



TWENTIETH REPORT

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## 1. Introduction

This session of the Expert Committee on Specifications for Pharmaceutical Preparations was held in Geneva from 19 to 23 November 1962.

Dr P. Dorolle, Deputy Director-General, opened the session on behalf of the Director-General, and welcomed the members of the Committee and the Temporary Advisers attending the session. He expressed the appreciation of the Organization for the co-operation of the members in its work in the field of pharmaceutical preparations and the control of their quality, and for the considerable work accomplished by some of them and a number of other specialists and laboratories in different countries for several years. This assistance had made it possible to prepare revised specifications of monographs of Volumes I and II of the first edition of the International Pharmacopoeia and its Supplement and to propose specifications for a number of new pharmaceutical preparations. A large number of documents were to be examined at the session to enable the preparation of a complete draft text of the International Pharmacopoeia in the course of the next year, to be sent out to Member States and members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations, as well as to other specialists and pharmacopoeia commissions. The specifications proposed by the Organization were of direct assistance to national laboratories dealing with pharmaceutical quality control. With the increasing introduction of new pharmaceutical preparations, this was of particular importance in developing countries where personnel and facilities were limited. It was also interesting to note that the text of a Volume of Specifications for the Reagents in the International Pharmacopoeia was ready and would be published shortly. A Cumulative List comprising lists 1-11 of proposed international non-proprietary names had just been printed in English, and French and Spanish editions of the list were now in preparation.

## 2. Revision of Draft Monographs and Appendices for the Second Edition of the International Pharmacopoeia (Ph.I.)

### 2.1 Appendices

There was considerable discussion of the appendices to the second edition and the topics which received detailed consideration are summarized below.

### 2.1.1 The biological assay of digitalis

It was generally agreed that the methods recommended for preparing solutions of the several cardiac glycosides should be revised and rewritten so that they were similar in each case, and it was further considered that the methods used in the calculation of assay results could with advantage be grouped together into a single chapter in the appendices dealing specifically with statistical methods for the evaluation of assay data. There was detailed consideration of the need to retain the frog method of assay in view of the present widespread adoption of various mammalian species such as the cat or guinea-pig as well as the frequent use of pigeons for these assays. It was decided to discontinue the frog method, although it was felt by some members of the Committee that it had some value if the warm-blooded species were difficult to procure. It was generally conceded to be a less accurate method.

It was also suggested, as a long-term project, that data should be collected on the embryonic chick heart assay since, although this was commended by some members, it was generally felt that the information presently available was insufficient for this method to be seriously considered for the second edition.

Some discussion took place concerning the possible use of glycoside preparations instead of the present International Standard of dried digitalis leaf. Most members of the Committee found no fault in the present standard and also were of the opinion that a standard as similar as possible in general composition to the material under test was usually to be preferred. It was therefore decided that no change of this kind should be made for the present.

### 2.1.2 Polarography

The Committee had for consideration an appendix on polarography, a well-established, analytical method applicable to a variety of analyses especially in other fields of science. This appendix dealt generally, and in a clear and concise manner, with the fundamental principles of polarography. Although at present the method is only used in few instances in drug analysis, it was the opinion of the Committee that the Ph.I. should be representative of the best current practices of drug control and specification and that such an appendix was therefore a desirable addition to the Pharmacopoeia. The fact that some commercial forms of apparatus for polarography were elaborate and expensive should not be a deterrent, especially as simpler apparatus capable of giving reliable results can be constructed in most laboratories at small expense.

### 2.1.3 Determination of the melting-range of drugs

There was some discussion of the influence of the composition of the glass of melting-point tubes upon the values so determined and the Committee had before it a report showing these variations. Capillaries made of hard glass (borosilicate type) gave more reliable results than those made of soft glass. It was decided to recommend that hard glass be used for all such determinations.

### 2.1.4 Spectrophotometric terminology

The increasing use of spectrophotometric methods over recent years has resulted in the wide use of a variety of different terms to describe the same parameters. Consideration was given to a report intended to unify the terms so employed. The Committee decided to seek advice upon the extent to which these terms were now accepted. If, in fact, they are internationally approved, they should be adopted for the second edition of Ph.I.

The Committee was of the opinion that the practice of specifying the extinction coefficients of drugs for use in spectrophotometric assays should be continued only until authentic chemical substances became available for use as standards. Users of the Pharmacopoeia should also be advised that wavelength maxima readings may vary a little from one instrument to another and the observed maxima should be made use of in the assay, not the actual wavelengths given in the monograph, when the observed and stated maxima do not differ by more than 1 m $\mu$ .

### 2.1.5 Chromatography

In view of the widespread use of chromatography both on paper sheets and thin layers of a stationary phase on glass plates, it was thought that a general appendix dealing with chromatography should also be included. It was also the opinion of the Committee that such an appendix should include as well the principal features of column chromatography and the newer but highly important vapour-phase or gas chromatography.

### 2.1.6 Tests for freedom from pyrogens and from undue toxicity

The Committee considered that the statements in the Pharmacopoeia should be written in a more definite fashion following the lines of the sixteenth edition of the United States Pharmacopoeia (U.S.P. XVI) and British Pharmacopoeia 1958 (B.P. 1958) which state more clearly the conditions under which samples are deemed to have passed or failed these tests.

The possibility of adopting a standard for toxicity of antibiotics was also considered but it was stressed that the test for freedom from toxicity is essentially an all-or-none test designed to detect gross toxicity in the rare event that this might occur and is not to be regarded in any sense as a biological assay of toxicity.

#### 2.1.7 Variation of the drug content of tablets

The Committee expressed very real concern about the possibility of wide variation in the content of the active drug in certain types of tablets and capsules.

Those tablets and capsules in which the active medicament is present in less than 10 per cent. of the total weight of the dose form may exhibit variation due to the great difficulty of mixing very small volumes of drugs with a large volume, often 100 times as great, of the diluent.

This problem will probably be resolved as manufacturers adopt more careful methods of mixing based upon a serial dilution technique in which smaller ratios of diluent to active drug are used in a number of stages.

In the meantime, however, it is essential that this difficult problem should be tackled by attempting to devise methods in which the drug content of individual tablets is analysed and the degree of variation specified instead of the present procedure of bulking a number, often 20, of tablets together and determining the mean drug content.

