Pharmacopoeia

Rules for drug prescription

Pharmacological databases

Jan Juřica, PharmD., Ph.D.

Pharmacology, definition, aims

„pharmacon“ + „logos“ / „logia“

Scientific discipline dealing with
INTERACTIONS BETWEEN SUBSTANCES..
introduced into the organism from the environment

..AND THE LIVING ORGANISM
on all levels of complexity:
molecular
cellular
organ
organism as a whole

Pharmacology

- Pharmacodynamics
  - systematic study of the effects of drugs on living systems
- Pharmacokinetics
  - systematic study of the effects of living systems on drugs

Reasons for drug administration (1)

- **therapeutic**
- **diagnostic**
- **preventive**

Therapeutic use:

-**suppression or mitigation of the cause or unpleasant symptom(s) of the disease**

-**substitution of endogenous substance (hormones, vitamins, bile salts, HCl, etc.)**

-**modulation of the organ function**

Therapeutic use of drugs can be: *„empiric“ or „aimed“*

performed on the base of **knowledge of the mechanism of the therapeutic effect** and/or **adverse effects, comparison with the effect of other drugs..**

„Evidence – based therapy“

Reasons for drug administration (2+3)

Diagnostic use:

- **functional tests (dexamethazone, histamin)**
- **substrates (markers, probe drugs)**
  for biochemical examinations or phenotype determination (CYPs)

Prevention / Prophylaxis:

- **vaccination**
- **immunoprofylaxis**
- **prophylaxis of myocardial infarction with ASA**
- **prophylaxis of Str. endocarditis, meningitis with penicillin**

Drug Names

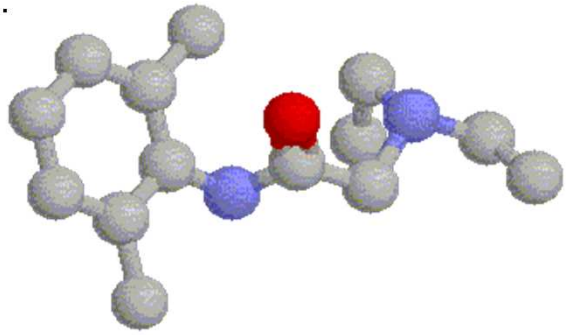
- **Chemical Name**
- **Generic Name**
- **Trade Name**

Chemical Name

- **describes its molecular structure and distinguishes it from other drugs**

- Chemical Name: 2-(diethylamino)-2',6'-acetooxylid monohydrochloride monohydrate.

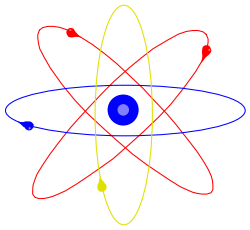
Not Particularly Useful!



Generic name

- **often determined by the pharmaceutical company**

(investigator)



- **Generic Name**: lidocaine hydrochloride
- Officinal Name: Lidocaini Hydrochloridum (Czech Pharmacopoea 2009)
- Brand (Trade) Name: Xylocaine®

Much
More
Useful

Trade Name

- **or brand name - the manufacturer selects alone…can become a registered trademark**
- **Pharma- Comp. is only one who can advertise and market the drug under that name**

International Nonproprietary Name

- INN, also known as rINN, for recommended International Nonproprietary Name
- official non-proprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization (WHO)
- provides a standard name for each substance
  ~ IUPAC names in chemistry
- WHO issues INN names in English, Latin, French, Russian, and Spanish
- Arabic and Chinese versions, although not included in the original scheme, are now also being issued

IUPAC name: N-(4-hydroxyphenyl)-acetamide
INN: Paracetamol
British Approved Name (BAN): Paracetamol
United States Adopted Name (USAN): Acetaminophen

Other generic names:
N-acetyl-p-aminophenol, APAP, p-Acetamidophenol, Acetamol

Proprietary names:
Tylenol®, Panadol®, Panamax®, Perdolan®, Calpol®, Doliprane®, Tachipirina®, Benuron®, Atasol®

Dosage Forms

- **drug substances are seldom administered alone, but rather as a part of a formulation in combination with one or more nonmedical agents that serve varied and specialized pharmaceutical functions**

Doses

- **DTS** – dosis therapeutica singula
- **DTD** – dosis therapeutica pro die
- **DMS** – dosis maxima singula
- **DMD** – dosis maxima pro die

- ED**50**, **LD50, TD50**

Determining Drug Dose

- **Factors**
  - **Body Weight, Surface Area, Sex, Tolerance**
  - **Concomitant Drug Therapy**
  - **Time of Administration**
  - **Dosage Form and Route of Administration**

How many ml of epinephrine solution can be injected to patient for the treatment of anaphylactic reaction?

Aqueous solution : available in dilution 1:1000.

A) calculate the min and max volume if the dose range is 0.1-0.5 mg

B) calculate volume of solution for child weighing 25kg if the dose is 0.01 mg/kg

C) calculate volume of epinephrine solution for the preparation of 500ml of infusion (dil. 1:100 000) by diluting the 1:1000 solution.

How many ml of epinephrine solution can be injected to patient for the treatment of anaphylactic reaction?

Aqueous solution in available in dilution 1:1000.

A) calculate the min and max volume if the dose range is 0.1-0.5 mg

1:1000 = 1 mg in 1000 mg= in 1g = in 1 ml aequous sol.

