BRITISH PHARMACOPŒIA 1968

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NOTICES

The British Pharmacopœia 1968 supersedes all previous editions of the British Pharmacopœia. It is published at the direction of the General Medical Council under the provisions of section 47 of the Medical Act, 1956. This section is printed in full on page xii. Under sub-section (4) of the section, the exclusive right of publishing, printing and selling the British Pharmacopœia is vested in the Council.

European Pharmacopœia

If any article which is the subject of a monograph in the British Pharmacopœia 1968 is also, or becomes, the subject of a monograph in the European Pharmacopœia, the British Pharmacopœia 1968 will be amended so as to secure that, as from the date on which the monograph in the European Pharmacopœia comes into effect, the standards for that article set out in the European Pharmacopœia will replace the standards for it given in the British Pharmacopœia 1968 and will thereafter constitute the standards of the British Pharmacopœia (see page xiv).

Patents

In this Pharmacopœia certain drugs and preparations have been included notwithstanding the existence of actual or potential patent rights. In so far as such substances are protected by Letters Patent their inclusion in this Pharmacopœia neither conveys, nor implies, licence to manufacture.

Legal Control

Substances described in monographs of the British Pharmacopœia may be subject to legal control in the United Kingdom or in other countries in which the British Pharmacopœia may have statutory force. Legal control may be concerned with the preparation and labelling of, and the standards for, substances described in the Pharmacopœia.

A statement with the heading 'Caution' is affixed to those monographs on substances which are subject (February, 1968) in the United Kingdom to the provisions of the Therapeutic Substances Act, 1956, and the Regulations made thereunder.

It must not be assumed that where no caution appears the subject of the monograph is free from legal restriction.

PREFACE

The British Pharmacopœia is published by the Council in discharge of the duty laid upon them by section 47 of the Medical Act, 1956. This section is as follows:

> '47.—(1) The General Council shall, at such intervals as they may determine, cause to be published under their direction new editions of the British Pharmacopœia, containing such descriptions of and standards for, and such notes and other matter relating to, medicines, preparations, materials and articles used in the practice of medicine, surgery, or midwifery, as the Council may direct.
> (2) The General Council may, if they think fit, cause to be published, between any two editions of the British Pharmacopœia, amendments of the current edition.
> (3) In connection with the publication of any new edition of the British Pharmacopœia, or of any amendment of the current edition, the General Council shall fix a date as from which the new edition, or the amendment, as the case may be, is to have effect, and shall cause to be inserted in every copy of the new edition, or of the document containing the amendment, as the case may be, a statement of the date so fixed.
> (4) The General Council shall have the exclusive right of publishing, printing and selling the British Pharmacopœia and any documents containing amendments thereof, subject however to any determination by the Treasury of the price at which copies are to be sold to the public.
> (5) A copy of the British Pharmacopœia, or of any such document as aforesaid, being a copy purporting to be printed by such person as may be named in a notice published in the London, Edinburgh and Belfast Gazettes as authorised by the General Council to print the Pharmacopœia, or that document, as the case may be, shall be received in evidence as being the Pharmacopœia, or that document, as the case may be, and shall be evidence that the date stated therein for the coming into effect thereof is the date fixed in that behalf by the General Council.
> (6) References in sections eleven and twelve of the Pharmacy and Medicines Act, 1941, to the edition of the British Pharmacopœia last published before a given date shall be construed as references to the latest edition which has taken effect in accordance with this section before the said date, as affected by any amendments which have so taken effect.
> (7) In this section references to amendments of the British Pharmacopœia shall be construed as including references to additions thereto and to deletions therefrom.'

The British Pharmacopœia 1968 is the eleventh edition of the British Pharmacopœia. In accordance with section 47 (3) of the

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Medical Act, 1956, the Council has fixed the date from which the British Pharmacopœia 1968 is to take effect. This date is stated on the title page, and as from that date the British Pharmacopœia 1968 will supersede the British Pharmacopœia 1963 as amended by the Addenda of 1964 and 1966.