Attention was drawn to this problem by the published work of Evers<sup>1</sup> in 1948, who showed that the content of vitamin C in tablets varied often more widely than would have been supposed from tablet to tablet. Other workers such as Moskalyk et al.,<sup>2</sup> Stephenson<sup>3</sup> and Train<sup>4</sup> have also described this problem in more detail.

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<sup>1</sup> Evers, N. (1948) Quart. J. Pharm. 21, 205

<sup>2</sup> Moskalyk, R. E., Chatten, L. G., Cox, C. E. & Pernarowski, M., (1961) J. Pharm. Sci. 50, 651

<sup>3</sup> Stephenson, D. (1961) Pharm. Weekbl. 96, 689

<sup>4</sup> Train, D. J. (1960) J. Amer. pharm. Ass., sci. Ed. 49, 265

Although the individual assay of 10 or 20 tablets greatly increases the work of analysis the problem is a real one and such work must be undertaken. Furthermore, there are instances of drugs where existing methods are insufficiently sensitive and further study is needed to develop such methods.

A careful survey of the tablets likely to show such variations should be undertaken in conjunction with advice from the pharmacologist concerning which of these products could give rise to dangerous or erratic therapy for such a reason. The frequency of dosage, the rate of absorption of the drug and its potency and toxicity are clearly factors which need to be taken into account before specifications can be developed aimed at the elimination of such errors. The increasing development of highly potent drugs of which the dosage is frequently less than 1 mg renders such research of major importance for the future.

#### 2.1.8 Concerning precautionary statements

The Committee was asked to consider the desirability of adding statements to certain monographs, in order to warn laboratory workers that the compound concerned might be irritant or toxic. The consensus of the Committee was that an elaborate statement was not needed, but that it was useful to warn against accidental inhalation or skin contact, as follows: "Compound X may produce irritation. Due care should be taken in all manipulations." An example of the substances to which the warning would apply is chlorpromazine.

#### 2.2 Monographs

The Expert Committee examined about 200 revised monographs which had been submitted for critical examination and laboratory checking by the members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and other specialists. In most cases a final text was agreed. About 100 monographs on pharmaceutical preparations not included in the first edition of the International Pharmacopoeia were discussed. Some of these monographs were deferred for the completion of further investigation before the final text can be agreed.

Members considered that the assay of vitamin D on the rachitic rat is such an unsatisfactory assay that attempts should be made to substitute a chemical method. In the monograph on Halibut Liver Oil, regarded by the Committee as a primary source of vitamin A, the assay of vitamin D was deleted as unimportant.

It was decided also no longer to include monographs designed to exhibit methods rather than drugs of therapeutic efficacy (see *Ratanhiae Radix*).

A notable addition is the inclusion of detailed chromatographic specifications for alkaloids of ergot and their salts. The Committee desired to express its thanks and appreciation to the consultants who took part in this work in collaboration with the Secretariat.

### 3. Authentic Chemical Substances

The Committee discussed a report of the work of the Centre for Authentic Chemical Substances established by WHO in the Apotekens Kontrollaboratorium in Stockholm. A sample set of melting-point substances was circulated to members and it was reported that they are now available at no charge to government laboratories and for 10 dollars a set to commercial laboratories. The proposed charge for a set of melting-point substances to commercial laboratories was considered rather low, taking into account the fact that 13 substances were provided in the set. The type of packing and closure was discussed and approved. It was also suggested that announcements in scientific publications such as Nature and Science should be published detailing the materials available from the Centre. The work of the Centre received high commendation from the members of the Committee.

The Committee noted the proposed expansion of the list of authentic substances by the inclusion of additional substances including cortisone acetate, diethylstilboestrol, estradiol benzoate, ethisterone, liothyromine and prednisone, for which testing had been satisfactorily completed.

Some of the new reference substances which the laboratory had been examining so far this year are not yet sufficiently pure to be distributed as such and further work is in progress.

Proposed authentic chemical substances such as desoxycorticosterone acetate, hydrocortisone and ethinyl oestradiol should be regarded as provisional standards pending the submission of the data on additional tests at the next meeting of the Expert Committee. The adoption of such materials as provisional standards would require the submission of additional data to members of the last Expert Committee and their approval for this action.

It was thought highly desirable to send full protocols of test results with the standard materials and to invite comments from the recipients of the standard chemical on tests which they may have performed in support of or different from those of the Centre.

It was also urged by the Committee that an estimate be given of total impurities. Although possibly not of high accuracy, such a figure is widely of value in using standard substances. A reproduction of the infra-red and ultra-violet spectrograms was also suggested for inclusion in the data supplied to users of these materials. In addition, if possible, the gas-vapour chromatograms might also be reproduced. A working party drew up the following recommendations for the guidance of the Centre in these matters.

### 3.1 Test information with WHO authentic chemical substances

In addition to the spectrophotometric and chemical assay data now supplied to users, with each authentic chemical substance, the Committee recommends that the Centre for Authentic Chemical Substances consider furnishing other valuable analytical data, for example:

- (1) Wherever thin-layer chromatography (TLC) is applicable, the report should describe the solvent system and spot detection system or reagent, the number of impurities found, the Rf values of the main component and the impurities, the relative polarity of the impurities (i.e. whether less polar (LP) or more polar (MP)) and an estimate of total impurities (ETI).
- (2) Wherever vapour-phase chromatography (VPC) is applicable, the report should describe the nature of the chromatographic column, the operation conditions, (including temperature programming, if any), the retention times (RT) of the main component and all significant impurities, and an estimate of the content of main component, as determined by the ratio of the area under the main peak to the total areas under all peaks on the chromatographic record.

The Committee took note of the availability of a recent publication<sup>1</sup> which records the infra-red, ultra-violet and visible absorption spectra of some U.S.P. and N.F. Reference Standards and their derivatives.

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<sup>1</sup> J. Ass. Official Agr. Chem. 1962, 45 (4)

The question of the adequacy of the Expert Committee to pronounce on the quality of these authentic chemical substances and approve them was also discussed and it was suggested that the matter was sufficiently important to appoint consultants to approve these standards on the basis of the collected information from the Centre. Another suggestion was that the Expert Committee should examine the work done by the collaborating laboratories undertaking these tests, and that its members should communicate and assess the collected results. Approval by the Expert Committee of the laboratories collaborating would then constitute a ratification of their recommendations.

