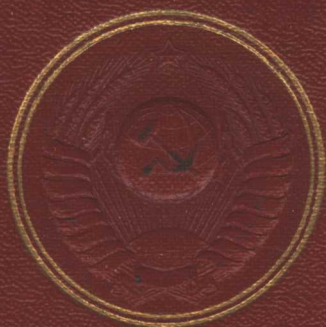


STATE
PHARMACOPOEIA
OF THE UNION OF SOVIET
SOCIALIST REPUBLICS



MINISTRY OF PUBLIC HEALTH OF THE USSR

STATE
PHARMACOPOEIA
OF THE UNION OF SOVIET
SOCIALIST REPUBLICS

EXTRACTS FROM THE EIGHTH EDITION

(translated from Russian)

MOSCOW

PUBLISHED FOR V/O "SOJUZCHIMEXPORT"

by

All-Union Publishing and Printing Corporation

VNESHTORGIZDAT

EDITOR'S PREFACE

TO THE EIGHTH EDITION OF THE STATE PHARMACOPOEIA OF THE UNION OF SOVIET SOCIALIST REPUBLICS IN THE ENGLISH LANGUAGE

The Eighth Edition of the State Pharmacopoeia of the Union of Soviet Socialist Republics was prepared during the period from 1938 to 1944. In 1952 the Addendum 1 to the Eighth Edition of the Pharmacopoeia was issued containing some new monographs.

The Pharmacopoeia includes descriptions of the most wide-spread preparations that justified themselves in practice.

The cooperation of the most authoritative scientific institutions, and of high qualification scientists and experts of the USSR in the work connected with the preparation of the State Pharmacopoeia was insured.

The present edition of the State Pharmacopoeia of the USSR in English has been undertaken by the Soviet foreign trade organization V/O "Sojuzchimexport". Most monographs of the original Eighth Edition, as well as those included in the Addendum 1 to the Eighth Edition, have been translated into English, preference being given to the preparations appertaining to the export list of the above organization.

GENERAL RULES WHICH MUST BE OBSERVED WHEN USING THE EIGHTH EDITION OF THE STATE PHARMACOPOEIA

a) Temperatures are given in degrees of Centigrade.

b) If the temperature is not given when it concerns specific gravity or solubility and in other cases when temperature is of any importance, the temperature is understood to be 20°.

Under "cold" or "cool" the temperature of 12 to 15° is understood, under "room temperature" — the temperature of 18 to 20°.

When speaking about the temperature of water under "warm" is meant the temperature of 40 to 50°, under "hot" — the temperature about 80 to 90°.

The temperature of a water-bath is 98 to 100°.

c) As units of measure and weight are taken the metrical ones.

d) Under "p." are understood parts of weight.

e) If an indicator is not defined in tests for acidity and alkalinity, the litmus test-paper is understood.

f) If for solutions the solvent is not indicated, only water solutions are understood.

g) Under "water" distilled water should be understood, if it is not indicated, that undistilled or common water is used.

If the strength of alcohol is not indicated, 90° alcohol (volume percentage) is used.

h) Under "accurately weighed" is understood weighing on analytical scales marking the fourth decimal sign. Samples of solutions for tests for admixtures or determination of compact and ash residue, if "accurately weighed" is not indicated, are to be taken marking the third decimal sign.

If there is no particular instruction, samples weighing 10 gm and more should be taken marking two decimal signs.

If there are no special instructions, samples for quantitative determinations of vegetable materials should be taken with 0.01 gm precision.

Under "per cent" are understood the weight's ratios.

Under "volume-weight per cent" is understood a quantity of grammes in 100 ml of solution.

Under "volume percentage" (vol. %) is understood a quantity of milliliters in 100 ml of solution.

Constant weight is considered attained when a difference of weight between two succeeding weighings does not exceed 0.0005 gm.

i) If in the description of a reaction the substances used as medical supplies are mentioned without any additional characterization, the preparations described in the Pharmacopoeia monographs should be used.

j) Under the adopted ways of marking solutions' strength as 1:10 should be understood contents of 1 weight part of substance in the indicated volume of a solution, i. e., when preparing a solution one should take 1 gm of the substance and enough solvent to obtain 10 ml of solution.

k) For counting drops, a normal drop-measurer giving 20 drops of distilled water in 1 gm should be used.

