

# EUROPEAN PHARMACOPŒIA

COUNCIL  
OF  
EUROPE

2<sup>nd</sup> EDITION

Part II

MAISONNEUVE

# EUROPEAN PHARMACOPOEIA

SECOND EDITION

Part II

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## TEXTS INCLUDED IN THE FIRST FASCICULE

### Revised Monographs with their Serial Number

<i>Latin title</i>	<i>English title</i>
<b>Acidum Boricum (1)</b>	Boric Acid
<b>Acidum Hydrochloricum Concentratum (2)</b>	Concentrated Hydrochloric Acid
<b>Acidum Hydrochloricum Dilutum (3)</b>	Dilute Hydrochloric Acid
<b>Acidum Phosphoricum Concentratum (4)</b>	Concentrated Phosphoric Acid
<b>Acidum Phosphoricum Dilutum (5)</b>	Dilute Phosphoric Acid
<b>Alumen (6)</b>	Alum
<b>Ammonii Chloridum (7)</b>	Ammonium Chloride
<b>Aqua Purificata (8)</b>	Purified Water
<b>Argenti Nitras (9)</b>	Silver Nitrate
<b>Barii Sulfas (10)</b>	Barium Sulphate
<b>Benzocainum (11)</b>	Benzocaine
<b>Bismuthi Subcarbonas (12)</b>	Bismuth Subcarbonate
<b>Borax (13)</b>	Borax
<b>Calcii Carbonas (14)</b>	Calcium Carbonate
<b>Calcii Chloridum (15)</b>	Calcium Chloride
<b>Chinini Hydrochloridum (18)</b>	Quinine Hydrochloride
<b>Frangulae Cortex (25)</b>	Frangula Bark
<b>Imipramini Hydrochloridum (29)</b>	Imipramine Hydrochloride
<b>Immunosera ad Usum Veterinarium (30)</b>	Immunosera for Veterinary Use
<b>Iodum (31)</b>	Iodine

<b>Lanugo Cellulosi Absorbens (34)</b>	Absorbent Viscose Wadding
<b>Lanugo Cellulosi Absorbens Sterilis (35)</b>	Sterile Absorbent Viscose Wadding
<b>Lanugo Gossypii Absorbens (36)</b>	Absorbent Cotton
<b>Lanugo Gossypii Absorbens Sterilis (37)</b>	Sterile Absorbent Cotton
<b>Magnesium Oxidum Leve (40)</b>	Light Magnesium Oxide
<b>Magnesii Subcarbonas Levis (42)</b>	Light Magnesium Carbonate
<b>Magnesii Subcarbonas Ponderosus (43)</b>	Heavy Magnesium Carbonate
<b>Magnesii Sulfas (44)</b>	Magnesium Sulphate
<b>Neostigmini Bromidum (46)</b>	Neostigmine Bromide
<b>Nicotinamidum (47)</b>	Nicotinamide
<b>Paracetamol (49)</b>	Paracetamol
<b>Procaini Hydrochloridum (50)</b>	Procaine Hydrochloride
<b>Ricini Oleum (51)</b>	Castor Oil
<b>Streptomycini Sulfas (53)</b>	Streptomycin Sulphate
<b>Tela Gossypii Absorbens (55)</b>	Absorbent Cotton Gauze
<b>Tela Gossypii Absorbens Sterilis (56)</b>	Sterile Absorbent Cotton Gauze
<b>Tetracaini Hydrochloridum (57)</b>	Tetracaine Hydrochloride
<b>Vaccina ad Usus Veterinarium (62)</b>	Vaccines for Veterinary Use

### Texts of Part I

V.3.2.3. Calcium (replacement text)