Discussion was held on the use of International Biological Standards for physico-chemical work and it was considered that these were set up with a different purpose in mind - the establishment of assay standards for biological comparisons. They are usually historically comparatively impure and it is often many years later before a sufficiently pure preparation is available for physico-chemical tests. The chances of a similar standard being suitable for both applications was considered to be unlikely and therefore the Centre for Authentic Chemical Substances must go ahead independently with standards for physico-chemical work. The guiding factor in the choice of new standards must be the use of the substance in pharmacopoeial testing. Consideration should not be given to the provision of authentic substances for research purposes although it is possible that the Centre might act as a repository for research chemical substances emanating from the laboratories of the workers primarily concerned.

It was considered that the Centre might hold stocks of holmium glass filters for the calibration of spectrophotometers and that a batch of such glass be obtained and calibrated by a collaborative arrangement in various national centres.

It was decided to attempt to establish a system for the selection of materials for which authentic chemical substances should be set up. Of more immediate urgency was the selection of authentic chemical substances to be worked on in the next year. In this connexion, the suggestion was made that where a monograph in Ph.I. calls for an authentic chemical substance this automatically shall require the Centre to undertake the work of preparing that substance.

At present, 23 such standards are required for infra-red spectra and 10 for colorimetric, some of which are at present available. It was further suggested that the order of precedence in working on these 33 substances should be based on the demands shown in the requests from other countries and other laboratories. Since these substances are required for the second edition of Ph.I., it is essential that they be made available at the time the new edition is printed. Collaboration with other pharmacopoeial bodies will also continue with the priorities of the Ph.I. in mind.

The Committee felt that work of the Centre for Authentic Chemical Substances was of great importance since it might receive demands in the future which it should be prepared to meet, and yet the magnitude of these demands can hardly be guessed at the moment. The Committee is, therefore, of the opinion that sufficient financial support should be given to the work of the Centre.

### 3.2 Reference samples of vegetable drugs

It has been found in India that there is extensive adulteration and even substitution in plant drugs.<sup>1</sup> The Indian Pharmacopoeia includes 77 botanical sources of vegetable drugs of which many are common to the pharmacopoeias of other countries. The problem is not one for India alone, especially as India is one of the largest exporters of drugs to other countries. An authentic crude drug specimen would need to be maintained as a reference for the drug itself or for the isolation of its active constituents.

The Committee expressed the opinion that a study should be made of the possible needs for a centre for authentic vegetable drug standards to be set up under the aegis of WHO on the lines of centres such as the WHO Centre for Authentic Chemical Substances in Stockholm. There is already the beginning of such an organization in the Central Drugs Laboratory in Calcutta, with samples and specimens of plants, plant extracts and tinctures.

The Committee discussed this problem extensively and suggested that WHO may seek advice from experts to determine what vegetable drugs are of interest in international commerce and whether the present standards are adequate.

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<sup>1</sup> Unpublished document, Pharm S.294 and Add.1, 2

#### 4. International Non-Proprietary Names

A report from the Sub-Committee on Non-Proprietary Names was tabled and discussed. Members were informed that some 200 requests for INN's were considered at a meeting of the Sub-Committee a few weeks earlier. It was pointed out that many of the names adopted had already been the subject of correspondence between the members of the Expert Committee and the Secretariat. The saving in time thus effected is of great importance since these names are usually required quite urgently. A good example of the value of INN's was seen in the case of the drug thalidomide, where legislation and regulatory control were greatly facilitated by its use.

The work of the Sub-Committee has shown the advantages of receiving requests from national authorities concerned with non-proprietary names rather than direct from individual manufacturers. The adoption of this procedure in other countries would be helpful.

The Sub-Committee devoted much of its time to the consideration of the general principles for the selection of INN's and these principles have become quite well developed over the years. On the occasion of the recent meeting, attention was given to radioactive drugs and appropriate nomenclature for them.

There was some feeling in the Sub-Committee that the names might be classified according to some pharmacological grouping. There were a number of difficulties in the adoption of such a scheme but it is a principle that, as far as is practicable, the INN includes syllables which have a pharmacological indication (e.g. "gly" is part of the name for many hypoglycaemic drugs).

The comment was made that in the lists there might be an indication as to which drugs were no longer of therapeutic interest, or important in commerce. One difficulty is that a drug which is "dead" in one country may still be used elsewhere; again, the name for such a compound still needs to be listed for reference purposes. It does not seem to be advisable to abandon any INN.

There was a suggestion from several members of the Committee that it was almost certainly impossible for any expert to recognize every drug in these lists and therefore it would seem a good idea to include one or two of the really commonly-used names

for each. The reply in this case was that whatever might be attempted in this way, there would still be the possibility that the Committee might be accused of discrimination between different manufacturers or different countries. Sometimes a name, e.g. "aspirin", might be official in some countries and yet be a proprietary name in another.

The Committee expressed its sincere appreciation of the amount of work put in by the Sub-Committee on Non-Proprietary Names and the Secretariat upon this work and congratulated them on an excellent achievement. It was also most pleasing to hear that the compilation of the first 11 lists of proposed names had now been printed and was available. Members were given copies of the publication and were very appreciative of what had been done.

#### 5. Collaborative Work on Specifications for Pharmaceutical Preparations

The Committee considered the work undertaken by different international organizations in order to unify a number of specifications and general methods for pharmaceutical analysis. The intention of the Pharmaceutical Committee of the Council of Europe to create a Western European pharmacopoeia, including minimum specifications for some 100 important pharmaceutical preparations, is of special interest. The Committee noted that the final stages of the preparation of a Nordic Pharmacopoeia are now being entered into and it should be available early in 1963. Mention was also made of a proposal of the Arab League to prepare a Pan Arab pharmacopoeia. It was considered important that WHO should work in co-operation with such groups.

#### 6. National Pharmacopoeias in Relation to Ph.I.

There was extensive discussion of the place of national pharmacopoeias and their relationship to the Ph.I. Very often there are differences due to the traditional use of vegetable drugs. Again, in countries less developed industrially, there may have to be modification of drug standards simply because those of the Ph.I. are impractical at the time.