--dose 0,1-0.5 mg = 0.1-0.5 ml

How many ml of epinephrine solution can be injected to patient for the treatment of anaphylactic reaction?

Aqueous solution in available in dilution 1:1000.

Calculate volume of solution for child weighing 25kg if the dose is 0.01 mg/kg

Dose = 0.25 mg; = 0.25 ml

How many ml of epinephrine solution can be injected to patient for the treatment of anaphylaxictic reaction?

Aqueous solution in available in dilution 1:1000.

Calculate volume of epinephrine solution for the preparation of 500ml of infusion (dil. 1:100 000) by diluting the 1:1000 solution.

= 1:100 000 / 1:1000 = 100.

Dilution 100 x = 5 ml of 1:100 sol. into 495 ml of water or

C*V = w1*V1 + w2*V2

0.00001*500 = 0.001*V1 + 0* (500-V1)

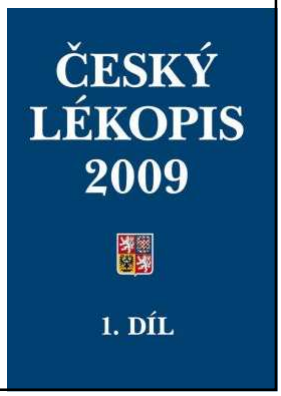
0.005=0.001V1 thus V1=0.005/0.001= 5 ml

➢ **Pharmacopoeia**

➢ *pharmacon* = drug

➢ *poieo* = prepare

Substances in pharmacopoeia- called **officinal** drugs



PharmDr. Jan Juřica, Ph.D.

Definition

- basic reference work for pharmaceutical drug specifications
- published by the authority of a government or a medical or pharmaceutical society

- book containing directions for the identification of samples and the preparation of compound medicines
- assures quality, efficacy, safety, standards

Pharmacopoeias may be:

- National e.g. Brazilian, British, Chinese, Indian, Japanese, Mexican, Spanish, United States
- Regional e.g. European (Ph.Eur.)
  The 7th Edition of the European Pharmacopoeia
- International *The International Pharmacopoeia*

National and regional pharmacopoeias

- Cover medicines used in the relevant country or region
- Are legally binding "official" in the relevant country or region
- Are prepared by a national or regional authority

International Pharmacopoeia

A few dates…

- The history of the *International Pharmacopoeia* dates back 1874…
- → **1948** First ***World Health Assembly*** established Expert Committee on Unification of Pharmacopoeia
- → **1950** WHA approved publication of *Pharmacopoeia Internationalis*

International Pharmacopoeia

→*implementation:* **"ready for use" by Member States**

"The Ph.Int […] is intended to serve as source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements. The pharmacopoeia, or any part of it, shall have legal status, whenever a national or regional authority expressly introduces it into appropriate legislation."

*[**World Health Assembly resolution WHA3.10**, WHO Handbook of Resolutions and Decisions, Vol. 1, 1977, p. 127]*

Scope since 1975

→ **Model Lists of Essential Medicines**

→ **Medicines recommended and specifications needed by WHO Programmes, e.g. to treat Malaria, TB, HIV/AIDS and**

→ **Medicines for children!**

International Pharmacopoeia
A collection of monographs and requirements for:

→ **Drug substances**
→ **Excipients**
→ **Finished dosage forms**
→ **General methods and requirements:**
dosage forms, *e.g. tablets, liquid preparation for oral use*
dissolution testing
→ **Supplementary information,** *e.g. General guidelines for Chemical Reference Substances*

→ **Infrared reference spectra**

Specifications of substances

- **Description, Chemistry, Solubility, Storage, Labelling**
- **Definition,** with information on **polymorphism** if relevant
- **Identification**
- **Assay**
- **Specific tests** (sulphated ash, optical rotation, loss on drying…)
- **Related substances**

Specifications of substances

- **Precise description of analytical methods**
- **Impurities** (chemical names, structures, origin)
- Any relevant information on
  - **Performance testing** (e.g. dissolution)
  - **Stability**
  - **Validation of analytical methods**

International Pharmacopoeia

current: **4th Edition + 1st Supplement**

→ Consolidated in : **2 Volumes**

Vol. 1: *pharmaceutical substances* (A-O)

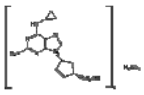
Vol. 2: *pharmaceutical substances (P-X)*

+ dosage forms + radiopharmaceuticals

+ methods of analysis + reagents

1st Supplement - *new requirements and revisions*

ABACAVIR SULFATE



Chemical name in accordance with IUPAC nomenclature rules

$(C_{14}H_{18}N_6O)_2.H_2SO_4$

Relative molecular mass. 670.8

Chemical name. Abacavir sulfate is (1*S*,4*R*)-4-[2-Amino-6(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol hemisulfate; CAS Reg. No. 188062-50-2.

Description. White to almost white powder.

CAS number

Solubility. Freely soluble in water.

Category. Antiretroviral (Nucleoside Reverse Transcriptase Inhibitor).

Storage. Abacavir sulfate should be kept in a well-closed container.

Requirements

Definition. Abacavir sulfate contains not less than 99.0 % and not more than 101.0 % of $(C_{14}H_{18}N_6O)_2.H_2SO_4$, calculated with reference to the anhydrous substance.

Manufacture. The production method is validated to demonstrate that the substance, if tested, would comply with a limit of not more than 0.5% for (1*R*, 4*S*)-abacavir enantiomer using a suitable chiral chromatographic method.