The administrative arrangements under which the British Pharmacopœia is prepared are based on recommendations made in 1928 by a Sub-Committee of the Committee of Civil Research, usually known as the Macmillan Committee. In accordance with these recommendations, the detailed work of preparing new editions of the Pharmacopœia is entrusted by the Council to a Pharmacopœia Commission. The Commission is appointed by the Council on the recommendations of a Selection Committee, which consists of representatives of the Council, of the Medical Research Council, and of the Pharmaceutical Societies of Great Britain, of Northern Ireland and of Ireland. The Commission itself is reconstituted periodically, and the term of office of each Commission normally corresponds to the period during which a new edition of the British Pharmacopœia is prepared for publication. The Commission by which the British Pharmacopœia 1968 was prepared took office on September 1, 1963,

The British Pharmacopœia Commission 1963–68 was responsible for producing two Addenda (published in 1964 and 1966 respectively) to the British Pharmacopœia 1963, as well as the British Pharmacopœia 1968, which is considerably larger than any previous edition. In addition the Commission has during the same period participated substantially in the work of the European Pharmacopœia Commission and its many groups of experts engaged on the preparation of the European Pharmacopœia. The Commission has also maintained close contact with other overseas Bodies who are concerned with pharmacopœial revision, especially in Australia, New Zealand, South Africa, Canada, the United States of America, and Scandinavia. In addition to strictly pharmacopœial matters, the Commission has devoted much time and thought to the provision of non-proprietary names for medicines, both nationally in the form of Approved Names, and internationally.

In each of these fields the Commission has made a valuable and distinctive contribution. The Council is fully sensible of the load of work which these activities have involved and desires to record both on its own behalf, and on behalf of the interested professions and of the public, its gratitude to the members of the Commission and its Committees and to the staff for the excellence of their work and the assiduity of their labours.

Reference has been made above to the European Pharmacopœia Commission. This Body was established under a Convention drawn up under the auspices of the Council of Europe (Partial Agreement) in July, 1964, and subsequently signed by representatives of the Governments of Belgium, France, the German Federal Republic, Italy, Luxembourg, the Netherlands, Switzerland, and the United Kingdom. Under the Convention these countries agreed to elaborate a European Pharmacopœia, and to take measures to ensure that the monographs which were included in the European Pharmacopœia should become the official standards applicable within their respective countries as from such dates as should be agreed in respect of each monograph. It is understood that the first volume of the European Pharmacopœia is likely to be published shortly.

The Council accepts the desirability of bringing the official standards for medicinal articles in the United Kingdom into line with the standards which will be adopted in the other European countries which have signed the Convention. In consultation with the Ministry of Health, the Council has given consideration to the steps which will need to be taken to give effect to the obligations undertaken by the United Kingdom under the Convention. The Council has accordingly given notice (page xi) that in due course the British Pharmacopœia 1968 will be amended to secure that, in the case of those articles for which standards are provided both by the British Pharmacopœia and by the European Pharmacopœia, the standards now set out in the British Pharmacopœia 1968 will be replaced by those of the European Pharmacopœia. At the appropriate times the Council will cause to be published, as amendments of the British Pharmacopœia 1968, lists of the articles concerned. These lists will state the date on which the substitution of standards will take effect: this date will be the date agreed upon by the countries participating in the European Pharmacopœia. As from this date the standards given in the European Pharmacopœia will constitute the standards of the British Pharmacopœia for the articles in question.

It seems that the British Pharmacopœia 1968 will be the last complete edition of the British Pharmacopœia to be published by the Council. The duty of publishing the British Pharmacopœia was first laid upon the Council by the Medical Act of 1858, and the first edition was published in 1864. One hundred and nine years later, in September, 1967, the Government issued a White Paper entitled

Forthcoming Legislation on the Safety, Quality and Description of Drugs and Medicines. This included proposals for transferring responsibility for the British Pharmacopœia from the General Medical Council to the Health Ministers and to a Medicines Commission. The Council, in common with other interested Bodies, was consulted by the Government in the formulation of the proposals, and accepted that it would be in the public interest to make new arrangements for the production of the British Pharmacopœia as part of comprehensive arrangements for the control of drugs and medicines. A Medicines Bill to give effect to the proposals in the White Paper was introduced into Parliament in February, 1968, and, when this legislation has been enacted and taken effect, the responsibility of the Council in these matters will cease.

General Medical Council,
44 Hallam Street,
London, W.1.

March, 1968.

