



# British Pharmacopœia 1988

## Addendum



# British Pharmacopœia 1988 Addendum 1991

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*see Notice, page xcii*



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## Notices

The General Notices and Appendices included in the British Pharmacopœia 1988 apply to all matter contained in this Addendum unless the contrary is specifically stated.

The Addendum has the same authority as the British Pharmacopœia 1988. General Notices, Monographs and Appendices of the British Pharmacopœia 1988 that are amended by this Addendum supersede, in their amended forms, the original general notices, monographs and appendices.

Monographs of the European Pharmacopœia are distinguished by a five-pointed star against the title.

## Patents

In this Addendum 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 Addendum neither conveys, nor implies, licence to manufacture.

## Effective Dates

Much of the material in this volume enters into force on 1 July 1991 but certain material that has been published earlier by Gazette Notices became effective on the date stated at the foot of the relevant entry.



# Preface

This Addendum adds new material to and amends the British Pharmacopoeia 1988. It is published by Her Majesty's Stationery Office for the Health Ministers on the recommendation of the Medicines Commission in accordance with sections 99(6) and 102 of the Medicines Act 1968.

The Medicines Commission expresses its gratitude to all who have helped to prepare this Addendum.

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\* Term of office ends 31 December 1993.

† Term of office ends 31 December 1991.



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# Introduction

In general, the effective date of this Addendum is 1 July 1991 but a number of items, particularly edited versions of European Pharmacopœia monographs, have already been, or will be, brought into effect at some other date. Where the effective date is not 1 July 1991, this is noted at the foot of the entry by means of an italicised statement of the month and the year. Where no such statement appears it is to be understood that the effective date is that of the Addendum as a whole. With the bringing into effect of this Addendum, the British Pharmacopœia 1988 will comprise Volume I, Volume II, the Addendum 1989, the Addendum 1990 and the Addendum 1991. It should be noted that material in Amendments No 4 to the British Pharmacopœia 1988 has been incorporated into this Addendum.

## Some Additions

Monographs introduced to the Pharmacopœia for the first time include the antibacterial agent Benethamine Penicillin, the histamine H<sub>1</sub>-receptor antagonist Brompheniramine Maleate and Brompheniramine Tablets, the local anaesthetic Oxethazaine, Chlortetracycline Ointment, Co-codamol Tablets, Co-danthrusate Capsules, Co-dydramol Tablets, Ephedrine Nasal Drops, Orciprenaline Oral Solution, Standardised Senna Granules and a triple vaccine against measles, mumps and rubella.

The monograph for Chlortetracycline Ointment uses a microbiological assay. It is hoped in a future Addendum to replace this, and the assays of a number of other tetracycline antibiotic preparations, by high-performance liquid chromatographic procedures.

## Revision

The general revision of the Pharmacopœia has been continued in a number of ways. For example, many monographs for dosage forms have been amended to maintain compatibility with revised monographs for the active ingredients, especially in respect of tests for manufacturing impurities. Also the limits for the content of the active ingredient have been tightened in a number of monographs for dosage forms.

A test to limit the content of the toxic impurity 2,3,7,8-tetrachlorodibenzo-*p*-dioxin has been included in the monograph for Hexachlorophane. The prescribed method requires the use of a gas chromatograph linked to a mass spectrometer and this is the first use of such a combination in the British Pharmacopœia. It is recognised that not all analysts will have the necessary facilities but the nature of the impurity and the stringency of the limit necessitate the use of this apparatus.

## European Pharmacopœia

This Addendum contains edited versions of material that has been published in fascicule 14 of Part II of the second edition of the European Pharmacopœia. With certain exceptions, monographs in that fascicule became effective on 1 January 1991.

General provisions for Ear Preparations, Nasal Preparations and Preparations for Inhalation have been introduced in fascicule 14. However, there are very few monographs for individual preparations in these categories in the British Pharmacopœia. These European Pharmacopœia texts and that previously published for Pressurised Pharmaceutical Preparations have been gathered together at the end of

the section entitled 'Monographs: Formulated Preparations'. Unless otherwise justified and authorised, these texts apply to all dosage forms of the type defined, whether or not an individual monograph is included in the British Pharmacopœia. This approach is an innovation and it may be extended in the next edition of the British Pharmacopœia.

