

Manual for Quality Control of Diphtheria, Tetanus and Pertussis Vaccines

Immunization, Vaccines and Biologicals



**World Health
Organization**

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Preface

In 1982, with the aim of providing guidance for the standardization of tests needed to ensure the safety and efficacy of vaccines, the World Health Organization (WHO) issued a document entitled Manual of details of tests required on final vaccines used in the WHO Expanded Programme on Immunization (unpublished document BLG/UNDP/82.1 Rev.1). This document was updated in 1985 (unpublished document BLG/UNDP/82.1 Rev. 1 Corr. 1). As a result of changes in some of the potency tests and the development of alternative techniques for testing the potency of bacterial vaccines, and in an attempt to present the information in a more useful way for testing laboratories, details of the potency tests for live viral vaccines and bacterial vaccines were revised and reissued provisionally in two documents, Laboratory methods for the titration of live virus vaccines using cell culture techniques (unpublished document BLG/EPI/89.1) and Laboratory methods for the testing for potency of diphtheria (D), tetanus (T), pertussis (P) and combined vaccines (unpublished document BLG/92.1). These two documents were field tested in workshops worldwide. They were revised in the light of comments received and combined to produce the manual, WHO/BLG/95.1. With the establishment of the Global Training Network, the document was revised in light of its relevance as a curriculum material for quality control test methodologies. In 1997, WHO publish the Manual of laboratory methods-For testing vaccines used in the WHO Expanded Programme on Immunization (WHO/VSQ/97.04) with the contribution of the following scientists: JH Bruning, F van Nimwegen, JW van der Gun and JL di Fabio, R Dobbelaer, P Knight, J Lyng, CFM Hendriksen, FR Marsman, HJM van de Donk, JG Kreeftenberg, P Knight, G Nyerges, M Weiz Bentzon, F Marsman. This Manual was widely used by the National Control Laboratories and vaccine manufacturers and has served as a training material in WHO Global Training Network programme since its establishment.

Recently, the amendment on potency testing of diphtheria vaccine and tetanus vaccine (TRS 927), and revised recommendations for whole cell pertussis vaccines

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