Canada and Australia were examples of countries in which there seemed to be no desire to establish national pharmacopoeias, but it was stated that the International Pharmacopoeia had a very valuable place as a book of standards of reference in both these countries.

7. European Technical Meeting on the Quality Control  
of Pharmaceutical Preparations

Preparations<sup>1</sup>

The Committee noted the report of this Meeting, held under the aegis of the World Health Organization, Regional Office for Europe. It was felt that such a meeting was of great practical interest and it was stressed that an important problem is to devise methods of safety control in order to lessen the risk of new pharmaceutical preparations when they are exposed to the test of long practical usage.

The Committee wished, therefore, to express its appreciation of the work undertaken in the European Region in holding this Meeting and was of the opinion that similar meetings would very usefully be held in other regions. They would help to draw the attention of governments to the need for adequate quality control of all drugs on the market in the different countries, and suggest ways and means of arranging for sufficient laboratory facilities and the training of personnel, in the best interest of public health and international commerce.

8. List of Unpublished Working Documents

1. Daily Records of the Session of the Expert Committee on Specifications for Pharmaceutical Preparations. Pharm S.347/20
2. Centre for Authentic Chemical Substances. Report on the Work in 1962. WHO/Pharm/404 and WHO/Pharm/400
3. Nineteenth Report of the Expert Committee on Specifications for Pharmaceutical Preparations. WHO/Pharm/395
4. Twelfth Report of the Sub-Committee on Non-Proprietary Names of the Expert Committee on Specifications for Pharmaceutical Preparations. WHO/Pharm/401
5. General Methods for the Second Edition of the International Pharmacopoeia. WHO/Pharm/Ed.Sec./111 (Dr F. Reimers); WHO/Pharm/Ed.Sec./111 Add.1 (Professor L. Domange); WHO/Pharm/Ed.Sec./111 Add.2 (Professor E. Vogelenzang); WHO/Pharm/Ed.Sec./111 Add.3 (Dr P. Zuman and Dr J. Vacek); WHO/Pharm/Ed.Sec./111 Add.4 (Mr Auerbach and Dr T. Dunham); WHO/Pharm/Ed.Sec./112 (Secretariat); WHO/Pharm/Ed.Sec./112 Add.1 (Dr L. Miller); WHO/Pharm/Ed.Sec./113 (Secretariat)

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<sup>1</sup> Report on a European Technical Meeting, Warsaw, 29 May - 2 June 1961, Wld Hlth Org. techn. Rep. Ser. 1962, 249

PROVISIONAL LIST OF MONOGRAPHS AND APPENDICES FOR THE SECOND EDITION  
OF THE INTERNATIONAL PHARMACOPOEIALISTE PROVISOIRE DES MONOGRAPHIES ET APPENDICES A INSERER DANS LA  
DEUXIEME EDITION DE LA PHARMACOPEE INTERNATIONALE

Item (a) Monographs from the first edition of the International Pharmacopoeia  
(a) Monographies figurant dans la première édition

- |                                  |                                |
|----------------------------------|--------------------------------|
| 1. Acetarsolum                   | 24. Aethisteronum              |
| 2. Acidum Acetizoicum            | 25. Aethylenediamini Hydras    |
| 3. Acidum Acetylsalicylicum      | 26. Aethylis Aminobenzoas      |
| 4. Acidum Ascorbicum             | 27. Aethylis Biscoumacetas     |
| 5. Acidum Benzoicum              | 28. Aethylis Chloridum         |
| 6. Acidum Boricum                | 29. Aethylis Hydnocarpas       |
| 7. Acidum Folicum                | 30. Aminophenazonum            |
| 8. Acidum Hydrochloricum         | 31. Aminophyllinum             |
| 9. Acidum Hydrochloricum Dilutum | 32. Amobarbitalum              |
| 10. Acidum Iopanoicum            | 33. Amobarbitalum Natricum     |
| 11. Acidum Lacticum              | 34. Amodiaquini Hydrochloridum |
| 12. Acidum Mersalylicum          | 35. Amphetamini Sulfas         |
| 13. Acidum Nicotinicum           | 36. Amyleni Hydras             |
| 14. Acidum Salicylicum           | 37. Amylis Nitris              |
| 15. Acidum Undecylenicum         | 38. Antazolini Hydrochloridum  |
| 16. Adrenalini Bitartras         | 39. Apomorphini Hydrochloridum |
| 17. Adrenalinum                  | 40. Aqua Demineralisata        |
| 18. Aethanolum                   | 41. Aqua Destillata            |
| 19. Aethanolum Absolutum         | 42. Aqua pro Injectione        |
| 20. Aethanolum Dilutum           | 43. Argenti Nitras             |
| 21. Aether Anaestheticus         | 44. Argentum Proteinicum       |
| 22. Aether Vinylicum             | 45. Arseni Trioxydum           |
| 23. Aethinyloestradiolum         | 46. Atropini Methonitras       |