ABBREVIATIONS USED IN THE EIGHTH EDITION
OF THE STATE PHARMACOPOEIA

p.	— part	kg	— kilogramme
sp.gr.	— specific gravity	gm	— gramme
1 n.	— normal solution	mg	— milligramme
0.5 n.	— half-normal solution	γ	— gamma = 0.001 milli- gramme
0.1 n.	— decinormal solution	cm	— centimeter
0.01 n.	— centinormal solution	sq.cm	— square centimeter
Mol.Wt.	— molecular weight	ml	— milliliter (= 1 cu.cm)
mol.	— molar	mm	— millimeter
At.Wt.	— atomic weight	μ	— micron = 0.001 millimeter
pH	— negative logarithm of hy- drogen ion concentration		

INTRODUCTION

In the process of preparation for the Eighth Edition of the Pharmacopoeia of the USSR, the Pharmacopoeia Committee adopted the following fundamental regulations:

1) The Pharmacopoeia represents a system of standards and obligatory norms for medical substances, drugs and preparations, included in the Pharmacopoeia, that are to be applied in the preparation of such medical forms mentioned in the Pharmacopoeia, as infusions, extracts, tablets, ointments etc.

2) Medical substances and drugs included in the Pharmacopoeia, are almost entirely of home origin.

3) While preparing the list of monographs for the Eighth Edition of the Pharmacopoeia, the Pharmacopoeia Committee tried to reflect the present-day state of medical science and requirements of the Public Health Organizations of the USSR.

The Pharmacopoeia Committee faced the same problems when standardizing the quality of pharmaceutical preparations and when choosing methods for their testing.

4) The Pharmacopoeia is not a text-book, but has legislative character; that is why the monographs dealing with separate preparations as well as those concerning general methods for testing and analysis are written as briefly as possible, without unnecessary details. Besides, it was taken into consideration that those using the Pharmacopoeia should be of special qualification, so as to secure on the basis of the monographs of the Pharmacopoeia correct preparation of medical substances as to the conformity of the preparation quality with the requirements of the Pharmacopoeia.

5) The Pharmacopoeia is the sole and obligatory one for all medical institutions and organizations of the USSR which are engaged in preparation and implementation of medical preparations. It should be also used in all the veterinarian institutions.

STATE PHARMACOPOEIA OF THE USSR

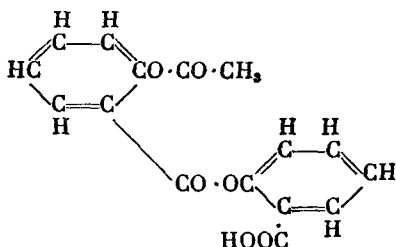
The Eighth Edition of the State Pharmacopoeia of the USSR was preceded by the following editions of the Pharmacopoeia in the Russian language: the first edition, 1866; the second edition, 1871; the third edition, 1880; the fourth edition, 1891; the fifth edition, 1902; the sixth edition, 1910, and the seventh edition, 1925.

MONOGRAPHS

ACESALUM (1)

ACESAL

Salicyl-acetyl-salicylic Acid



$\text{C}_{20}\text{H}_{18}\text{O}_8$

Mol. Wt. 300.25

Description and properties. A white fine powder or white lamellated crystals. Insoluble in water, soluble in 3 parts of hot alcohol, readily soluble in solutions of alkalis. Melting-point 150 to 157° (with decomposition).

Tests for identity. Dissolve 0.5 gm in 5 ml of 1 n. sodium hydroxide solution and boil for 2 minutes. When the cooled solution is acidified with dilute sulfuric acid, crystals of salicylic acid are evolved. The filtrate, when heated, displays the odour of acetic acid.

Tests for purity. Shake 0.1 gm with 20 ml of water and filter. On addition of 1 drop of ferric chloride solution to the obtained filtrate, only a scanty violet coloration may be formed. The intensity of this coloration should not exceed that of 20 ml of a Standard Solution containing 0.5 ml of 0.01 per cent aqueous solution of salicylic acid and 1 drop of this same ferric chloride solution (limit for salicylic acid).

Shake 1 gm with 25 ml of water and filter.