Identity tests

• Either tests A, B, D and E or tests C, D and E may be applied

A. Carry out test A.1 or, where UV detection is not available, test A.2.

A.1 Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica gel IR6 as the coating substance and a mixture of 8 volumes of dichloromethane R and 2 volumes of 2-propanol R as the mobile phase. Apply separately to the plate 5 µl of each of 2 solutions in methanol containing (A) 5 mg of the test substance per ml and (B) 5 mg of abacavir sulfate RS per ml. After removing the plate from the chromatographic chamber, allow it to dry exhaustively in air or in a cu
nm).

International chemical reference substance (ICRS)

intensity to that obtained with solution B.

A.2 Carry out the test as described under 1.14.1 Thin-layer chromatography, using the conditions described above under test A.1 but using silica gel IR5 as the coating substance. Spray with vanillin/sulfuric acid TS1.
120°C. Examine the chromatogram in daylight.

Cross-reference t a general method

The principal spot obtained with solution A corresponds in position and intensity to that obtained with solution B.

B. The absorption spectrum (1.6) of a 15 µg per ml solution, when observed between 210 and 300 nm, exhibits a maximum at about 291nm; the specific absorbance ($A^{1\%}_{1cm}$) is between 399 and 441 nm.

C. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from abacavir sulfate RS or with the *reference spectrum* of abacavir sulfate.

D. Determine the specific optical rotation (1.4) using a 10 mg/ml solution and calculate with reference to the anhydrous substance; $[\alpha]_D^{20°C}$ between −52° and −57°.

E. A 10 mg/ml solution yields reaction A described under 2.1 General identification tests, as characteristic of sulfates.

Heavy metals. Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 1; determine the heavy metal content according to Method A; not more than 20 µg/g.

Sulfated ash (2.3). Not more than 2.0 mg/g.

Water. Determine as described under 2.8 Determination of water by the Karl Fischer method, Method A. Use 1.0 g of the test substance. The water content is not more than 5 mg/g.

Related substances. Carry out the test as described under 1.14.4 High-performance liquid chromatography, using a stainless steel column (15 cm x 4.6 mm), packed with octadecylsilyl silica gel for chromatography (5 µm).

The mobile phases for gradient elution consist of a mixture of Mobile phase A and Mobile phase B, using the following conditions:

Mobile phase A: 0.05 % solution of trifluoroacetic acid R.
Mobile phase B: 85 volumes of methanol R and 15 volumes of water.

Time (min)	Mobile phase A (%v/v)	Mobile phase B (%v/v)	Comments
0 - 20	95 to 70	5 to 30	Linear gradient
20 - 35	70 to 10	30 to 90	Linear gradient
35 - 40	10 to 95	90 to 5	Return to initial composition

Operate with a flow rate of 0.8 ml per minute and the column oven temperature at 30 °C. As a detector use an ultraviolet spectrophotometer set at a wavelength of about 254 nm.

Prepare the following solutions in the dissolution solvent prepared by diluting 1 ml of phosphoric acid (~1440g/l) TS in 1 litre of water.

For solution (1) dissolve 10 mg of the test substance in the dissolution solvent and dilute to 50.0 ml with the same solvent. For solution (2) dilute 5.0 ml of solution (1) to 50.0 ml with the dissolution solvent. Then dilute 5.0 ml of this solution to 50.0 ml with the same solvent. For solution (3) dissolve 5 mg of abacavir sulfate for system suitability RS (containing abacavir sulfate and impurities B to F) in the dissolution solvent and dilute to 25 ml with the same solvent.

Inject separately 20µl each of solutions (1), (2) and (3) and of the dissolution solvent in the chromatographic system. Examine the blank chromatogram for any extraneous peaks and disregard the corresponding peaks observed in the chromatogram obtained with solution (1).

In the chromatogram obtained with solution (3), the impurity peaks are eluted at the following relative retention with reference to abacavir (retention time about 19 minutes): impurity C about 0.6; impurity D about 1.05; impurity E about 1.10; impurity B about 1.3; impurity F about 1.7. The test is not valid unless the resolution between the peaks corresponding to abacavir and impurity D is at least 1.5.

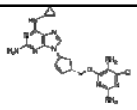
In the chromatogram obtained with solution (1) the area of any individual peak corresponding to impurity C, D, E, B, or F is not greater than 0.3 times the area of the principal peak obtained with solution (2) (0.3%). The area of any other impurity peak is not greater than 0.1 times the area of the principal peak obtained with solution (2) (0.1%). The sum of the areas of all peaks, other than the principal peak, is not greater than the area of the principal peak obtained with solution (2) (1%). Disregard any peak with an area less than 0.05 times the area of the principal peak obtained with solution (2) (0.05%).

Assay. Dissolve about 0.300 g, accurately weighed, in 50 ml of water and titrate with sodium hydroxide (0.1 mol/l) VS, determining the end-point potentiometrically.

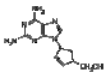
Each ml of sodium hydroxide (0.1 mol/l) is equivalent to 33.54 mg of $(C_{14}H_{18}N_6O)_2.H_2SO_4$.