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| 47. | Atropini Sulfas                             | 78.  | Chlorobutanolum                  |
| 48. | Barbitalum Natricum                         | 79.  | Chlorcyclizini Hydrochloridum    |
| 49. | Barii Sulfas                                | 80.  | Chlorobutanolum Hydratum         |
| 50. | Belladonnae Herba                           | 81.  | Chlorocresolum                   |
| 51. | Pulvis Belladonnae Herbae                   | 82.  | Chloroformium Anaestheticum      |
| 52. | Pulvis Belladonnae Herbae<br>Standardisatus | 83.  | Chlorophenothanum Technicum      |
| 53. | Belladonnae Radix                           | 84.  | Chloroquini Diphosphas           |
| 54. | Pulvis Belladonnae Radicis                  | 85.  | Chloroquini Sulfas               |
| 55. | Benzalkonii Chloridum                       | 86.  | Chlorpromazini Hydrochloridum    |
| 56. | Benzethonii Chloridum                       | 87.  | Chlortetracyclini Hydrochloridum |
| 57. | Benzylis Benzoas                            | 88.  | Cocaini Hydrochloridum           |
| 58. | Benzylpenicillinum Kalicum                  | 89.  | Codeini Phosphas                 |
| 59. | Benzylpenicillinum Natricum                 | 90.  | Codeinum                         |
| 60. | Bismuthi Subcarbonas                        | 91.  | Coffeinum                        |
| 61. | Bismuthi Subnitras                          | 92.  | Coffeinum et Natrii Benzoas      |
| 62. | Bismuthi Subsalicylas                       | 93.  | Coffeinum et Natrii Salicylas    |
| 63. | Calciferolum                                | 94.  | Cochicinum                       |
| 64. | Calcii Chloridum Crystallisatum             | 95.  | Compressi Acidi Acetylsaliclici  |
| 65. | Calcii Gluconas                             | 96.  | Compressi Acidi Ascorbici        |
| 66. | Calcii Lactas                               | 97.  | Compressi Acidi Iopanoici        |
| 67. | Calcii Para-aminosalicylas                  | 98.  | Compressi Aethisteroni           |
| 68. | Calcii Saccharas                            | 99.  | Compressi Amidopyrini            |
| 69. | Camphora                                    | 100. | Compressi Aminophyllini          |
| 70. | Carbacholum                                 | 101. | Compressi Amobarbitali           |
| 71. | Carbarsonum                                 | 102. | Compressi Amphetamini Sulfatis   |
| 72. | Carbimazolium                               | 103. | Compressi Atropini Sulfatis      |
| 73. | Carbonei Dioxydum                           | 104. | Compressi Barbitali Natrici      |
| 74. | Cascara Sagrada                             | 105. | Compressi Calcii Gluconatis      |
| 75. | Cetrimonii Bromidum                         | 106. | Compressi Calcii Lactatis        |
| 76. | Chlorali Hydras                             | 107. | Compressi Carbarsoni             |
| 77. | Chloramphenicolum                           | 108. | Compressi Carbimazoli            |

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| 109. Compressi Chlorcyclizini<br>Hydrochloridi  | 140. Compressi Obducti                                   |
| 110. Compressi Chloroquini Diphosphatis         | 141. Compressi Pethidini Hydrochloridi                   |
| 111. Compressi Chloroquini Sulfatis             | 142. Compressi Phenacetini                               |
| 112. Compressi Codeini Phosphatis               | 143. Compressi Phenobarbitali                            |
| 113. Compressi Chlorpromazini<br>Hydrochloridi  | 144. Compressi Phenobarbitali Natrici                    |
| 114. Compressi Colchicini                       | 145. Compressi Primidoni                                 |
| 115. Compressi Dextro Emphetamini<br>Sulfatis   | 146. Compressi Proguanili Hydrochloridi                  |
| 116. Compressi Diaethylcarbamazini<br>Citratiss | 147. Compressi Promethazini<br>Hydrochloridi             |
| 117. Compressi Dicoumaroli                      | 148. Compressi Pyrimethamini                             |
| 118. Compressi Dienoestrolis                    | 149. Compressi Quinidini Sulfatis                        |
| 119. Compressi Diethylstilboestrolis            | 150. Compressi Quinini Hydrochloridi                     |
| 120. Compressi Digitalis                        | 151. Compressi Quinini Sulfatis                          |
| 121. Compressi Digitoxosidi                     | 152. Compressi Riboflavini                               |
| 122. Compressi Digoxini                         | 153. Compressi Santonini                                 |
| 123. Compressi Ephedrini Hydrochloridi          | 154. Compressi Secobarbitali Natrici                     |
| 124. Compressi Ergometrini Maleatis             | 155. Compressi Succinylsulfathiazoli                     |
| 125. Compressi Ergotamini Tartratis             | 156. Compressi Sulfadiazini                              |
| 126. Compressi Ferrosi Sulfatis                 | 157. Compressi Sulfadimidini                             |
| 127. Compressi Glycerylis Trinitratiss          | 158. Compressi Sulfaguanidini                            |
| 128. Compressi Hydromorphonis<br>Hydrochloridi  | 159. Compressi Sulfamerazini                             |
| 129. Compressi Hyoscini Hydrobromidi            | 160. Compressi Sulfanilamidis                            |
| 130. Compressi Isoprenalini Sulfatis            | 161. Compressi Sulfathiazoli                             |
| 131. Compressi Lanatosidi C                     | 162. Compressi Theobromini Natrici et<br>Natrii Acetatis |
| 132. Compressi Menadioni                        | 163. Cortisoni Acetas                                    |
| 133. Compressi Mepacrini Hydrochloridi          | 164. Cresolum  |
| 134. Compressi Mepyramini Maleatis              | 165. Cyanocobalaminum                                    |
| 135. Compressi Methamphetamini<br>Hydrochloridi | 166. Cyclopropanum                                       |
| 136. Compressi Methyltestosteroni               | 167. Desoxycortoni Acetas                                |
| 137. Compressi Natrii Salicylatis               | 168. Dextro Amphetamini Sulfas                           |
| 138. Compressi Neostigmini Bromidi              | 169. Diethylcarbamazini Citras                           |
| 139. Compressi Nicotinamidi                     | 170. Dicoumarolum  |
|   | 171. Dienoestrolum                                       |
|   | 172. Diethylstilboestrolum                               |