10 ml of the filtrate should not contain more chlorides than 10 ml of the Standard Solution, i. e., not more than 0.005 per cent in the preparation.

10 ml of the same filtrate should not contain more sulfates than 10 ml of the Standard Solution, i. e., not more than 0.025 per cent in the preparation.

Place about 0.5 gm (accurately weighed) in a weighed crucible, moisten with 0.5 ml of concentrated sulfuric acid, cautiously heat on a wire-gauze until the sulfuric acid vapours are removed and ignite to constant weight. The residue should not exceed 0.1 per cent and should not give reaction for heavy metals.

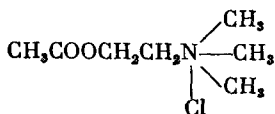
Assay. Dissolve about 0.75 gm (accurately weighed) in 10 ml of alcohol under heating, add 40 ml of 0.5 n. sodium hydroxide solution and on fitting the flask to a reflux condenser, warm on a water-bath for 1 hour. After cooling titrate the excess of sodium hydroxide with 0.5 n. hydrochloric acid solution (using phenolphthalein as indicator).

1 ml of 0.5 n. sodium hydroxide solution is equivalent to 0.05004 gm of acesal, its contents should not be less than 99 per cent in the preparation.

Storage. In well-stoppered jars.

ACETYLCHOLINUM CHLORATUM (3)

ACETYLCHOLINE CHLORIDE



$\text{C}_7\text{H}_{16}\text{O}_2\text{NCl}$

Mol. Wt. 181.66

Description and properties. Colourless crystals, deliquescent when exposed to air. Readily soluble in alcohol, water, chloroform; insoluble in ether.

Tests for identity. Add silver nitrate solution to a solution of the preparation. A white precipitate, insoluble in nitric acid, soluble in ammonia solution, falls out.

Heat a solution of the preparation with dilute sulfuric acid; the odour of acetic acid appears.

Tests for purity. Dissolve 0.1 gm in 3 ml of water. The solution should be colourless and clear. Add one drop of a solution of bromphenol-blue to the obtained solution; a yellow coloration, which appears, should not be changed on adding not more than 0.2 ml of a 0.1 n. sodium hydroxide solution (limit for acidity).

Dissolve 0.1 gm in 5 ml of dehydrated chloroform. The solution should not grow turbid when energetically shaken (test for moisture).

Moisten about 0.5 gm (accurately weighed) with 0.5 ml of concentrated sulfuric acid, cautiously heat on a wire-gauze until the sulfuric acid vapours are removed and ignite to constant weight. The residue should not exceed 0.1 per cent and should not give reaction for heavy metals.

Assay. Dissolve 0.1 gm (the contents of one ampoule) in 25 ml of water, acidify with nitric acid, add 10 ml of a 0.1 n. solution of

silver nitrate and 10 minutes afterwards titrate the excess of silver nitrate with a 0.1 n. ammonia rhodanide solution, until a pinkish-yellowish colour is formed (using ammonium ferric alum as indicator).

1 ml of a 0.1 n. silver nitrate solution is equivalent to 0.01817 gm of acetylcholine chloride, its contents in the preparation should not be less than 95 per cent.

Storage. *With precautions (list B)* in sealed ampoules, containing 0.1 or 0.2 gm of acetylcholine chloride.

Maximum single dose, subcutaneously and intramuscularly — 0.2 gm.

Maximum daily dose, subcutaneously and intramuscularly — 0.6 gm.

ACIDUM ARSENICOSUM ANHYDRICUM (6)

ARSENIOUS ANHYDRIDE. WHITE ARSENIC

As_2O_3

Mol. Wt. 197.82

Description and properties. Heavy white lumps of porcelain or vitreous appearance, frequently of lamellar structure with a conchoidal fracture, or a heavy white powder. Very slowly soluble in water (65 to 85 parts), readily soluble in hydrochloric acid and in solution of alkalis or carbonates of alkali metals.

Tests for identity. Arsenious anhydride, when slowly heated in a test-tube (under hood) sublimes in the form of small transparent crystals.

A solution of 0.2 gm in 5 ml of dilute hydrochloric acid gives a yellow precipitate when adding 3 to 5 drops of sodium sulfide solution.