**Index** The numbering of the pages in this Addendum is consecutive with that of the British Pharmacopœia 1988 and the Addenda 1989 and 1990. The index, which is cumulative, contains references to all material published in the British Pharmacopœia 1988 and the three Addenda.

**Acknowledgements** The British Pharmacopœia Commission records its continued indebtedness to the members of its advisory committees and consultative groups. Without their dedicated enthusiasm and assistance its objectives could not be achieved.

Finally, the Commission expresses its appreciation of the contribution made by Professor J B Stenlake CBE who served as a member of the Commission for over 25 years and as its Chairman from 1980 to 1990.

**Additions** The following monographs are added to the British Pharmacopœia 1988 by means of this Addendum.

<b>Medicinal and Pharmaceutical Substances</b>		ORAL LIQUIDS
		Orciprenaline Oral Solution
		PARENTERAL PREPARATIONS
		Magnesium Sulphate Injection
		TABLETS
		Brompheniramine Tablets
		Co-codamol Tablets
		Co-dydramol Tablets
<b>Formulated Preparations</b>		Immunological Products
		Measles, Mumps and Rubella Vaccine, Live
		Surgical Materials
		Knitted Polyamide and Cellulose Contour Bandage
CAPSULES		
Co-danthrusate Capsules		
GRANULES		
Standardised Senna Granules		
NASAL DROPS		
Ephedrine Nasal Drops		
OINTMENTS		
Chlortetracycline Ointment		

**Amendments** The following monographs of the British Pharmacopœia 1988 are amended by means of this Addendum.

<b>Medicinal and Pharmaceutical Substances</b>		Dihydrocodeine Tartrate
		Dispersible Cellulose
		Dithranol
		Docusate Sodium
		Dried Aluminium Phosphate
		Estramustine Sodium Phosphphate
		Formaldehyde Solution
		Fosfestrol Sodium
		Hexachlorophane
		Hydrocortisone Sodium Phosphate
		Hydrous Benzoyl Peroxide
		Hyoscine Butylbromide
		Inositol Nicotinate
		Isoxsuprine Hydrochloride
		Levamisole Hydrochloride
		Levorphanol Tartrate
		Liquefied Phenol
Adrenaline		
Aloin		
Anhydrous Sodium Sulphite		
Carbenoxolone Sodium		
Carbomer		
Chorhexidine Gluconate Solution		
Chlormethiazole		
Chlormethiazole Edisylate		
Clomiphene Citrate		
Dacarbazine		
Danthron		
Desferrioxamine Mesylate		
Desmopressin		
Dichlorphenamide		



Nandrolone Phenylpropionate  
 Naproxen  
 Nortriptyline Hydrochloride  
 Oleic Acid  
 Orciprenaline Sulphate  
 Potassium Acetate  
 Potassium Nitrate  
 Riboflavine Sodium Phosphate  
 Sodium Starch Glycollate  
 Sodium Hydroxide  
 Sorbitan Monolaurate  
 Sorbitan Mono-oleate  
 Sorbitan Monostearate  
 Suxamethonium Bromide  
 Urea

#### Formulated Preparations

##### APPLICATIONS

Benzyl Benzoate Application

##### CAPSULES

Capsules  
 Chloromethiazole Capsules  
 Cloxacillin Capsules  
 Estramustine Phosphate Capsules  
 Flucloxacillin Capsules  
 Ketoprofen Capsules  
 Mefenamic Acid Capsules

##### COLLODIONS

Salicylic Acid Collodion

##### CREAMS

Diethylamine Salicylate Cream  
 Hydrocortisone and Neomycin Cream

##### EAR DROPS

Ear Drops  
 Hydrocortisone and Neomycin Ear Drops

##### EXTRACTS

Deglycyrrhizinised Liquorice Extract

##### EYE DROPS

Amethocaine Eye Drops  
 Homatropine Eye Drops  
 Hydrocortisone and Neomycin Eye Drops