Impurities

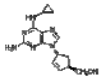
A. (1*R*, 4*S*)-abacavir sulfate enantiomer [see under Manufacture],



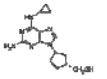
B. N^6-cyclopropyl-9-((1*R*,4*S*)-4-[[(2,5-diamino-6-chloro-4-pyrimidinyl)oxy]methyl]-2-cyclopenten-1-yl)-9*H*-purine-2,6-diamine,



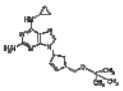
C. [(1*S*,4*R*)-4-(2,6-diamino-9*H*-purin-9-yl)-2-cyclopenten-1-yl]methanol,



D. [(1*R*,4*R*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopenten-1-yl]methanol,



E. [(1*R*,4*S*)-3-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl] cyclopentyl]methanol,



F. N^6-cyclopropyl-9-((1*R*,4*S*)-4- [[(1,1-dimethylethyl)oxy]methyl]-2-cyclopenten-1-yl)-9*H*-purine-2,6-diamine.

ABACAVIRI COMPRESSI
ABACAVIR TABLETS

Category. Antiretroviral (Nucleoside Reverse Transcriptase Inhibitor).

Storage. Abacavir tablets should be kept in a well-closed container.

Labelling. The designation of the container of Abacavir tablets should state that the active ingredient is in the sulfate form and the quantity should be indicated in terms of the equivalent amount of abacavir.

Additional information. Strength in the current WHO Model list of essential medicines: 300 mg of abacavir. Strength in the current WHO Model list of essential medicines for children: 300 mg of abacavir.

Requirements

Cross-reference to the general monograph

Comply with the monograph for "Tablets".

Definition. Abacavir tablets contain Abacavir sulfate. They contain not less than 90.0% and not more than 110.0% of the amount of abacavir ($C_{14}H_{18}N_6O$) stated on the label.

Identity tests

• Either tests A, C and D, or tests B, C and D may be applied.

A. Carry out test A.1 or, where UV detection is not available, test A.2.

A.1 Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica R6 as the coating substance and a mixture of 8 volumes of dichloromethane R, 2 volumes of 2-propanol R as the mobile phase. Apply separately to the plate

5 µl of each of the following 2 solutions in methanol R. For solution (A) shake a quantity of the tablets containing the equivalent of 25 mg of abacavir with 5 ml, filter, and use the clear filtrate. For solution (B) use 6 mg of abacavir sulfate RS per ml. After removing the plate from the chromatographic chamber, allow it to dry exhaustively in air or in a current of cool air. Examine the chromatogram in ultraviolet light (254 nm).

The principal spot obtained with solution A corresponds in position, appearance and intensity to that obtained with solution B.

A.2. Carry out the test as described under 1.14.1 Thin-layer chromatography, using the conditions described above under test A.1 but using silica gel R5 as the coating substance. Spray with vanillin/sulfuric acid TS1. Heat the plate for a few minutes at 120°C. Examine the chromatogram in daylight.

The principal spot obtained with solution A corresponds in position, appearance and intensity to that obtained with solution B.

B. See method A described under Assay. The retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that in the chromatogram obtained with solution (2).

C. To a quantity of powdered tablets containing the equivalent of 15 mg abacavir add 100 ml of water R, shake and filter. Dilute 5 ml of the filtrate to 50 ml with the same solvent. The absorption spectrum (1.6) of the resulting solution, when observed between 220 nm and 320 nm, exhibits a maximum at about 291 nm.

quantity of the powdered tablets containing the equivalent of) mg of abacavir add 5 ml of water R and shake. The resulting yields reaction A described under 2.1 General identification tests as characteristic of sulfates.

Related substances. Carry out the test as described under 1.14.4 High-performance liquid chromatography, using the chromatographic conditions as described under Assay method A.

Prepare the following solutions in the dissolution solvent prepared by diluting 1 ml of phosphoric acid (~ 1440 g/l) TS in 1 litre of water R.

For solution (1) transfer a quantity of the powdered tablets containing the equivalent of 10 mg of abacavir in the dissolution solvent and dilute to 50.0 ml with the same solvent. For solution (2) dilute 5.0 ml of solution (1) to 50.0 ml with the dissolution solvent. Then dilute 5.0 ml of this solution to 50.0 ml with the same solvent. For solution (3) dissolve 5 mg of abacavir sulfate for system suitability RS (containing abacavir sulfate and impurities B to F) in the dissolution solvent and dilute to 25 ml with the same solvent.

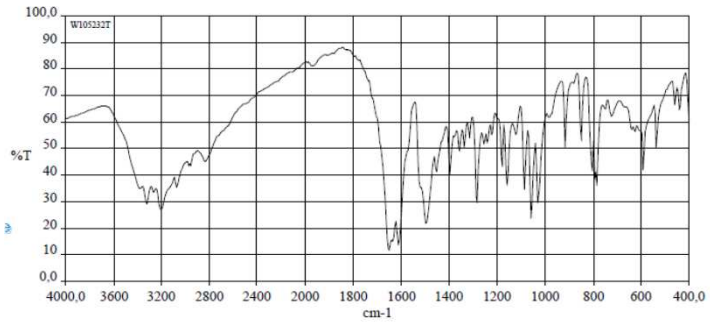
Inject separately 20 µl each of solution (1), (2) and (3) and of dissolution solvent in the chromatographic system. Examine the blank chromatogram for any extraneous peaks and disregard the corresponding peaks observed in the chromatogram obtained with solution (1).

In the chromatogram obtained with solution (3), the impurity peaks are eluted at the following relative retention with reference to abacavir (retention time about 19 minutes): impurity C about 0.7; impurity D about 1.05; impurity E about 1.10; impurity B about 1.3; impurity F about 1.7. The test is not valid unless the resolution between the peaks due to abacavir and impurity D is at least 1.5.