## New Monographs with their Serial Number

<i>Latin title</i>	<i>English title</i>
<b>Capsulae (16)</b>	Capsules
<b>Chinidini Sulfas (17)</b>	Quinidine Sulphate
<b>Chinini Sulfas (19)</b>	Quinine Sulphate
<b>Dextromethorphan Hydrobromidum (20)</b>	Dextromethorphan Hydrobromide
<b>Dextromoramidi Tartaras (21)</b>	Dextromoramide Tartrate
<b>Diazepamum (22)</b>	Diazepam
<b>Diphenhydramini Hydrochloridum (23)</b>	Diphenhydramine Hydrochloride
<b>Fibrinogenum Humanum Cryodesiccatum (24)</b>	Dried Human Fibrinogen
<b>Globuli (26)</b>	Pessaries
<b>Guanethidini Monosulfas (27)</b>	Guanethidine Monosulphate
<b>Guttae Ophthalmicae (28)</b>	Eye-drops
<b>Kanamycini Monosulfas (32)</b>	Kanamycin Monosulphate
<b>Kanamycini Sulfas Acidus (33)</b>	Kanamycin Acid Sulphate
<b>Levodopum (38)</b>	Levodopa
<b>Magnesii Hydroxidum (39)</b>	Magnesium Hydroxide
<b>Magnesii Oxidum Ponderosum (41)</b>	Heavy Magnesium Oxide
<b>Methyldopum (45)</b>	Methyldopa
<b>Ouabainum (48)</b>	Ouabain
<b>Rifampicinum (52)</b>	Rifampicin

**Suppositoria (54)**

**Triamterenum (58)**

**Trifluoperazini**

**Hydrochloridum (59)**

**Trimethoprimum (60)**

**Unguenta Ophthalmica (61)**

**Vaccinum Aphtharum Epizooti-  
carum Inactivatum pro Rumi-  
nantibus (63)**

**Vaccinum Erysipelatis Suillae  
Inactivatum (64)**

**Vaccinum Pestis Classicae  
Suillae ex Cuniculo Vivum  
Cryodesiccatum (65)**

Suppositories

Triamterene

Trifluoperazine Hydrochloride

Trimethoprim

Eye Ointments

Foot-and-mouth Disease  
(Ruminants) Inactivated Vaccine

Inactivated Swine Erysipelas  
Vaccine

Freeze-dried Classical Swine-fever  
Live Vaccine Prepared in the  
Rabbit

## **Texts of Part I**

**VIII.8 Classical swine-fever vaccine prepared in the rabbit —  
choice of the virus strain.**

## **PART II**

## ACIDUM BORICUM

### Boric Acid

 $M_r$  61.8

Boric acid contains not less than 99.0 per cent and not more than the equivalent of 100.5 per cent of  $\text{H}_3\text{BO}_3$ .

#### CHARACTERS

A white, crystalline powder, colourless shiny plates greasy to the touch or white crystals, odourless, soluble in water and in alcohol, freely soluble in boiling water and in glycerol (85 per cent).

#### IDENTIFICATION

- A. Dissolve 0.1 g by gently heating in 5 ml of methanol R, add 0.1 ml of sulphuric acid R and ignite the solution. The flame has a green border.
- B. Solution S (see Tests) is acid (V.6.3.2).

#### TESTS

**Solution S** Dissolve 3.3 g in 80 ml of boiling distilled water, cool and dilute to 100 ml with carbon dioxide-free water R prepared from distilled water.

**Appearance of solution** Solution S is clear (V.6.1) and colourless (Method II, V.6.2).

**pH** (V.6.3.1) The pH of solution S is 3.8 to 4.8.

**Solubility in alcohol** Dissolve 1.0 g in 10 ml of boiling alcohol R. The solution is clear or slightly opalescent (V.6.1) and colourless (Method II, V.6.2).

**Organic matter** It does not darken on progressive heating to dull redness.

**Sulphates** (V.3.2.13) 10 ml of solution S diluted to 15 ml with distilled water complies with the limit test for sulphates (450 ppm).

**Heavy metals** (V.3.2.8) 12 ml of solution S complies with limit test A for heavy metals (15 ppm). Prepare the standard using a mixture of 2.5 ml of lead standard solution (2 ppm Pb) R and 7.5 ml of water.

### ASSAY

Dissolve 1.000 g with heating in 100 ml of water containing 15 g of mannitol R. Titrate with 1N sodium hydroxide, using 0.5 ml of phenolphthalein solution R as indicator, until a pink colour is obtained.

1 ml of 1N sodium hydroxide is equivalent to 61.8 mg of  $\text{H}_3\text{BO}_3$ .

## ACIDUM HYDROCHLORICUM CONCENTRATUM

### Concentrated Hydrochloric Acid

HCl

$M_r$  36.46

Concentrated hydrochloric acid contains not less than 35.0 per cent  $m/m$  and not more than 39.0 per cent  $m/m$  of HCl.

#### CHARACTERS

A clear, colourless, fuming liquid with a pungent odour, miscible with water.

It has a relative density of about 1.18.