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| 173. | Digitalis Folium                         | 202. | Hexobarbitalum Natricum                     |
| 174. | Pulvis Digitalis Folii                   | 203. | Histamini Phosphas                          |
| 175. | Pulvis Digitalis Folii<br>Standardisatus | 204. | Homatropini Hydrobromidum                   |
| 176. | Digitoxosidum                            | 205. | Hyaluronidasum pro Iniectione               |
| 177. | Digoxinum                                | 206. | Hydrargyri Aminochloridum                   |
| 178. | Dihydrostreptomycini Sulfas              | 207. | Hydrargyri Oxycyanidum                      |
| 179. | Diiodohydroxy-quinolinum                 | 208. | Hydrargyri Oxydum Flavum                    |
| 180. | Dimercaprolum                            | 209. | Hydrargyrum                                 |
| 181. | Diphenhydramini Hydrochloridum           | 210. | Hydrocodoni Bitartras                       |
| 182. | Emetini Hydrochloridum                   | 211. | Hydrocortisoni Acetas                       |
| 183. | Ephedrini Hydrochloridum                 | 212. | Hydrocortisonum                             |
| 184. | Ergometrini Maleas                       | 213. | Hydromorphoni Hydrochloridum                |
| 185. | Ergotamini Tartras                       | 214. | Hyoscini Hydrobromidum                      |
| 186. | Erythromycinum                           | 215. | Hyoscyami Herba                             |
| 187. | Ferrosi Sulfas                           | 216. | Pulvis Hyoscyami Herbae                     |
| 188. | Ferrosi Sulfas Exsiccatus                | 217. | Hyoscyami Mutici Herba                      |
| 189. | Filix Mas                                | 218. | Pulvis Hyoscyami Mutici Herbae              |
| 190. | Pulvis Filicis Malis                     | 219. | Iniectiones                                 |
| 191. | Fluoresceinum Natricum                   | 220. | Iniectio Acetrizoici Natrici                |
| 192. | Gallamini Triaethiodidum                 | 221. | Iniectio Adrenalini                         |
| 193. | Gammabenzeni Hexachloridum               | 222. | Iniectio Aminophyllini                      |
| 194. | Glucosum                                 | 223. | Iniectio Apromorphini Hydrochlorid          |
| 195. | Glycerolum                               | 224. | Iniectio Atropini Sulfatis                  |
| 196. | Glycerolum Dilutum                       | 225. | Iniectio Bismuthi Subsalyclatis             |
| 197. | Gonadotrophinum Chorionicum              | 226. | Iniectio Calcii Gluconatis                  |
| 198. | Gonadotrophinum Sericum                  | 227. | Iniectio Carbacholi                         |
| 199. | Heparinum                                | 228. | Iniectio Coffeini et Natrii<br>Benzoatis    |
| 200. | Hexamethonii Tartras                     | 229. | Iniectio Coffeini et Natrii<br>Salicyclatis |
| 201. | Hexobarbitalum                           | 230. | Iniectio Desoxycortoni Acetatis             |

231. Injunctio Digoxini  
232. Injunctio Dimercaprolis  
233. Injunctio Emetini Hydrochloridi  
234. Injunctio Ergometrini Maleatis  
235. Injunctio Ergometrini Tartratis  
236. Injunctio Glucosi  
237. Injunctio Heparini  
238. Injunctio Hexamethonii Tartratis  
239. Injunctio Histamini Phosphatis  
240. Injunctio Hydromorphonis  
Hydrochloridi  
241. Injunctio Hyoscini Hydrobromidi  
242. Injunctio Insulini  
243. Injunctio Insulini Zinci  
Protaminati  
244. Injunctio Lanatosidi C  
245. Injunctio Levarterenoli  
246. Injunctio Lobelini Hydrochloridi  
247. Injunctio Menadioni  
248. Injunctio Mersalyli et Theophyllini  
249. Injunctio Morphini  
250. Injunctio Nalorphini Hydrochloridi  
251. Injunctio Natrii Chloridi  
252. Injunctio Natrii Chloridi Composita  
253. Injunctio Natrii Lactatis Composita  
254. Injunctio Neostigmini Methylsulfatis  
255. Injunctio Nicethamidi  
256. Injunctio Nicotinamidi  
257. Injunctio Oestradioli Benzoatis  
258. Injunctio Oestroni  
259. Injunctio Oxytocini  
260. Injunctio Pentetrazoli  
261. Injunctio Pethidini Hydrochloridi  
262. Injunctio Phenobarbitali Natrici  
263. Injunctio Picrotoxini  
264. Injunctio Pituitarii Posterioris  
265. Injunctio Procainamidi Hydrochloridi  
266. Injunctio Procaini Hydrochloridi  
267. Injunctio Riboflavini  
268. Injunctio Stibopheni  
269. Injunctio Sulfadizaini Natrici  
270. Injunctio Sulfamerazini Natrici  
271. Injunctio Sulfathiazoli Natrici  
272. Injunctio Suxamethonii Chloridi  
273. Injunctio Testosteroni Propionatis  
274. Injunctio Tetracaini Hydrochloridi  
275. Injunctio Tubocurarini Chloridi  
276. Injunctio Vasopressini  
277. Iodum  
278. Ipecacuanhae Radix  
279. Pulvis Ipecacuanhae Radicis  
280. Pulvis Ipecacuanhae Radicis  
Standardisatus  
281. Isoniazidum  
282. Isoprenalini Hydrochloridum  
283. Isoprenalini Sulfas  
284. Kalii Bromidum  
285. Kalii Chloridum  
286. Kalii Hydroxydum  
287. Kalii Iodidum  
288. Kalii Nitras  
289. Lanatosidum C

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| 290. | Levarterenoli Bitartras        | 321. | Oleoresina Filicis Malis       |
| 291. | Lidocaini Hydrochloridum       | 322. | Oleum Anisi                    |
| 292. | Lidocainum                     | 323. | Oleum Hydnocarpi               |
| 293. | Lobelini Hydrochloridum        | 324. | Oleum Jecoris Aselli           |
| 294. | Menadionum                     | 325. | Oleum Jecoris Hippoglossi      |
| 295. | Mepacrini Hydrochloridum       | 326. | Oleum Ricini                   |
| 296. | Mepyramini Maleas              | 327. | Opium                          |
| 297. | Methadoni Hydrochloridum       | 328. | Pulvis Opii Standardisatus     |
| 298. | Methamphetamini Hydrochloridum | 329. | Ouabainum                      |
| 299. | Methoxamini Hydrochloridum     | 330. | Oxophenarsini Hydrochloridum   |
| 300. | Methylthiouracilum             | 331. | Oxycodoni Hydrochloridum       |
| 301. | Methyltestosteronum            | 332. | Oxydum Nitrosum                |
| 302. | Morphini Hydrochloridum        | 333. | Oxygenium                      |
| 303. | Morphini Sulfas                | 334. | Oxytetracyclini Hydrochloridum |
| 304. | Nalorphini Hydrochloridum      | 335. | Papaverini Hydrochloridum      |
| 305. | Natrii Bromidum                | 336. | Pentetrazolum                  |
| 306. | Natrii Chloridum               | 337. | Pethidini Hydrochloridum       |
| 307. | Natrii Citras                  | 338. | Phenacetinum                   |
| 308. | Natrii Iodidum                 | 339. | Phenazonum                     |
| 309. | Natrii Nitris                  | 340. | Phenobarbitalum                |
| 310. | Natrii Para-aminosalicylas     | 341. | Phenobarbitalum Natricum       |
| 311. | Natrii Pyrosulfis              | 342. | Phenolum                       |
| 312. | Natrii Salicylas               | 343. | Phenylhydrargyri Nitras        |
| 313. | Natrii Tetraboras              | 344. | Phenytoinum                    |
| 314. | Neoarsphenaminum               | 345. | Phthalysulfathiazolum          |
| 315. | Neostigmini Bromidum           | 346. | Physostigmini Salicylas        |
| 316. | Neostigmini Methylsulfas       | 347. | Picrotoxinum                   |
| 317. | Nicethamidum                   | 348. | Pilocarpini Nitras             |
| 318. | Nicotinamidum                  | 349. | Pituitarium Posterius          |
| 319. | Oestradioli Benzoas            | 350. | Podophylli Resina              |
| 320. | Oestronum                      | 351. | Polymyxini B. Sulfas           |