Tests for purity. Dissolve 1 gm in 10 ml of ammonia solution and heat to 60°; no residue should remain (test for insoluble admixtures). This solution on adding an equal volume of water and excess of hydrochloric acid should not give a yellow coloration or a precipitate (test for arsenic sulfides).

Assay. Dissolve about 0.1 gm (accurately weighed) in 2 to 3 ml of sodium hydroxide solution in a stoppered flask of 100 ml capacity; add 15 ml of concentrated hydrochloric acid (sp. gr. 1.19) and titrate slowly with a 0.1 n. potassium bromate solution until the solution is discoloured (using methyl red as indicator).

1 ml of a 0.1 n. potassium bromate solution is equivalent to 0.004946 gm of arsenious anhydride, its contents in the preparation should not be less than 99 per cent.

Storage. *In a safe (list A)* in well-stoppered bottles. All devices necessary for the dispensing of the preparation should be kept in the same safe.

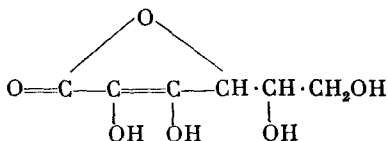
Maximum single dose 0.003 gm.

Maximum daily dose 0.01 gm.

Note. For the preparation of powder, moisten lumps of white arsenic with 96 per cent alcohol and triturate cautiously in a porcelain mortar; the powder is then dried in the air.

ACIDUM ASCORBINICUM (7)

ASCORBIC ACID. VITAMIN "C"

 $\text{C}_6\text{H}_8\text{O}_6$

Mol. Wt. 176.12

Description and properties. Colourless lamellated crystals of acid taste. Soluble in 5 parts of water, in 40 parts of alcohol. Melting-point 186 to 190° (with decomposition).

Tests for identity. Dissolve 0.1 gm in 2 ml of water and add 0.5 ml of a solution of silver nitrate; a precipitate of metallic silver falls out.

Tests for purity. Dissolve 0.25 gm in 5 ml of water. The solution obtained can have a faint colour, but not more intensive than that of 5 ml of the Standard Solution No. 5.

The same solution, when diluted with water to 10 ml, should not contain more sulfates than 10 ml of the Standard Solution, i. e., not more than 0.04 per cent in the preparation.

Place about 0.5 gm (accurately weighed) in a weighed crucible, moisten with 0.5 ml of concentrated sulfuric acid, heat cautiously on a wire-gauze until the sulfuric acid fumes are removed and ignite to constant weight. The residue should not exceed 0.1 per cent and should not give reaction for heavy metals.

Assay. Dissolve about 0.25 gm (accurately weighed) in 25 ml of water and titrate with a 0.1 n. iodine solution (using starch as indicator), until a stable blue coloration appears.

1 ml of a 0.1 n. iodine solution is equivalent to 0.008806 gm of ascorbic acid, its contents in the preparation should be not less than 98 per cent.

Storage. In a place protected from light, in small filled up orange-coloured glass jars, well-stoppered and sealed with paraffin. The preparation, when stored may acquire a greyish-yellowish tint.

ACIDUM BORICUM (9)

BORIC ACID

 H_3BO_3

Mol. Wt. 61.84

Description and properties. Colourless, glittering little scales, slightly greasy to the touch, or a fine crystalline odourless powder. Soluble in 25 parts of water, 3 parts of boiling water, 25 parts of alcohol, rather readily in glycerin. Volatile with water or alcohol vapours. Heated for a long time (to 100°) loses part of the water and is converted into metaboric acid (HBO_2); when heated to a high degree,

forms a vitreous melted mass, which while heated further swells and looses all the water leaving boric anhydride (B_2O_3). The aqueous solutions of boric acid show a slight acid reaction.

Tests for identity. A turmeric paper (curcuma paper) moistened with a solution (1:50) of boric acid and several drops of hydrochloric acid develops on drying a pink or brownish-red colour, which on moistening with ammonia solution changes to greenish-black. An alcohol solution of boric acid burns with a flame having a green border.

Tests for purity. A solution of 0.3 gm in 10 ml of water should be transparent and colourless.

Dissolve 10 gm, when heated, in 40 ml of water. Allow the solution to cool, shake and dilute to 100 ml, then filter off the separated boric acid.