Established by **WHO COLLABORATING CENTRE FOR CHEMICAL REFERENCE SUBSTANCES**

→ **155 International Infrared Reference Spectra**

(125 published in *Ph.Int. 4th Ed. Suppl. 1*)



PHARMACOPOEIA BOHEMICA

- 3 volumes + CD, 2009
- Translation of 7th ed. of Eur. Pharmacopoieia
- Issued by The Czech Ph. Comm. Of Ministry of Health

- **Vol. 1 General methods and requirements**

- **Vol. 2 Monographs A-N**
  - Medicines, excipients
- **Vol. 3**
  - **Monographs N-Z**
    - Medicines, excipients

  National part

- **General methods and requirements**
- **Tables** (I-XII)

  - Medicines, excipients

Drug dosology in paediatrics.

Doses divided into 3 age groups

0-1 1-6 6-15

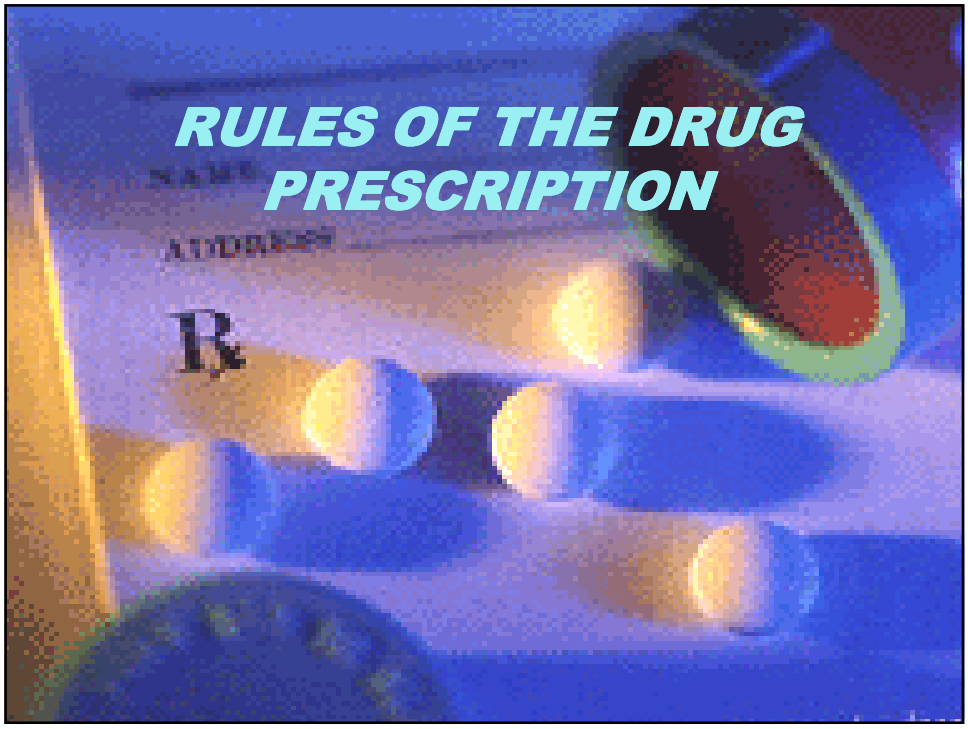
Calculation according to the body surface

$$\text{Dose for children} = \frac{\text{body surface}[m^2]}{1{,}73} \times \text{adult dose}$$

- $$\text{Body surface } [m^2] = \frac{7 * \text{age (yrs)} + 45}{100}$$

PHARMACOPOEIA

- **WHAT we can not find there !**
  - pharmacological properties of drugs, their pharmacodynamics, pharmacokinetics
  - indications, contra-indications
  - toxic effects



PRESCRIPTION

- official document compiled in accordance with fixed rules.
- written in Latin
- must have all parts filled up, must be legible
- corrections should be signed by the physician following the abbreviation corr.(*correxit*-corrected)na
- written in a non-erasible manner
- max. 2 kinds of medicines/Rx

RULES FOR DRUG PRESCRIPTION

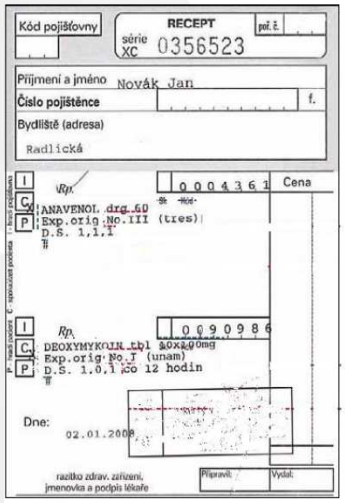
- refers to the valid Pharmaceuticals Act and from the related acts and regulations.