352. Primaquini Diphosphas  
353. Primadonum  
354. Procainamidi Hydrochloridum  
355. Procaini Benzylpenicillinum  
356. Procaini Hydrochloridum  
357. Profenamini Hydrochloridum  
358. Progesteronum  
359. Proguanili Hydrochloridum  
360. Promethazini Hydrochloridum  
361. Propylthiouracilum  
362. Pyridoxini Hydrochloridum  
363. Pyrimethaminum  
364. Quinidini Sulfas  
365. Quinini Hydrochloridum  
366. Quinini Sulfas  
367. Riboflavinum  
368. Santoninum  
369. Secobarbitalum Natricum  
370. Secale Cornutum  
371. Pulvis Secalis Cornuti  
Standardisatus  
372. Solutio Benzalkonii Chloridi  
373. Solutio Benzethonii Chloridi  
374. Solutio Formaldehydi  
375. Solutio Iodi Aquosa  
376. Solutio Iodi Spirituosa  
377. Solutio Kalii Arsenitis  
378. Stibophenum  
379. Stramonii Herba  
380. Pulvis Stramonii Herbae  
381. Streptomycini Sulfas  
382. Strychni Semen  
383. Pulvis Strychni Seminis  
384. Pulvis Strychni Seminis  
Standardisatus  
385. Succinylsulfathiazolum  
386. Sulfadiazinum  
387. Sulfadiazinum Natricum  
388. Sulfanilamidum  
389. Sulfathiazolum  
390. Sulfathiazolum Natricum  
391. Suraminum Natricum  
392. Suspensio Insulini Zinci  
393. Suspensio Insulini Zinci Amorphi  
394. Suspensio Insulini Zinci  
Crystallisati  
395. Suxamethonii Chloridum  
396. Testosteroni Propionas  
397. Tetracaini Hydrochloridum  
398. Tetrachloroaethylenum  
399. Tetracyclini Hydrochloridum  
400. Theobrominum Natricum et Natrii  
Acetas  
401. Theobrominum Natricum et Natrii  
Salicylas  
402. Theophyllum  
403. Theophyllum Natricum et Natrii  
Acetas  
404. Thiamini Hydrochloridum  
405. Thiopentalum Natricum cum Natrii  
Carbonate  
406. Thyroidea  
407. Tincturae  
408. Tinctura Digitalis  
409. Tinctura Hyoscyami  
410. Tinctura Ipecacuanhae

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| 411. | Tinctura Opii                   | 419. | Tripelannamini Hydrochloridum |
| 412. | Tinctura Opii Benzoica          | 420. | Tryparsamidum                 |
| 413. | Tinctura Stramonii              | 421. | Tuberculinum Pristinum        |
| 414. | Tinctura Strychni               | 422. | Tubocurarini Chloridum        |
| 415. | Tribromoethanolum               | 423. | Urethanum                     |
| 416. | Trichloroethylenum              | 424. | Zinci Oxydum                  |
| 417. | Trihexyphenydyli Hydrochloridum | 425. | Zinci Sulfas                  |
| 418. | Trimethadionum                  |      |                               |

Item (b) New monographs

1. Acetazolamide
2. Acetazolamide tablets
3. Adonis Vernalis herb
4. Aloe
5. Benzathine penicillin
6. Bendrofluazide
7. Bacitracin
8. Bemegride
9. Betazole hydrochloride
10. Betazole hydrochloride injection
11. Bethanechol chloride
12. Bethanechol chloride injection
13. Bethanechol chloride tablets
14. Busulfan
15. Busulfan tablets
16. Calcium disodium edetate
17. Calcium disodium edetate injection
18. Cetyl pyridinium chloride
19. Chlormerodrin tablets
20. Chlormethin hydrochloride
21. Chlormethine injection
22. Chlorothiazide
23. Chlorothiazide tablets
24. Chlorpheniramine maleate
25. Chlorpheniramine maleate injection
26. Chlorpheniramine maleate tablets
27. Corticotrophine
28. Cyclizine hydrochloride
29. Cyclizine hydrochloride tablets
30. Cyclobarbital calcium
31. Cyclobarbital calcium tablets
32. Dextromoramide
33. Diaphenylsulfone
34. Diaphenylsulfone tablets
35. Diatrizoate sodium
36. Diatrizoate sodium injection
37. Dimenhydrinate
38. Diprophylline
39. Doxylamine succinate
40. Doxylamine succinate tablets
41. Edrophonium chloride
42. Edrophonium chloride injection
43. Ferrous gluconate
44. Fludrocortisone acetate
45. Fludrocortisone tablets
46. Gluthetimide
47. Glycobiarsol
48. Glycobiarsol tablets
49. Griseofulvin
50. Helium
51. Hydralazine hydrochloride
52. Hydralazine tablets
53. Hydrochlorothiazide
54. Hydrocortisone hydrogen succinate
55. Hydrocortisone sodium succinate
56. Iodipamide methylglucamine injection
57. Isoflurophate
58. Levallorphan tartrate
59. Levallorphan tartrate injection
60. Lucanthone hydrochloride
61. Lucanthone tablets
62. Mecamylamine hydrochloride

