

# Recent publications

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## Biological standards: international standards and reference reagents

This book provides a catalogue of tabulated information on the availability and specifications of international biological standards and international biological reference reagents. The categories of substances listed include allergens, antibiotics, antibodies, antigens, blood products and related substances, cytokines and endocrinological substances.

International biological standards are intended to be used in laboratory assays to calibrate national or working standards. They provide a means of ensuring uniformity throughout the world in the designation of the potency, activity and specificity of biological substances used in medicine, when these cannot be expressed directly in terms of physical or chemical properties. International biological reference reagents are established to provide materials of high specificity for the identification of biological substances used in the diagnosis of disease, and particularly for identifying micro-organisms and their products.

Each substance listed is characterized in terms of its biological activity, expressed as the total number of international units per ampoule; a weight definition of the unit, where necessary; the form in which the substance is provided; the year in which it was established; pertinent references; and the address of the laboratory from which it is available.

*Biological Substances: International Standards and Reference Reagents 1990.* WHO Geneva 1991. ISBN 92 4 154429 5

## WHO Expert Committee on Biological Standardization

The most recent report of this long-standing expert advisory committee demonstrates the rapid pace of innovation in the preparation and development of biological substances that, before the introduction of recombinant DNA techniques, could not be manufactured in commercial quantities.

Since the potency and specificity of each new highly active substance needs to be assured, the challenge to assure their quality, and particularly the interchangeability of equivalent products, is immediate and demanding. This is reflected in several of the topics covered in this report, which include guidelines for the quality assurance of pharmaceutical and biological products made using recombinant DNA technology, and discussions of the need to standardize and improve the reliability of assays for residual DNA; the need for further evaluation of certain substances before an acceptable international standard can be established; and the specific need to establish international reference materials for growth factors and cytokines.

These annual reports also provide the vehicle to establish international requirements to be observed in the manufacture and licensing of potent biological products in order to assure their potency and safety. In this report full and detailed requirements are provided for *Haemophilus* type b conjugate vaccines and inactivated influenza vaccine.

*WHO Expert Committee on Biological Standardization, Forty-first Report.* Technical Report Series, No 814. WHO Geneva, 1991. ISBN 92 4 120814 7

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# SELECTED WHO PUBLICATIONS OF RELATED INTEREST

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	<i>Price* (Sw. fr.)</i>
<b>The use of essential drugs</b> Fifth report of the WHO Expert Committee WHO Technical Report Series, No. 825 1992 (75 pages)	10.-
<b>WHO model prescribing information: drugs used in anaesthesia</b> 1989 (53 pages)	11.-
<b>WHO model prescribing information: drugs used in parasitic diseases</b> 1990 (128 pages)	21.-
<b>WHO model prescribing information: drugs used in mycobacterial diseases</b> 1991 (40 pages)	9.-
<b>Guidelines for developing national drug policies</b> 1988 (iv + 52 pages)	11.-
<b>The International Pharmacopoeia, third edition</b> Volume 1: general methods of analysis. 1979 (223 pages) Volume 2: quality specifications. 1981 (342 pages) Volume 3: quality specifications. 1988 (407 pages)	24.- 36.- 64.-
<b>Basic tests for pharmaceutical substances</b> 1986 (vi + 204 pages)	34.-
<b>Basic tests for pharmaceutical dosage forms</b> 1991 (v + 129 pages)	24.-
<b>International Nonproprietary Names (INN) for Pharmaceutical Substances, Cumulative List No. 8</b> 1992 (xivi + 692 pages)	140.-

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Further information on these and other World Health Organization publications can be obtained from  
Distribution and Sales, World Health Organization, 1211 Geneva 27, Switzerland

*\* prices in developing countries are 70% of those listed here.*