##### EYE OINTMENTS

Hydrocortisone and Neomycin Eye Ointment

##### GRANULES

Granules

##### INHALATIONS

Inhalations

##### INSUFFLATIONS

Insufflations  
 Sodium Cromoglycate Insufflation

##### INTRANASAL SOLUTIONS

Intranasal Solutions  
 Desmopressin Intranasal Solution

##### NASAL DROPS

Nasal Drops  
 Xylometazoline Nasal Drops

##### OINTMENTS

Hydrocortisone Acetate and Neomycin Ointment

##### ORAL LIQUIDS

Oral Liquids  
 Cloxacillin Oral Solution

Codeine Linctus  
 Co-trimoxazole Oral Suspension  
 Magnesium Sulphate Mixture  
 Paediatric Chalk Mixture  
 Simple Linctus  
 Sodium Valproate Oral Solution

##### PARENTERAL PREPARATIONS

Parenteral Preparations  
 Adrenaline Injection  
 Aprotinin Injection  
 Betamethasone Injection  
 Biphasic Isophane Insulin Injection  
 Bupivacaine and Adrenaline Injection  
 Bupivacaine Injection  
 Compound Sodium Lactate Intravenous Infusion  
 Desferrioxamine Injection  
 Dopamine Intravenous Infusion  
 Iron Dextran Injection  
 Lignocaine and Adrenaline Injection  
 Meglumine Diatrizoate Injection  
 Meglumine Iodipamide Injection  
 Meglumine Iothalamate Injection  
 Methotrexate Injection  
 Pancuronium Injection  
 Procyclidine Injection  
 Sodium Calciumedetate Intravenous Infusion  
 Sodium Lactate Intravenous Infusion  
 Thiotepa Injection  
 Trisodium Edetate Intravenous Infusion  
 Tubocurarine Injection

##### PASTES

Dithranol Paste  
 Zinc and Salicylic Acid Paste

##### PRESSURISED INHALATIONS

Pressurised Inhalations

##### SOLUTIONS

Adrenaline Solution  
 Alcoholic Iodine Solution

##### SUPPOSITORIES

Metronidazole Suppositories  
 Naproxen Suppositories

##### TABLETS

Tablets  
 Aspirin Tablets  
 Baclofen Tablets  
 Bisacodyl Tablets  
 Carbenoxolone Tablets  
 Chlordiazepoxide Tablets  
 Chlorthalidone Tablets  
 Cortisone Tablets  
 Diazepam Tablets  
 Dichlorphenamide Tablets  
 Dipyridamole Tablets  
 Ephedrine Hydrochloride Tablets  
 Ergometrine Tablets  
 Erythromycin Tablets  
 Ethacrynic Acid Tablets  
 Ethinyloestradiol Tablets  
 Lorazepam Tablets  
 Metronidazole Tablets  
 Naproxen Tablets  
 Niclosamide Tablets  
 Nitrazepam Tablets  
 Pancreatin Tablets  
 Phenoxymethylpenicillin Tablets

Prednisolone Tablets  
 Procyclidine Tablets  
 Sodium Valproate Tablets  
 Spironolactone Tablets  
 Tamoxifen Tablets  
 Thioridazine Tablets  
 Trimeprazine Tablets  
 Warfarin Tablets

TINCTURES  
 Camphorated Opium Tincture  
 Concentrated Camphorated Opium Tincture  
 Opium Tincture

AROMATIC WATERS  
 Concentrated Camphor Water

## European Pharmacopœia

Monographs of the European Pharmacopœia that are reproduced in edited form in this Addendum replace the monographs in the British Pharmacopœia 1988. Where a monograph appears in the British Pharmacopœia under a different title, the British Pharmacopœia title is given in parentheses.