5 ml of the filtrate obtained, diluted with water to 10 ml should not contain more sulfates than 10 ml of the Standard Solution, i. e., not more than 0.02 per cent in the preparation.

4 ml of the same filtrate, diluted with water to 10 ml, should not contain more chlorides than 10 ml of the Standard Solution, i. e., not more than 0.005 per cent in the preparation.

5 ml of the same filtrate, diluted with water to 10 ml, should not contain more calcium than 10 ml of the Standard Solution, i. e., not more than 0.06 per cent in the preparation.

10 ml of the same filtrate should not contain more iron than 10 ml of the Standard Solution, i. e., not more than 0.003 per cent in the preparation.

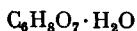
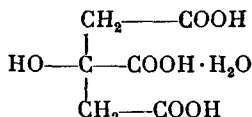
5 ml of the same filtrate diluted with water to 10 ml should not contain more heavy metals than 10 ml of the Standard Solution, i. e., not more than 0.001 per cent in the preparation. 2 ml of the same filtrate diluted with water to 10 ml should give a yellow but not orange or pink colour on addition of one drop of a methyl orange solution (test for mineral acids).

0.5 gm of the preparation should not give reaction for arsenic with the Thiele's reagent.

Assay. Dissolve about 0.2 gm (accurately weighed) in a neutralized mixture of 10 ml of freshly boiled and cooled water and 10 ml of glycerin and titrate with a 0.1 n. sodium hydroxide solution until a pink colour appears (using phenolphthalein as indicator).

1 ml of a 0.1 n. sodium hydroxide solution is equivalent to 0.006184 gm of boric acid, its contents in the preparation should not be less than 99 per cent.

Storage. In well-stoppered jars.

ACIDUM CITRICUM (10)**CITRIC ACID**

Mol. Wt. 210.14

Description and properties. Colourless translucent crystals or a white crystalline powder without any odour, of a very acid taste. It is slowly efflorescent when exposed to dry warm air. Soluble in 0.6 parts of cold water, in 0.5 parts of hot water, in 1.5 parts of alcohol, in 50 parts of ether.

Tests for identity. Add lime water (40 to 50 ml) to 1 ml of a solution of citric acid (1:10) until alkaline reaction; the solution should remain transparent for 10 minutes. When boiled for 10 minutes, a white precipitate is formed.

Citric acid, when slowly heated, gradually decomposes evolving vapours of an acute odour, but not that of burnt sugar (distinction from tartaric acid).

Tests for purity. Add 10 ml of a 5 per cent alcoholic solution of potassium acetate to 5 ml of acetic acid. No crystalline precipitate should appear even when stirring with a glass rod (test for tartaric acid).

Heat a mixture of 0.5 gm of citric acid with 5 ml of concentrated sulfuric acid for 15 minutes on a water-bath. The liquid should become yellow, but not brown (test for tartaric acid, sugar and other carbonizable substances).

A solution of citric acid (1:10) should not give reaction for sulfates and calcium. A mixture of 5 ml of the same solution (1:10) with 2 ml of calcium chloride solution should not grow turbid in the course of one hour (test for oxalic acid).

10 ml of a citric acid solution (1:50) should not contain more heavy metals than 10 ml of the Standard Solution, i. e., not more than 0.0025 per cent in the preparation.

0.5 gm of citric acid should not give the reaction for arsenic acid with Thiele's reagent. Burn cautiously and ignite 0.5 gm of citric acid. The residue should not exceed 0.1 per cent.

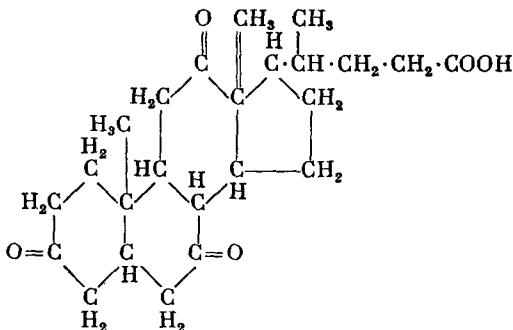
Assay. Dissolve about 1.5 gm (accurately weighed) in a 250 ml measuring flask and bring with water to the mark. Titrate 25 ml of the solution with a 0.1 n. solution of sodium hydroxide (using thymolphthalein as indicator) to a light blue coloration.

