And Levine Method Procedures Preparation of Sample Preparation of Column Separation of APC Organic base Combination **APC Barbiturate Combinations TURI** Method Procedures Preparation of Column **Preparation of Samples** Separation of Fractions Spectrophotometric Measurement Koshy Method **Procedures** Preparation of Column **Preparation of Samples** Separation of Components **Determination of Components** Determination by Gas Chromatography Hoffman and Mitchell Method Procedures Calibration Analysis of Samples **Crippen & Freinuth Method** Procedure Preparation of Column **Operating Conditions** Preparation of Methylating Reagent Preparation of Samples & Standards Analysis of Samples Calculations **Direct Spectrophotometric Procedure** Procedure **Preparation of Mixed Solvents Preparation of Refernce Solutions** Analysis of Samples **Development of Equations** Infrared and Ultraviolet Spectrometry Procedures Mixtures of Aspirin, Phenacetin and Caffeine Mixtures of Aspirin, Phenacetin and Caffeine and Cadeine Phosphate

Mixtures of Aspirin, Phenacetin and Caffeine and Thenylpyramine Hydrochloride **Nonaqueous Titrations** Wollish Methods **Procedures** Determination of Aspirin in the Presence of Stearic Acid Determination of Aspirin in the Absence of Stearic Acid Determination of Phenacetin **Determination of Caffeine** APC Tablets in Combination with Phenindamine Tartrate **Determination of Phenacetin** Determination of phenindamine Tartrate Lin and Blake Methods Procedures Determination of Aspiring in APC Mixtures Differentiating Titration of Phenacetin and Caffeine Differentiating Titration of Aspirin and Phenobarbital Nuclear Magnetic Resonance Spectrometry Procedures **Determination of Spectra** Calculations Derivatives of Aniline and p-Aminophenol Methods of Manufacture **Commercial Grades and Specifications** Methods of Analysis Separation and Identification Separation by Ion Exchange Paper Chromatography **Procedures** Preparation of Iodoplatinate Reagents Extraction Chromatography Separation by Gas-Chromatography Procedures Preparation of Column **Operationg Conditions** Calibration **Preparation of Samples** Separation of Components **Assay Methods Gravimetric Methods** Procedure **Titrimetric Methods Titration with Sodium Nitrite** Procedure **Iodometric Titration** Procedure Assay Through Ethoxy Content Procedure Preparation of Reagent Analysis of Sample Calculations **Colorimetric Methods** Hydroxamic Acid Method Procedure

Diazotation Procedures Procedure Procedures Preparation of Buffer Solution Calibration of the Method Hydrolysis of Phenacetin Mouton and Masson Method Procedure **Chromic Acid Method** Procedure Ultraviolet Spectrophotometry Procedure **Determination of Impurities** Impurities in Phenacetin **Procedures Determination of Acetanilide** Determination of P-Chloroacetanilide **Determination of P-Phenetidine** Free P-Amino Phenol in Acetaminophen Procedures **Determination in Mixtures Derivatives of Quinoline** Methods of Manufacture **Commercial Grades and Specifications** Methods of Analysis Separation and Identification Cinchophen Neocinchophen Assay Mthods **Gravimetric Methods** Procedure **Titrimetric Methods** Procedures Assay of Cinchophen Powder Assay of Cinchophen Tablets Procedure Procedure Spectrophotometric Methods Procedure **Determination of Impurities** Procedures Aniline Derivatives in Cinchophen **Readily Carbonizable Substances** Cinchophen in Neocinchophen **Determination in Mixtures Derivatives of Pyrazolone** Methods of Manufacture **Commercial Grades and Specifications** Methods of Analysis Separation and Identification Antipyrine Separation by Gas Chromatography Aminopyrine