INTRODUCTION

Since 1948 the British Pharmacopœia has been published at intervals of five years, and it was formerly the practice to issue an Addendum to each edition approximately two and a half years after publication with the object of keeping it up to date. When the British Pharmacopœia Commission 1963–1968 assumed office on September 1, 1963, it readily concurred with the suggestion put forward in the Preface of the British Pharmacopœia 1963 that more frequent issue of Addenda was desirable in view of the increasing rapidity with which new medicinal articles were coming into use. A first Addendum to the British Pharmacopœia 1963 was accordingly published in 1964 and became official on June 1, 1965. It was followed in 1966 by a second Addendum, which came into effect on September 1 of that year, and these two Addenda added 132 new monographs on drugs and preparations to the Pharmacopœia. They also afforded an opportunity for the publication of important alterations to over 100 of the monographs in the main volume and to certain Appendices. Concurrently with the work of preparing the Addenda, the Commission also proceeded with the complete revision of the Pharmacopœia.

Close and fruitful co-operation was maintained with the Department of Pharmaceutical Sciences of the Pharmaceutical Society of Great Britain and the Codex Revision Committee, and their assistance and that of members of the staff of the following Government Departments and other bodies is acknowledged with gratitude: Board of Customs and Excise, Association of the British Pharmaceutical Industry, Laboratory of the Government Chemist of the Ministry of Technology, Home Office, Drugs Branch, Central Public Health Laboratory, Ministry of Health, Patent Office, Trade Marks Registry, Scottish Home and Health Department, Ministry of Health and Social Services of Northern Ireland, and Ministry of Defence.

Acknowledgement is made to the British Standards Institution for permission to include material from British Standards in the Pharmacopœia.

Cordial relationships have been maintained with overseas bodies including the Australian Committee on Pharmacopœial Revision, National Biological Standards Laboratory (Australia), Department of National Health and Welfare (Canada), Indian Pharmacopœia Committee, Department of Health (New Zealand), Department of Health (South Africa), Committee of Revision of the United States Pharmacopœia, American Pharmaceutical Association, Nordic Pharmacopœia Council, and Pharmaceuticals Unit of the World Health Organisation.

Lists of the monographs added to or deleted from the Pharmacopœia by this, the eleventh edition, are given in the following pages. The Pharmacopœia now contains 1149 monographs, an increase of more than 150 over the last edition. The new monographs cover a wide range of synthetic drugs, antibiotics, and biological materials, together with preparations such as capsules, injections, and tablets. They include cephaloridine and sulphomyxin sodium, the two new insulin preparations, biphasic and neutral insulin injections (bringing the total number of preparations of the antidiabetic principle to nine), the steroids, betamethasone valerate and triamcinolone acetonide, used for topical application, and two substances, magnesium chloride and sodium acetate, which have been added because of their wide use in peritoneal dialysis and hæmodialysis. Urea, which has appeared in earlier editions, returns as a basis for the monograph on the purified injectable material employed in the relief of intracranial tension, and lævulose is also re-admitted in recognition of its increasing use by parenteral administration. The oral and parenteral forms of iron therapy already in the Pharmacopœia are supplemented by ferrous fumarate, ferrous succinate, and iron sorbitol injection, and four diuretics, chlorthalidone, cyclopenthiazide, frusemide, and triamterene appear for the first time. Two new antitubercular drugs are ethionamide and pyrazinamide, and the more potent form of Bacillus Calmette-Guérin vaccine required for pressure inoculation is introduced under the distinguishing title Percutaneous Bacilius Calmette-Guérin Vaccine. Additional preparations of human blood comprise plasma protein fraction, in liquid and dried forms, and the monographs on human gamma globulin and its injection are now combined in one monograph under the title Human Normal Immunoglobulin Injection.

