

The rules governing medicinal products
in the European Union

Volume 7B

Guidelines

Veterinary medicinal products

Immunologicals, quality

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THE RULES GOVERNING MEDICINAL PRODUCTS IN THE EUROPEAN UNION

- Volume 1 Pharmaceutical legislation
Medicinal products for human use
- Volume 2 Notice to applicants
Medicinal products for human use
- Volume 3 Guidelines
Medicinal products for human use
- Volume 4 Good manufacturing practices
Medicinal products for human and veterinary use
- Volume 5 Pharmaceutical legislation
Veterinary medicinal products
- Volume 6 Notice to applicants
Veterinary medicinal products
- Volume 7 Guidelines
Veterinary medicinal products
- Volume 8 Maximum residue limits
Veterinary medicinal products
- Volume 9 Pharmacovigilance
Medicinal products for human and veterinary use

These notes for guidance have been prepared by the Committee for Veterinary Medicinal Products, in consultation with the competent authorities of the Member States, to assist applicants for a marketing authorisation for a veterinary medicinal product. In case of doubt, reference should be made to the relevant EC Directives.

FOREWORD

Directive 81/852/EEC describes the requirements for the demonstration of the quality, safety and efficacy of veterinary medicinal products. The conduct of tests and studies for such demonstration has been harmonised, both within the European Union and internationally.

Volume 7 of “The Rules Governing Medicinal Products in the European Union” incorporates testing guidelines prepared within the European Union

It is presented in two parts:

- Volume 7A – general, efficacy, environmental risk assessment
- Volume 7B – immunologicals, quality

These guidelines serve a two-fold objective. Firstly, they are intended to provide a basis for a practical harmonisation of the manner in which the Member States and the European Agency for the Evaluation of Medicinal Products interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community directives. Secondly, they are intended to facilitate the preparation of applications for marketing authorisation which will be recognised as valid by all Member States and the European Agency for the Evaluation of Medicinal Products.

The use of guidelines, which are not legally binding, rather than a formal legal instrument, such as a directive, has been preferred in order to maintain an element of flexibility and not to place undue legislative restraints on scientific progress. It is recognised that in some cases, as a result of scientific developments, an alternative approach may be appropriate. However, where an applicant chooses not to apply a guideline, that decision must be explained and justified in the Expert Reports submitted by the company in support of the application. By their very nature, the guidelines must be updated in the light of scientific and technical progress. Moreover, further guidelines are currently under discussion, thus it is intended that this volume should be updated and revised as necessary.

These notes for guidance, which have no legal force, have been prepared by the Committee for Veterinary Medicinal Products of the European Agency for the Evaluation of Medicinal Products, in consultation with the competent authorities of the Member States, to assist applicants for a marketing authorisation for a medicinal product. In case of doubt, reference should be made to the text of the relevant EEC Directives.

The CVMP has recognised as suitable for veterinary medicinal products a series of guidelines on the quality of medicinal products for human use adopted by the Committee for Proprietary Medicinal Products (CPMP). These guidelines are listed at the end of this Volume. Some specific guidelines also relevant for veterinary medicinal products will be published in Volume 8 (Maximum residue limits for veterinary medicinal products) and Volume 9 (Pharmacovigilance for medicinal products for human use and veterinary medicinal products).

For ease of reference, and by kind permission of the Organisation for Economic Co-operation and Development (OECD) this volume also contains the OECD principles of good laboratory practice (GLP) which must be complied with during the conduct of safety tests on medicinal products.

TABLE OF CONTENTS

FOREWORD.....	iii
GUIDELINES FOR PRODUCTION AND CONTROL OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS.....	1
GENERAL REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF LIVE MAMMALIAN BACTERIAL AND VIRAL VACCINES FOR VETERINARY USE.....	3
GENERAL REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF INACTIVATED MAMMALIAN BACTERIAL AND VIRAL VACCINES FOR VETERINARY USE.....	21
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF AVIAN LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES.....	39
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF BOVINE LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES.....	55
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF PIG LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES.....	63
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF OVINE AND CAPRINE LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES.....	69
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF EQUINE LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES.....	77
HARMONISATION OF REQUIREMENTS FOR EQUINE INFLUENZA VACCINES SPECIFIC REQUIREMENTS FOR SUBSTITUTION OF A STRAIN.....	83
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF LIVE AND INACTIVATED VACCINES INTENDED FOR FISH.....	91
TABLE OF EXTRANEIOUS AGENTS TO BE TESTED FOR IN RELATION TO THE GENERAL AND SPECIES SPECIFIC GUIDELINES ON PRODUCTION AND CONTROL OF MAMMALIAN VETERINARY VACCINES.....	99
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF ALLERGEN PRODUCTS.....	107
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF IMMUNOSERA AND COLOSTRUM SUBSTITUTES.....	119
SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES FOR CATS AND DOGS.....	127

■ **Table of Contents** _____

INCLUSION OF ANTIMICROBIAL PRESERVATIVES IN IMMUNOLOGICAL
VETERINARY MEDICINAL PRODUCTS 137

QUALITY GUIDELINES143

MANUFACTURE OF THE FINISHED DOSAGE FORM 145

IN USE STABILITY TESTING OF VETERINARY MEDICINAL PRODUCTS (EXCLUDING
IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS) 153

ADDITIONAL QUALITY REQUIREMENTS FOR PRODUCTS INTENDED FOR
INCORPORATION INTO ANIMAL FEEDINGSTUFFS (MEDICATED PRE-MIXES) 159

INVESTIGATION OF CHIRAL ACTIVE SUBSTANCES 165

INCLUSION OF ANTIOXIDANTS AND ANTIMICROBIAL PRESERVATIVES IN
MEDICINAL PRODUCTS 177

LIST OF QUALITY GUIDELINES ACCEPTED FROM THE GUIDELINES FOR HUMAN USE 183

LIST OF ABBREVIATIONS 185

LIST OF LEGISLATION 189

INDEX 193