Assay Methods Antipyrine Spectrophotometric Methods Procedure Preparation of Reagent Analysis of Sample **Gravimetric Method Titrimetric Method Polarographic Method** Procedure Aminopyrine **Gravimetric Methods** Procedure Assay of Elixir Assay of Tablets Acid-base Titration **Complexometric Titration** Procedures **Preparation of Reagents** Analysis of Samples **Bromate Titration** Procedure **Oxidative-Cleavage Method** Procedure **Colorimetric Methods** Procedure Preparation of Diazotized P-Nitroaniline Preparation of Sample Solution **Determination by Ferric Chloride** Determination of Diazotized P-Nitroaniline **Determination of Impurities** Antipyrine in Aminopyrine Procedure **Determination in Mixtures** Antipyrine Aminopyrine

25. ANTI-ASTHMATIC AGENTS Adrenergic Stimulants Anticholinergics Inhibitors of the release of Allergic Mediators Xanthine Derivatives Prostaglandins Other Drugs

26. PENICILLINS AND RELATED COMPOUNDS Properties General Method of Analysis Separartion and Identification Chromatography Spectroscopy Other Methods Assay Methods

Microbiological Methods Chemical Methods Iodometric Titration Procedure **Acid-Base Titration** Hydroxylamine Colorimetric Method Procedure Ultraviolet Spectrophotometric Method Procedure **Determination of Impurities** Benzylpenicillin Analysis of Benzylpenicillin Microbiological Assay Methods Procedure Procedure **Chemical Assay methods** Procedure Procedure Allyimercaptomethylpenicillin Analysis of Pencillin O **Microbiological Assay Methods Chemical Assay Methods** Phenoxymethylpenicillin Analysis of Phenoxymethylpenicillin Microbiological Assay Methods **Chemical Assay Methods** Phenethicillin Analysis of Phenethicillin Microbiological Assay Methods **Chemical Assay Methods** Methicillin Analysis of Methicillin **Microbiological Assay Methods** Chemical Assay Methods Carbenicillin Analysis of Carbenicillin Microbiological Assay Methods Procedure **Chemical Methods** Ampicillin Analysis of Ampicillin Microbiological Assay Methods Procedure **Chemical Assay Methods** Isoxazolypenicillins Analysis of Isoxazolylpenicillins **Microbiological Assay Methods Chemical Assay Methods** Nafcillin Microbiological Assay Methods **Chemical Assay Methods** Cephalsoporins Analysis of Cephalosporins

Microbiological Assay Methods Chemical Assay Methods

27. SULFONAMIDES **Therapeutic Aspects** Systemic infections **Urinary Tract Infections Physical and Chemical Properties Theoretical Aspects Biological Mechanism of Action** Structure-Activity Relationship Preparation and Manufacture N1-Heterocyclic Sulfanilamides N1-Acylsulfanilamides N1-Heterocyclic-N4-Acylsulfanilamides N1-Heterocyclic-N1-Acetylsulfanilamides **Miscellaneous Compounds** General Anesthetics, Volatile and Gaseous Nitrous Oxide Cyclopropane **Diethyl Ether** Fluroxene Methoxyflurane Halothen Enflurane Isoflurane General Anesthetics, Fixed **Ultrashort-Acting Barbiturates** Propanidid Ketamine Innovar Althesin Etomidate **Spinal Anesthetics** Metabolism and Toxicity of Volatile Anesthetics Adjuncts to General Anesthesia Local Anesthetics Benzocaine **Bupivacaine Hydrochloride Cocaine Hydrochloride Dibucaine Hydrochloride** Dimethisoquin Hydrochloride Dyclonine Hydrochloride Lidocaine Hydrochloride Pramoxine Hydrochloride Procaine Hydrochloride **Tetracaine Hydrochloride**

28. INFRARED SPECTRA OF SOME COMPOUNDS OF PHARMACEUTICAL INTEREST

DIRECTORY SECTION

PHARMACEUTICAL / BIOTECHNOLOGY COMPANIES

WORLD WIDE PHARMACY RESOURCES

PHARMACEUTICAL, BULK DRUGS, MEDICINES & RAW MATERIALS

PHARMACEUTICAL MACHINERY & EQUIPMENT

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