Numerous changes have been made to the monographs retained from the previous edition. The use of Latin in the main titles of monographs was abandoned in the 1953 edition of the Pharmacopœia and succeeding editions have seen a gradual withdrawal of such names as were retained as subsidiary titles. This process has been taken a step further in the present book by the omission of full Latin titles from all the pharmaceutical preparations and the abbreviated Latin forms from the vegetable drugs. The abbreviated names are retained for the pharmaceutical preparations for a further edition

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because of their continued use, and the full Latin names have been kept for the vegetable drugs where they are significantly different from the English titles. A number of changes have also been made to main titles which were official in the last edition. These are listed in the succeeding pages and attention is drawn to the modified title, Water for Injections, and to the alterations concerning acetylsalicylic acid and its preparations. The Committee on Safety of Drugs, in referring to the hazards attending the use of acetylsalicylic acid by some patients, has recommended that steps should be taken to ensure that the presence of the substance was declared by its popular name Aspirin. In conformity with this request, the main title of the monograph on Acetylsalicylic Acid has been changed to Aspirin and corresponding changes have been made to the titles of the preparations. It has been necessary to retain the former official titles but when they are used the presence of Aspirin must be declared as such on the label. The changes cannot apply in certain countries where proprietary rights in the name 'Aspirin' are still claimed and provision is made in the monographs for the alternative use of Acetylsalicylic Acid in the official titles in these countries.

The modified name, Strong Calciferol Tablets, has been adopted for the high potency tablet used in the treatment of hypoparathyroidism. The former title, Calciferol Tablets, is no longer official and when it is used Strong Calciferol Tablets should not be supplied without confirmation that they are required.

When Diamorphine Injection was added to the British Pharmacopœia 1963, the propensity of the substance to deteriorate in solution was recognised and advice was given that the Injection should be recently prepared; a limit test for the products of degradation was also provided. Further reports have since confirmed that the Injection should preferably be prepared as soon as possible before use. Manufacturers were approached through the Association of the British Pharmaceutical Industry and, as a result, diamorphine hydrochloride will be made available in a form suitable for the extemporaneous preparation of the Injection. The monograph has been altered accordingly and the co-operation of the pharmaceutical industry is acknowledged.

The statements on dosage have been reviewed and the principle formerly applied of expressing most oral doses as a quantity that might be repeated three or four times a day no longer applies. Instead, the quantity suitable for administration over a period of twenty-four hours is given, with, where appropriate, directions that it shall be administered in divided doses.

The group of monographs on the iodine-containing substances used for diagnostic purposes was examined in light of the recommendations put forward in Technical Report Series No. 307 (Quality of Radio-opaques) issued by the World Health Organisation and

improved specifications have been prepared. The monographs on thyroid and its tablets have been retained because of continuing wide use, but tests have been added to ensure the presence of at least a minimum content of liothyronine. The sources of protamine which may be used in the preparation of Protamine Sulphate Injection have been modified to allow the use of material obtained from the herring. Modifications have been made to the requirements for warfarin sodium and its tablets since one method of preparation of the substance results in the occlusion of a marked proportion of isopropyl alcohol in the form of a clathrate. This material is now recognised in addition to the substance which does not contain isopropyl alcohol and more stringent requirements are specified for the content of warfarin sodium in the tablets as a means of ensuring the minimum of variation in successive batches of the tablets.

Descriptions of odour and taste continue to be included in monographs because they frequently supply useful information but analysts should be aware that the indiscriminate examination of these characteristics may be hazardous.

Changes have been made in the provisions for eye ointments, which are now to comply with tests for sterility. The impracticability of submitting the finished ointments to a sterilising process demands the use of sterile ingredients and the application of a strict aseptic technique during preparation. Care should also be taken that the collapsible tubes in which the ointments are to be packed have been sterilised and that metal tubes comply with the Specification for Metal Collapsible Tubes for Eye Ointment published by the British Standards Institution (British Standard 4230:1967). The British Standard was prepared by the Institution in response to a request by the Commission and the Pharmaceutical Society of Great Britain acting on the advice of a Joint Committee set up by the two bodies to investigate means of controlling the occurrence of metal particles in eye ointments. The publication of the British Standard and its recognition in the Pharmacopœia fulfil the first stages of the procedure recommended by the Joint Committee for alleviating the problem, and future work will be concerned with the development of a test applicable to the eye ointment packed in metal tubes.

Improved controls on the nature of the rubber closures used for containers of injectable materials are set out in the general monograph on injections, which also specifically recognises the use of plastic containers and provides a test to control the amount of matter extracted from a plastic container by an infusion fluid.