Electronic Prescription

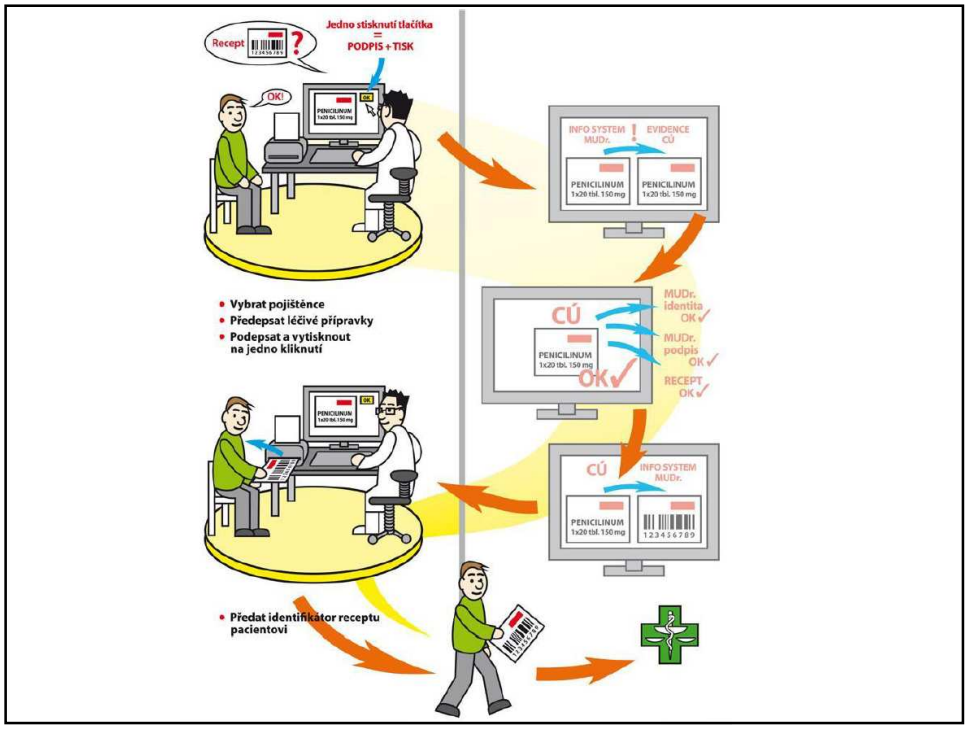
- Physician
- Central server for data storage (SÚKL)
- Pharmacy

- Patient + his password/PIN

Common and E- prescription



www.sukl.cz/erecept



- **Ready-made preparations (RMP)-** final preparations made by pharm. companies, ready to be issued by the pharmacy to patients without any further modifications
- **Individually prepared preparations (IPP) –** prepared in the pharmacies on the base of individual medical prescriptions

Drug preparations

Covered by insuarance company (fully)

Covered by patient + ins. comp. (in part)

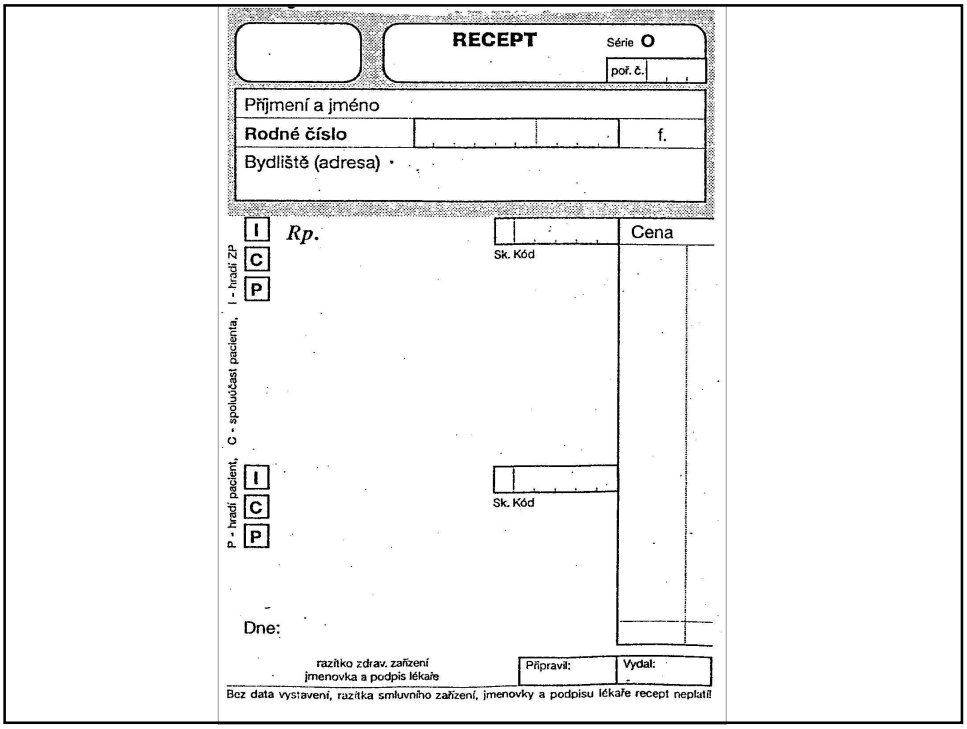
Covred by patient (fully)

→ Expedition is bound upon prescription

→ unbound upon Rx **(OTC)**

- Both in pharmacies and in other places (supermarkets, petrol stations, etc
- only in pharmacies

„earmarked drugs" (since 1998): act 378/ 2007, 106/2008 Sb., „about good pactice of the sellers of earmarked drugs and about the specialized education of sellers of earmarked drugs"



RECEPT Série O poř. č.

Příjmení a jméno

Rodné číslo f.