### REVISED AND AMENDED MONOGRAPHS

#### Medicinal and Pharmaceutical Substances

Alexandrian Senna Pods (Alexandrian Senna Fruit)  
 Amoxicillin Trihydrate (Amoxycillin Trihydrate)  
 Anaesthetic Ether  
 Bentonite  
 Benzyl Alcohol  
 Calcium Carbonate  
 Carbamazepine  
 Castor Oil  
 Chlorhexidine Hydrochloride  
 Chlortetracycline Hydrochloride  
 Codeine Phosphate Hemihydrate (Codeine Phosphate)  
 Desipramine Hydrochloride  
 Ephedrine Hydrochloride  
 Glycerol  
 Glycerol (85 per cent)  
 Heparin Calcium  
 Heparin Sodium  
 Hydrated Aluminium Oxide (Dried Aluminium Hydroxide)

### NEW MONOGRAPHS

#### Medicinal and Pharmaceutical Substances

Amiloride Hydrochloride  
 Anhydrous Niclosamide  
 Baclofen  
 Beclometasone Dipropionate (Beclomethasone Dipropionate)  
 Chlordiazepoxide  
 Chlorhexidine Acetate  
 Chlorhexidine Gluconate Solution

### Immunological Products

Inactivated Influenza Vaccine (Surface Antigen)

### Surgical Materials

Extension Plaster  
 Framycetin Gauze Dressing  
 Impermeable Plastic Surgical Adhesive Tape  
 Permeable Plastic Surgical Adhesive Tape  
 Semipermeable Waterproof Plastic Surgical Adhesive Tape  
 Zinc Oxide Surgical Adhesive Tape

Hyoscyamine Sulphate  
 Methyl Parahydroxybenzoate (Methyl Hydroxybenzoate)  
 Methyl dopa  
 Morphine Hydrochloride  
 Nifedipine  
 Olive Oil  
 Pancreas Powder (Pancreatic Extract)  
 Paracetamol  
 Phenobarbitone Sodium  
 Phenylephrine Hydrochloride  
 Propyl Parahydroxybenzoate (Propyl Hydroxybenzoate)  
 Suxemethonium Chloride  
 Testosterone Propionate  
 Water for Injections  
 Zinc Sulphate

### Blood Products

Human Albumin Solution (Albumin Solution)

### Radiopharmaceutical Preparations

Cyanocobalamin [ $^{57}\text{Co}$ ] Solution  
 Cyanocobalamin [ $^{58}\text{Co}$ ] Solution  
 Sodium Iodide [ $^{131}\text{I}$ ] Solution

Chlorhexidine Hydrochloride  
 Cloxacillin Sodium  
 Daunorubicin Hydrochloride\*  
 Dicloxacillin Sodium\*  
 Dopamine Hydrochloride  
 Econazole Nitrate  
 Flucloxacillin Sodium  
 Gentamicin Sulphate  
 Idoxuridine  
 Iodine  
 Magnesium Sulphate



Medroxyprogesterone Acetate  
 Metoclopramide Hydrochloride  
 Metronidazole  
 Natural Camphor  
 Niclosamide Monohydrate\*  
 Pancuronium Bromide  
 Pepsin Powder (Pepsin)\*  
 Phenylpropanolamine Hydrochloride  
 Physostigmine Sulphate  
 Polyvidone (Povidone)  
 Protamine Hydrochloride\*  
 Racemic Camphor  
 Salbutamol Sulphate  
 Sodium Hydroxide  
 Sodium Valproate  
 Spironolactone  
 Terbutaline Sulphate  
 $\alpha$ -Tocopherol (Alpha Tocopherol)\*

$\alpha$ -Tocopherol Acetate Concentrate (Powder Form) (Alpha Tocopheryl Acetate Concentrate (Powder Form))\*  
 Tretinoin  
 Trypsin\*  
 Urokinase\*  
 Warfarin Sodium  
 Warfarin Sodium Clathrate\*

#### Radiopharmaceutical Preparations

Indium[<sup>111</sup>In] Pentetate Injection\*  
 Technetium[<sup>99m</sup>Tc] Colloidal Tin Injection\*

#### Surgical Materials

Sterile Synthetic Absorbable Braided Sutures\*  
 Sterile Synthetic Absorbable Monofilament Sutures\*

The general provisions of the European Pharmacopœia relating to the types of dosage form listed below are either included in edited form in the appropriate general monograph in that section of the British Pharmacopœia entitled Monographs: Formulated Preparations† or they are reproduced with only minor editorial changes at the end of that section.

Ear Preparations\*  
 Nasal Preparations\*  
 Oral Liquids†

Preparations for Inhalation\*  
 Pressurised Pharmaceutical Preparations\*

\*Addition to the British Pharmacopœia