A number of alterations have also been made to the general requirements for tablets and capsules. The restriction hitherto imposed on the addition of colour, except when specifically allowed in an individual monograph, has been removed and in the test for the disintegration of enteric-coated tablets the use of pepsin and pancreatin

has been abandoned and the acidity of the media has been modified with the object of excluding undesirable forms of coating. The tests for Uniformity of Weight of Capsules and Tablets have been revised and now provide more stringent requirements. They, in common with all other tests and assays in the Pharmacopœia, are designed for use in examining official preparations and are not necessarily suitable for application to preparations not described in the Pharmacopœia. The statements in the individual monographs of the tolerances for the content of active principle are expressed in terms of the weight or volume which is stated on or implied by the prescription or the order. The tolerances relate to the result of an assay in which normally a group of not fewer than twenty capsules or tablets is examined. The possibility that the result of the assay may comply with the tolerances but that there could be an undesirably large fluctuation in the amounts of the active principle among the individual members of the group is recognised and considerable attention has been given to the desirability of supplementing the group assay with the examination of single capsules and tablets, particularly for those medicaments where an adequate response from a single dose is necessary. An inherent difficulty in tests of this nature when applied to preparations containing very small quantities of the active ingredient is that they usually involve the total destruction of the sample and allow no opportunity for repetition. This and other problems connected with the introduction of such tests are still under investigation but as an interim measure the general monographs now direct that tablets and capsules which show, when examined individually, gross deviation from the prescribed or stated content are not acceptable.

For many years it has been the practice to require Capsules, Injections, and Tablets to be labelled with the name of the active ingredient. For Capsules and Tablets, a proviso has always been included exempting from this requirement preparations supplied in accordance with a medical prescription. Statements on the identification of dispensed medicines, particularly tablets, have frequently referred to the need for rapid identification in cases of poisoning or overdosage, but the most important aspect of the case for this knowledge arises from the need for the doctor to know the nature of the medication that a patient is receiving. Lack of information on a patient's treatment may confuse diagnosis and render further treatment hazardous. Changes in the habits of doctors are increasing this hazard. Patients are now frequently attended in their homes by doctors doing night or week-end duty and not familiar with the treatment being given or in a position to consult the records. Similar conditions also apply when patients attend hospital for emergency treatment. It was the view of the Commission that every endeavour should be made to secure early acceptance, both from the medical and pharmaceutical sides, that it should become normal practice for the

name of the preparation to be stated on the label on the container when a medicine is dispensed in compliance with a prescription unless the prescriber specifically directs otherwise. The labelling requirements for Capsules and Tablets have accordingly been modified to permit the addition of the name to dispensed medicines.

In 1967 amendments to the British Pharmacopœia 1963 introduced additional labelling requirements for the oral preparations of antibiotics. The requirements, which comprised a declaration of the date after which the preparation was not intended to be used, the conditions under which it should be stored, and a means of tracing the history of the preparation, are now extended to all substances and preparations controlled by the Regulations made under the Therapeutic Substances Act and also to the official injections. In addition, the labels on injections will have to show the names of any substances incorporated with the object of stabilising the preparation or buffering the acidity or alkalinity.

There is considerable variation in the manner in which the strengths of preparations such as capsules, injections, and tablets are expressed. For the older drugs the strengths are usually based on a stated weight of the official substance but for some preparations, and the practice is increasing, they are related to a form of the drug other than that actually employed. For example, the strength may be in terms of the base when the hydrochloride has been used in the formulation. Lack of an agreed policy in this matter has led to confusion and the Commission has expressed the view that the difficulty this causes to prescribers and pharmacists might be avoided if as a general rule the strengths were expressed in terms of the therapeutically active entity. The practice to be followed with each substance should be instituted when it is first formulated and the recommendation is not intended to apply retrospectively. Consequently no changes have been made in this respect to the preparations described in this edition and their strengths continue to be stated in the manner which has become established in use for each particular preparation.