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| 63. | Mecamylamine hydrochloride tablets   | 94.  | Phenindamine tablets                             |
| 64. | Meclizine hydrochloride  | 95.  | Phenoxyethylpenicillin                           |
| 65. | Meclizine hydrochloride tablets  | 96.  | Phenoxyethylpenicillin calcium                   |
| 66. | Mephentermine sulfate  | 97.  | Phenoxyethylpenicillin potassium                 |
| 67. | Mephentermine sulfate injection  | 98.  | Phenoxyethylpenicillin tablets                   |
| 68. | Mephobarbital  | 99.  | Phenylbutazone                                   |
| 69. | Mephobarbital tablets  | 100. | Phentolamine methanesulfonate                    |
| 70. | Meprobamate  | 101. | Phentolamine methanesulfonate for injection      |
| 71. | Meprobamate tablets  | 102. | Pholcodine                                       |
| 72. | Meralluride  | 103. | Phytonadione                                     |
| 73. | Mercaptomerine   | 104. | Phytonadione tablets                             |
| 74. | Mercaptopurine   | 105. | Piperazine adipate                               |
| 75. | Mercaptopurine tablets   | 106. | Piperazine adipate tablets                       |
| 76. | Methylene blue   | 107. | Piperazine citrate                               |
| 77. | Methylene blue injection   | 108. | Piperazine phosphate                             |
| 78. | Neomycin   | 109. | Piperazine phosphate tablets                     |
| 79. | Nitrofurantoin   | 110. | Piperocaine hydrochloride                        |
| 80. | Nitrofurantoin tablets   | 111. | Piperocaine hydrochloride injecti                |
| 81. | Noscapine  | 112. | Polyethylene glycol 400 (suitable for injection) |
| 82. | Novobiocin calcium   | 113. | Polyoxyl 40 stearate                             |
| 83. | Novobiocin sodium  | 114. | Polysorbate 80                                   |
| 84. | Novobiocin sodium tablets  | 115. | Pralidoxime iodide                               |
| 85. | Nystatin   | 116. | Prednisolone                                     |
| 86. | Nystatin tablets   | 117. | Prednisolone tablets                             |
| 87. | Papaverine sulfate   | 118. | Prednisolone acetate                             |
| 88. | Paramethadione   | 119. | Prednisone                                       |
| 89. | Paramethadione capsules  | 120. | Prednisone tablets                               |
| 90. | Pentamidine isothionate  | 121. | Prednisone acetate                               |
| 91. | Pentamidine injection  | 122. | Probenecid                                       |
| 92. | Peppermint leaves (to give a generally applicable method for the determination of volatile oil in vegetable drugs) | 123. | Probenecid tablets                               |
| 93. | Phenindamine tartrate  | 124. | Prochlorperazine dimaleate                       |
|     |  | 125. | Prochlorperazine dimaleate injecti               |

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| 126. | Prochlorperazine dimaleate tablets  | 144. | Sodium levothyroxine tablets                 |
| 127. | Procyclidine hydrochloride  | 145. | Sodium liothyronine                          |
| 128. | Procyclidine tablets  | 146. | Sodium liothyronine tablets                  |
| 129. | Propantheline bromide   | 147. | Solasulfone (Solapsone)                      |
| 130. | Propantheline bromide injection   | 148. | Sulfacetamide sodium                         |
| 131. | Propantheline bromide tablets   | 149. | Sulfamethoxypyridazine                       |
| 132. | Propylene glycol  | 150. | Sulfamethoxypyridazine tablets               |
| 133. | Pyridostigmin bromide   | 151. | Sulfisoxazole                                |
| 134. | Psyllium seed (to give a generally applicable method for the determination of the swelling factor of vegetable drugs) | 152. | Sulfisoxazole tablets                        |
| 135. | Pyridostigmin bromide   | 153. | Sulfisoxazole, Acetyl                        |
| 136. | Pyridostigmin bromide tablets.  | 154. | Sulfoxone sodium                             |
| 137. | Pyridostigmin bromide injection   | 155. | Sulfoxone sodium tablets                     |
| 138. | Reserpine   | 156. | Testosterone cyclopentylpropionate           |
| 139. | Senega root (to give a generally applicable method for the determination of saponins in vegetable drugs)              | 157. | Testosterone cyclopentylpropionate injection |
| 140. | Senna leaves  | 158. | Tolbutamide                                  |
| 141. | Senna pods  | 159. | Tolbutamide tablets                          |
| 142. | Sodium fluoride   | 160. | Trimethaphan camphorsulfonate                |
| 143. | Sodium levothyroxine  | 161. | Trimethaphan camphorsulfonate injection      |
|      |   | 162. | Warfarin sodium                              |
|      |   | 163. | Warfarin sodium injection                    |
|      |   | 164. | Warfarin sodium tablets                      |

Item (c) Appendices for the second edition of the International Pharmacopoeia

1. List of reagents and test solutions
2. Solutions employed in volumetric determination
3. pH ranges and colour changes of indicators
4. Identification tests for substances mentioned in the International Pharmacopoeia
5. Determination of weight per millilitre, density, and specific gravity
6. Determination of melting-range, melting-temperature and congealing-temperature
7. Determination of optical rotation and specific rotation

8. Determination of refractive index
9. Spectrophotometry, photometry, and colorimetry
10. Determination of infra-red absorption spectra
11. Fluorometry
12. Chromatographic analysis
13. Determination of related foreign steroids
14. Limit test for arsenic
15. Limit test for heavy metals
16. Limit test for chloride
17. Limit test for sulfate
18. Limit test for iron
19. Buffer solutions and determination of pH
20. Oxygen combustion method
21. Determination of nitrogen
22. Determination of methoxyl
23. Determination of acid value
24. Determination of iodine value
25. Determination of saponification value
26. Determination of unsaponifiable matter
27. Determination of ash
28. Residue on ignition
29. Determination of calcium with disodium edetate
30. Determination of water
31. Biological assay of antibiotics
32. Test for undue toxicity
33. Test for pyrogens
34. Tests for sterility
35. International Biological Standards and International Biological Reference Preparations
36. Assay of vitamin A
37. Fluorometric assay of thiamine hydrochloride
38. Disintegration test for tablets

39. Rapid test for glass containers for injections
40. Calibration of the apparatus for the determination of resistivity
41. Weights and measures
42. Powders and sieves