

Contents

Preface	vii
Acknowledgements	x
1 Chemical purity and its control	1
Introduction, 1; the source of impurities in pharmaceutical chemicals, 2; standardization of pharmaceutical chemicals and formulated products, 11; pharmacopoeial standards, 14; identification, 16; measurement of physical constants, 17; assay, 21; limit tests, 22; general limit tests for non-specific impurity, 24; limit tests for metallic impurities, 30; limit tests for acid radical impurities, 39; limit tests for non-metallic impurities, 44; the control of organic impurity in organic medicinal substances, 44	
2 Registration and assessment of medicines	56
Introduction, 56; clinical trial applications, 63; product licence applications, 66	
3 The theoretical basis of quantitative analysis	83
Acid-base titrations, 83; precipitation and complex formation, 95; oxidation-reduction titrations, 101	
4 Technique of quantitative analysis	112
General information, 112; balances, 114; weighing the sample, 119; technique of volumetric analysis, 123; technique of gravimetric analysis, 129; variables in quantitative analysis, 133	
5 Acidimetry and alkalimetry	137
Standard volumetric solutions, 137; direct titration of strong acids, 143; direct titration of weak acids, 145; direct titration of strong bases, 148; direct titration of weak bases, 153; back titrations, 153; back titrations with blank determinations, 157; determination of organically combined nitrogen, 161	

6 Titration in non-aqueous solvents	165
Theory, 165; titration of alkali metal salts of organic acids, 167; titration of amines and amine salts of organic acids, 169; titration of halogen acid salts of bases, 169; titration of acidic substances, 170; aquametry, 172	
7 Oxidation-reduction titrations	176
Introduction, 176; determinations involving the use of potassium permanganate solution, 176; direct titration with iodine, 179; iodine-sodium thiosulphate titrations, 182; iodine Value of fixed oils, 188; potassium iodate titrations, 191; ammonium cerium(IV) sulphate titrations, 194	
8 Precipitation and complexometric methods	197
Argentimetric titrations, 197; ammonium thiocyanate titration of silver salts, 199; ammonium thiocyanate titration of mercury compounds, 202; theory of complexometric analysis, 202; end point detection in complexometric titration using pM indicators, 209; complexometric methods, 219; direct titration with disodium edetate, 220; back-titrations with disodium edetate, 223 displacement of one complex by another, 224; miscellaneous complexometric methods, 224; gravimetric methods, 225	
9 Solvent extraction methods	228
Theory, 228; determination of the salts of organic acids and bases, 229; determination of alkaloids in crude drugs and galenicals, 225; determination of acids in crude drugs and galenicals, 245; determination of unsaponifiable matter, 246; Indicator extraction titrations, 247	
10 Miscellaneous methods	250
Determination of cineole, 250; determination of ethanol in liquid galenicals, 251; Mercurimetric titrations, 253; determination of methoxyl, 254; oxygen flask combustion, 254; determination of phenols as alkalinsoluble matter, 256; sodium nitrite titrations, 257; Enzymes in pharmaceutical analysis, 259; microbiological assays, 260; biological tests on animals, 263	
11 Medicaments in formulations	264
Introduction, 264; quality control of formulated products, 264; sterility testing of pharmaceutical products, 266 microbial contamination of formulated products, 270; aerosol inhalations, 270 capsules, 274; creams, 278; emulsions, 279; eye drops, 280 injections, 282; lozenges, 286; mixtures, 288; ointments, 295 suppositories, 297; tablets, 299; radiopharmaceuticals, 308	
Index	312