A new General Notice on Added Substances brings together the statements under this title which were formerly included in the general monographs on Capsules and Tablets and extends the provisions to all official preparations. In addition to the earlier requirements that any substances added to the active ingredient in the course of making a preparation shall be innocuous and free from any adverse influence on the therapeutic efficacy of the active ingredient, the Notice introduces the new principle that such added substances must not interfere with the official Assays and Tests, which remain the final arbiter on the acceptability of the preparations for pharmacopœial purposes. This requirement will impose a further restriction on the choice of excipients and other ingredients but the Commission is prepared to consider modification of the Assays and Tests when cases of

difficulty, arising from the application of this principle or for any other reason, are brought to its attention. The General Notice on Added Substances also contains a warning that such substances should be free from harmful organisms. In 1965 a report to the National Board of Health, Sweden, drew attention to the occurrence of microbial contamination in formulated preparations and the raw materials used in their manufacture. The Commission, in consultation with the Central Public Health Laboratory, is studying the possibility of introducing tests to control the degree of infection and in the meantime draws attention to the need for care in selecting ingredients. Among the substances especially indicted in the Swedish report were some varieties of starch, especially that of potato, but attention was also directed at the contamination found in thyroid tablets, and strict precautions should be taken to ensure that the glands are collected, stored, and processed under hygienic conditions.

One of the chief features of the preparation of the monographs for this edition has been the greatly increased emphasis placed on the detection and control of impurities which may be present not only in the substances but also in their formulated preparations as a result of the manufacturing processes or from degradation on storage. This has been made possible largely by the rapid development of thin-layer chromatography as reliable means of detecting and assessing small quantities of material and in consequence the technique is now widely used both for the limitation of impurities and for purposes of identification. It has also made possible the introduction of an improved test for related foreign steroids in corticosteroids and a more stringent and reliable limit of 4-chloroacetanilide in phenacetin. The application of infra-red light absorption for the identification of substances, and in some cases their preparations, has also been greatly widened and now applies to all the penicillins, barbiturates, and sulphonamides in addition to many other substances.

Ultra-violet light absorption continues to be widely used and a manually scanning instrument is now expected to be used for quantitative determinations and a recording instrument for qualitative tests. Accordingly, the tests for identification have been amended to direct the measurement of the absorption of a 2-cm. layer of the solution under examination since it is considered preferable to increase the path length rather than the concentration in order to achieve the higher extinction values which are suitable for many types of recording instruments. The permission to modify the conditions to suit a particular instrument is, however, maintained.

The successful application of chromatographic and light absorption methods of analysis in the control of drug quality requires the use as reference materials of authenticated specimens of the substances under examination, and where necessary, of the impurities which are likely to be present. In general, it is sufficient that the

substances be of good quality and not especially purified. Many of them are not, however, readily available to the analyst and a collection has, therefore, been set up of the necessary materials. They are described under the title Authentic Specimens, and a complete list of those required for the examination of the substances and preparations described in this edition are given in Appendix I B. The majority of the specimens were made available by the manufacturers and the Commission wishes to record its appreciation of their generosity and co-operation. There is also a need, in certain circumstances, for specimens of highly purified substances, and when these are required for the purposes of the Pharmacopœia the analyst is directed to use the appropriate British Chemical Reference Substance, which has been established by the Joint Committee on British Chemical Reference Substances of the General Medical Council and the Pharmaceutical Society of Great Britain. Those required for the purposes of this edition are also listed in Appendix I B. The tests and assays of the Pharmacopœia in which the Authentic Specimens and British Chemical Reference Substances are employed have been devised on the basis of the particular specimens which are supplied and it is important that these official materials shall be used, especially for impurity tests and assays.

The appendices of the Pharmacopœia have been adjusted in light of the changes made in the individual monographs and now include for the first time descriptions of analysis by flame photometry and gas-liquid chromatography. The former is applied in the control of certain alkali and alkaline earth metals in monographs on magnesium, potassium, and sodium salts. Gas-liquid chromatography is now widely recognised as a valuable analytical technique and has been introduced in several monographs, where it is used either in the detection and control of impurities or to estimate the proportion of bound solvent from which the products have been isolated. A difficulty encountered in introducing this method of chromatography arose from the wide variety of instruments in use in different laboratories, and to overcome this the principle was adopted of using an internal standard for each test and laying down performance criteria for the apparatus. The suggested conditions given in each test for carrying out the determinations have been developed experimentally but they are not compulsory and may be varied by the analyst, providing the official criteria are met. With the introduction of gas-liquid chromatography into the Pharmacopœia further and more varied applications will arise in future revisions.

The adaptation of gas-liquid chromatography to the purposes of the Pharmacopœia was carried out largely in the Commission's own laboratory and illustrates that its functions are not merely confirmatory but extend to the investigation of methods, particularly new techniques, with the object of providing unequivocal descriptions

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