#### IDENTIFICATION

A. Dilute with water. The solution is strongly acid (V.6.3.2).

B. It gives the reactions of chlorides (V.3.1.1).

#### TESTS

**Appearance of solution** A mixture of 2 ml with 8 ml of water is clear (V.6.1) and colourless (Method II, V.6.2).

**Free chlorine** To 15 ml add 100 ml of carbon dioxide-free water R, 1 ml of a 10 per cent  $m/V$  solution of potassium iodide R and 0.5 ml of iodide-free starch solution R. Allow to stand in the dark for 2 min. Any blue colour disappears on the addition of 0.2 ml of 0.01N sodium thiosulphate (4 ppm).

**Sulphates** (V.3.2.13) To 6.4 ml add 10 mg of sodium bicarbonate R and evaporate to dryness on a water-bath. Dissolve the residue in 15 ml of distilled water. The solution complies with the limit test for sulphates (20 ppm).

**Arsenic** (V.3.2.2) Dilute 4.2 ml to 10 ml with water. 1 ml of the solution complies with limit test A for arsenic (2 ppm).

**Heavy metals** (V.3.2.8) Dissolve the residue obtained in the test for residue on evaporation in 1 ml of dilute hydrochloric acid R and dilute to 25 ml with water. Dilute 5 ml of this solution to 20 ml with water. 12 ml of the solution complies with limit test A for heavy metals (2 ppm). Prepare the standard using lead standard solution (2 ppm Pb) R.

**Residue on evaporation** Not more than 10 mg (0.01 per cent), determined on 100 g.

### ASSAY

Weigh accurately a ground-glass-stoppered flask containing 30 ml of water. Introduce 1.5 ml of the acid and weigh again. Titrate with 1N sodium hydroxide, using methyl red solution R as indicator.

1 ml of 1N sodium hydroxide is equivalent to 36.46 mg of HCl.

### STORAGE

Store in a stoppered container of glass or other inert material at a temperature below 30 °C.

## ACIDUM HYDROCHLORICUM DILUTUM

### Dilute Hydrochloric Acid

Dilute hydrochloric acid contains 9.5 per cent *m/m* to 10.5 per cent *m/m* of HCl ( $M_r$  36.46).

#### PREPARATION

To 274 g of concentrated hydrochloric acid add 726 g of water and mix.

#### IDENTIFICATION

A. It is strongly acid (V.6.3.2).

B. It gives the reactions of chlorides (V.3.1.1).

#### TESTS

**Appearance** It is clear (V.6.1) and colourless (Method II, V.6.2).

**Free chlorine** To 60 ml add 50 ml of carbon dioxide-free water R, 1 ml of a 10 per cent *m/V* solution of potassium iodide R and 0.5 ml of iodide-free starch solution R. Allow to stand in the dark for 2 min. Any blue colour disappears on the addition of 0.2 ml of 0.01N sodium thiosulphate (1 ppm).

**Sulphates** (V.3.2.13) To 26 ml add 10 mg of sodium bicarbonate R and evaporate to dryness on a water-bath. Dissolve the residue in 15 ml of distilled water. The solution complies with the limit test for sulphates (5 ppm).

**Arsenic** (V.3.2.2) Dilute 17 ml to 20 ml with water. 2 ml of the solution complies with limit test A for arsenic (0.5 ppm).

**Heavy metals** (V.3.2.8) Dissolve the residue obtained in the test for residue on evaporation in 1 ml of dilute hydrochloric acid R and dilute to 25 ml with water. Dilute 5 ml of this solution to 20 ml with water. 12 ml of the solution complies with limit test A for heavy metals (2 ppm). Prepare the standard using lead standard solution (2 ppm Pb) R.

**Residue on evaporation** Not more than 10 mg (0.01 per cent), determined on 100 g.

## ASSAY

To 6.00 g add 30 ml of water. Titrate with 1N sodium hydroxide, using methyl red solution R as indicator.

1 ml of 1N sodium hydroxide is equivalent to 36.46 mg of HCl.

## ACIDUM PHOSPHORICUM CONCENTRATUM

### Concentrated Phosphoric Acid

$\text{H}_3\text{PO}_4$

$M_r$  98.0

Concentrated phosphoric acid contains not less than 84.0 per cent *m/m* and not more than 90.0 per cent *m/m* of  $\text{H}_3\text{PO}_4$ .

#### CHARACTERS

A clear, colourless, syrupy liquid, corrosive, miscible with water and with alcohol. When stored at a low temperature it may solidify into a mass of colourless crystals which do not melt at a temperature below 28 °C.