1 ml of a 0.1 n. sodium hydroxide solution is equivalent to 0.007005 gm of citric acid, its contents in the preparation should not be less than 98.8 per cent.

Storage. In well-stoppered jars.

ACIDUM DEHYDROCHOLICUM (11)

DEHYDROCHOLIC ACID. CHOLOGON

 $C_{24}H_{34}O_5$

Mol. Wt. 402.5

Description and properties. White, light, odourless crystalline powder of bitter taste. Almost insoluble in water, soluble in alcohol. Melting-point 230 to 237°.

Tests for identity. Dissolve 0.1 gm in 5 ml of a sodium carbonate solution and add several granules of diazobenzene sulfuric acid; the solution obtains a red colour.

Tests for purity. Shake up 0.5 gm with 50 ml of water and filter.

10 ml of the filtrate should not contain more chlorides than 10 ml of the Standard Solution, i. e., not more than 0.02 per cent in the preparation.

10 ml of the same filtrate should not contain more sulfates than 10 ml of the Standard Solution, i. e., not more than 0.1 per cent in the preparation.

Add 1 or 2 drops of a bromophenol blue solution to 10 ml of the same filtrate. A blue coloration is produced, which should not change on addition of 1 drop of a 0.1 n. hydrochloric acid solution.

Dissolve 0.1 gm in 5 ml of chloroform. The solution should be colourless and transparent (test for foreign organic admixtures).

Dry about 1 gm (accurately weighed) at 100 to 105° to constant weight. The loss of weight must not exceed 0.5 per cent.

Moisten the dried weighed sample with 0.5 ml of concentrated sulfuric acid in a weighed crucible, heat cautiously on a wire-gauze until the sulfuric acid fumes are removed and ignite to constant weight. The residue should not exceed 0.1 per cent and should not give reaction for heavy metals.

Assay. Dissolve about 0.5 gm (accurately weighed), when heated, in 50 ml of neutralized alcohol and titrate with 0.1 n. solution of sodium hydroxide until a pink colour is produced (using phenolphthalein as indicator).

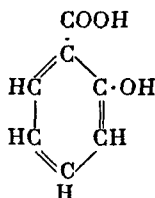
1 ml of 0.1 n. solution of sodium hydroxide is equivalent to 0.04025 gm of dehydrocholic acid, its contents in the preparation should not be less than 99.5 per cent.

Storage. In well-stoppered orange-coloured glass containers, in a dry and cool place.

Note. A solution of natrium dehydrocholate is used for subcutaneous injections under the name "decholin".

ACIDUM SALICYLICUM (22)

SALICYLIC ACID



$\text{C}_7\text{H}_6\text{O}_3$

Mol. Wt. 138.12

Description and properties. White small crystalline needles or a light crystalline odourless powder of a sweetish-sour taste. Soluble in 500 parts of water, in 15 parts of boiling water, in 3 parts of alcohol and in 2 parts of ether. Melting-point 157 to 159.5°.

Cautiously warmed sublimes without decomposition; when quickly heated is partly decomposed, evolving phenol which is recognized by its odour.

Tests for identity. Solutions of salicylic acid have an acid reaction and on adding 1 drop of ferric chloride solution become blue-violet.

Tests for purity. Dissolve 0.5 gm in 5 ml of concentrated sulfuric acid. The coloration of the solution obtained should not be more intense than that of 5 ml of the Standard Solution No. 5 (test for foreign organic admixtures).

Evaporate 0.5 gm of salicylic acid in a small quantity of 95 per cent alcohol at room temperature in a place protected against dust. The residue should be absolutely white (test for phenol, iron, colouring substances).

A solution of 0.5 gm of salicylic acid in 10 ml of sodium carbonate solution should be transparent (oxydiphenil); on extracting this solution with an equal volume of ether and evaporating the latter, there should not be more than 0.1 per cent residue.

A solution of 1 gm of salicylic acid in 20 ml of alcohol should be colourless (test for foreign organic admixtures).

10 ml of this solution should not contain more chlorides than 10 ml of the Standard Solution, i. e., not more than 0.004 per cent in the preparation.