It has a relative density of about 1.7.

#### IDENTIFICATION

- A. Dilute with water. The solution is strongly acid (V.6.3.2).
- B. Solution S (see Tests) neutralised with dilute sodium hydroxide solution R gives the reactions of phosphates (V.3.1.1).

#### TESTS

**Solution S** Dilute 10.0 g to 150 ml with water.

**Appearance of solution** Solution S is clear (V.6.1) and colourless (Method II, V.6.2).

**Substances precipitated with ammonia** To 10 ml of solution S add 8 ml of dilute ammonia R1. Any opalescence in the solution is not more intense than that in a mixture of 10 ml of solution S and 8 ml of water.

**Hypophosphorous acid and phosphorous acid** To 5 ml of solution S add 2 ml of silver nitrate solution R2 and heat on a water-bath for 5 min. The solution shows no change in appearance.

**Chlorides** (V.3.2.4) 15 ml of solution S complies with the limit test for chlorides (50 ppm).

**Sulphates** (V.3.2.13) 1.5 g diluted to 15 ml with distilled water complies with the limit test for sulphates (100 ppm).

**Arsenic** (V.3.2.2) 7.5 ml of solution S complies with limit test A for arsenic (2 ppm).

**Heavy metals** (V.3.2.8) To 2.5 g add 4 ml of dilute ammonia R1 and dilute to 25 ml with water. 12 ml of the solution complies with limit test A for heavy metals (10 ppm). Prepare the standard using lead standard solution (1 ppm Pb) R.

**Iron** (V.3.2.9) 3 ml of solution S diluted to 10 ml with water complies with the limit test for iron (50 ppm).

#### ASSAY

To 1.000 g add a solution of 10 g of sodium chloride R in 30 ml of water. Titrate with 1N sodium hydroxide, using phenolphthalein solution R as indicator.

1 ml of 1N sodium hydroxide is equivalent to 49.00 mg of  $\text{H}_3\text{PO}_4$ .

#### STORAGE

Store in a well-closed, glass container.

## ACIDUM PHOSPHORICUM DILUTUM

### Dilute Phosphoric Acid

Dilute phosphoric acid contains 9.5 per cent *m/m* to 10.5 per cent *m/m* of  $\text{H}_3\text{PO}_4$  ( $M_r$  98.0).

#### PREPARATION

To 115 g of concentrated phosphoric acid add 885 g of water and mix.

#### IDENTIFICATION

- A. It is strongly acid (V.6.3.2).
- B. Solution S (see Tests), neutralised with dilute sodium hydroxide solution R, gives the reactions of phosphates (V.3.1.1).

#### TESTS

**Solution S** Dilute 86 g to 150 ml with water.

**Appearance of solution** Solution S is clear (V.6.1) and colourless (Method II, V.6.2).

**Substances precipitated with ammonia** To 10 ml of solution S add 8 ml of dilute ammonia R1. Any opalescence in the solution is not more intense than that in a mixture of 10 ml of solution S and 8 ml of water.

**Hypophosphorous acid and phosphorous acid** To 5 ml of solution S add 2 ml of silver nitrate solution R2 and heat on a water-bath for 5 min. The solution shows no change in appearance.

**Chlorides** (V.3.2.4) 15 ml of solution S complies with the limit test for chlorides (6 ppm).

**Sulphates** (V.3.2.13) 15 ml of the substance to be examined complies with the limit test for sulphates (10 ppm).

**Arsenic** (V.3.2.2) 7.5 ml of solution S complies with limit test A for arsenic (0.2 ppm).

**Heavy metals** (V.3.2.8) To 20 g of the substance to be examined add 4 ml of dilute ammonia R1 and dilute to 25 ml with water. 12 ml of the solution complies with limit test A for heavy metals (1 ppm). Prepare the standard using a mixture of 8 ml of lead standard solution (1 ppm Pb) R and 2 ml of water.

**Iron** (V.3.2.9) 3 ml of solution S diluted to 10 ml with water complies with the limit test for iron (6 ppm).

## ASSAY

To 8.60 g add a solution of 10 g of sodium chloride R in 30 ml of water. Titrate with 1N sodium hydroxide, using phenolphthalein solution R as indicator.

1 ml of 1N sodium hydroxide is equivalent to 49.00 mg of  $\text{H}_3\text{PO}_4$ .