Bydliště (adresa)

I C P *Rp.* Sk. Kód Cena

P - hradí pacient, C - spoluúčast pacienta, I - hradí ZP

I C P Sk. Kód

Dne:

razítko zdrav. zařízení jmenovka a podpis lékaře

Připravil: Vydal:

Bez data vystavení, razítka smluvního zařízení, jmenovky a podpisu lékaře recept neplatil

Prescription composition

- ***Inscriptio*** the heading of the prescription
- ***Personalia aegroti*** patient s personal data (name, surname, birth number and domicile).
- ***Invocatio*** - induced by the abbreviation *Rp.* (*recipe* take).
- ***Ordinatio*** - the actual prescription of the healing preparation

= compositio + subscriptio + signatura

compositio

- **RMP** – the trade name in the nominative, specification of pharmaceutical dosage form,
  dose and package
- **IPP** – list of pharmacopoeial (officinal) names of substances in the genitive of singular + dosages

subscriptio

- **RMP** – how many packages should be issued
- **IPP** – how the preparation should be made of the prescribed components
- **signatura** – instructions how the preparation should be used by the patients.

- date
- the stamp of the health facility, the identification of the physician, and the physician s personal signature

Validity of Prescription

- **Common Rx – 14 days**
- **ATB – 5 days**
- **ATB topically – 14 days**
- **Narcotics, Psychotropics – 14 days**
- **Rx for repeated issue – 6 moths, max 1 Year**
- **Rx issued by emergency next day after the Rx issue (= max. 48 h)**
- **Date – Rx not valid if missing**
- Validity may be prolonged by physician (pollen vaccines-allergology)

Rx for repeated issue

- **Max. no. of medicines usually for 3 months (= usually max. 3 packages)**
- **If more packages to be issued → „Rx. for repeated issue“**
- **6 months of validity if not specified differently**
- **Max. number of issues has to be specified**

REPETATUR

2x bis

3x ter

4x quater

5x quinquies

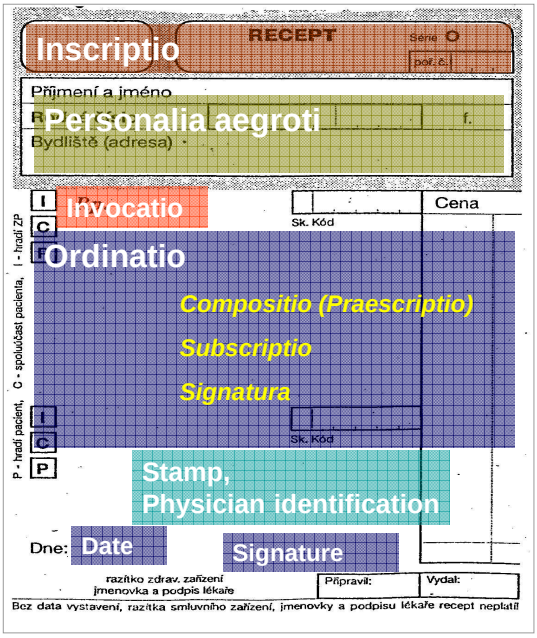
6x sexies

7x septies

8x octies

9x nonies

10x decies



Symbols in Rx formulary

! – when max. dose was exceeded

® - physician specify „not to be substituted with generic medicine“

„PERICULUM IN MORA“ – emergency situation,when normal form is not available

RMP

- introduced into the marked under their trade names
- ready to be issued by the pharmacy to patients without any further modifications
- are manufactured in charges(= amount of product manufactured in one production cycle)
- charge number must be given on the package of the preparation
- longer usable life than IPP (on the outer and inner package –“Exspir./ Exp./ Best before“)

PRAESCRIPTIO

- the trade name in the nominative
- specification of pharmaceutical dosage form, dose and package
- If not specified – the lowes strenght and smallest package is issued

SUBSCRIPTIO

- how many original packages (ampules, tablets)

Expeditionem originalem numero unam –

Exp.orig.No.I (unam)

Amp. Orig. No. I (unam)

Expeditiones originales numero duas –

Exp.orig.No.II (duas)

Tbl. orig. No. XXX (triginta)

SIGNATURA

- necessary data, which inform patient about the proper use of the preparation respecting the optimum dosage scheme

Rp.

BRUFEN 400 por. tbl. flm.
Tbl.100x400mg
Exp.orig.no.II(duas)
D.S. 1-3 tablets/day

IPP

prepared in the pharmacies on the base of individual medical prescriptions (magistraliter)

enables individualization of prescriptions

3-8 % of receipts ➔ (e.g. ophthalmology, dermatology, ORL, dentistry).

Risk of incompatibilities and mistakes in prescription and preparation

IPP

Ordinatio –

= compositio + subscriptio + signatura

- = **compositio**

composition of preparation

= list of pharmacopoeial (officinal) names of substances in the genitive of singular + dosages

e.g. Paracetamoli	0.5
Morphini hydrochloridi trihydrici	0.03

Compositio

- *remedium cardinale-* component showing the major therapeutic effect
- *remedium adiuvans-* supplementary substance improving the effect of the major active component or attenuating its adverse effects,
- *remedium corrigens* - component modifying/ unpleasant taste and/or improving undesirable appearance and/or aroma of the preparation,
- *remedium constituens* or *vehiculum-* pharmaceutical excipient

- Doses – DTS
- Exceeding of D max. !
- Doses always in units of grams
- Use decimals !
- Doses of some drugs spec. in IU, ggts
- Doses of vehiculum „q.s.“

Subscriptio

detailed instructions for the pharmacy how to prepare

fixed Latin abbreviations are being used

Most often:

Misce fiat (sg.) or *Misce fiant* (pl.) = mix to make

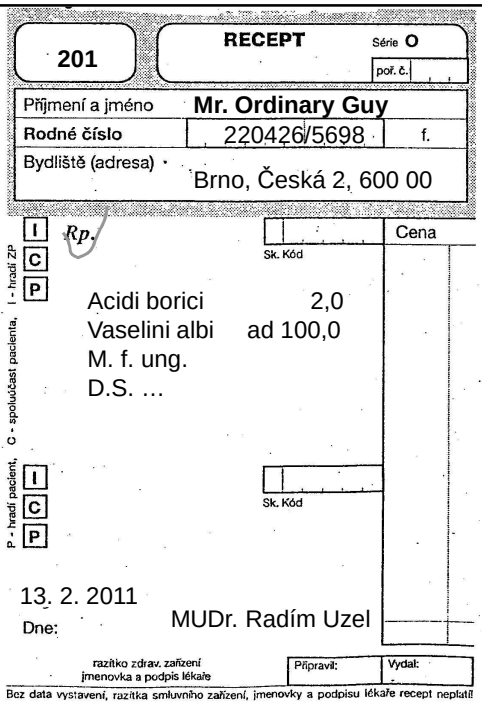
e.g. M. f. sol./ung./oculogutt.

Signatura

detailed instructions for the patient how to use the medicine

or drug is **prescribed for the physician´s use**

Ad usum medici, Pro medico, Pro ordinatione



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RECEPT Série O poř. č.

Příjmení a jméno: Mr. Ordinary Guy

Rodné číslo: 220426/5698 f.

Bydliště (adresa): Brno, Česká 2, 600 00

I C P

Rp.

Sk. Kód

Cena

Acidi borici 2,0
Vaselini albi ad 100,0
M. f. ung.
D.S. ...

P - hradí pacient, O - spoluúčast pacienta, I - hradí ZP

I C P

Sk. Kód

13. 2. 2011

Dne:

MUDr. Radím Uzel

razítko zdrav. zařízení
jmenovka a podpis lékaře

Připravil: Vydal:

Bez data vystavení, razítka smluvního zařízení, jmenovky a podpisu lékaře recept neplatí

Drugs of abuse and psychotropic substances

- §§ - Drugs of abuse group I
  very strong narcotic effect
  e.g. fentanyl, morphine, cocaine, methadone

- § psychotropic substances, group II
  strong psychotropic effect
  e.g. amphetamin, flunitrazepam

Narcotic substances

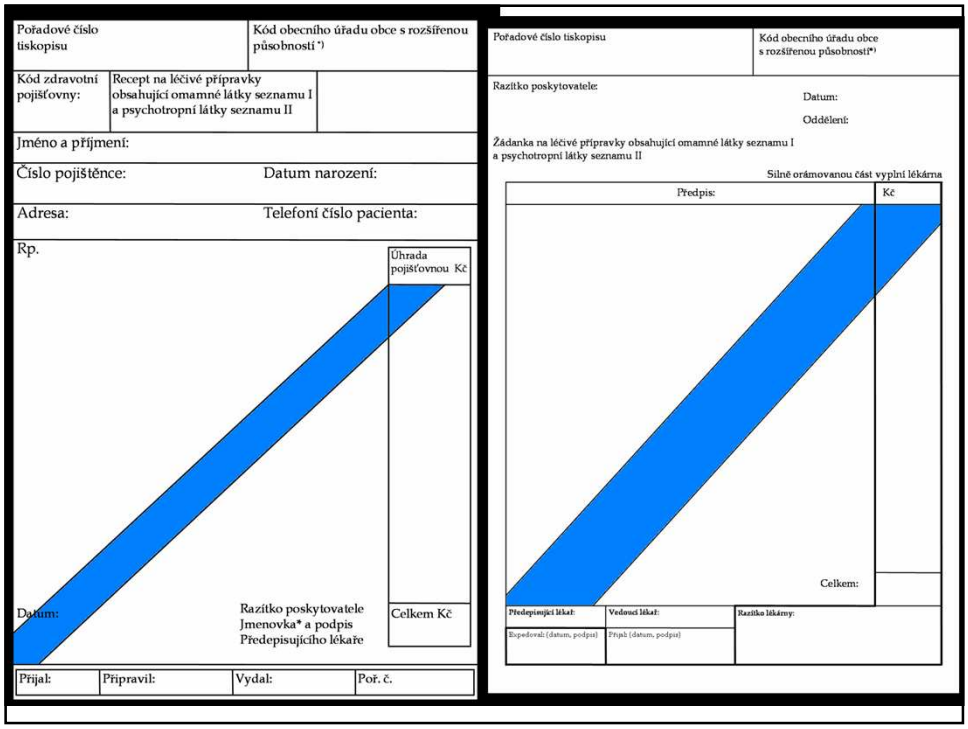
- §§ alfentanyl
- §§ diphenoxylate
- §§ fentanyl
- §§ hydrocodone
- §§ cocaine
- §§ methadone
- §§ morphine
- §§ oxycodon
- §§ oxymorfon
- §§ pethidine
- §§ sufentanyl
- §§ remifentanyl
- §§ tilidin
- §§ opium crudum

Psychotropic substances

- § aphetamin
- § buprenorfin
- § phencyclidin
- § flunitrazepam (Rohypnol)
- § methamphetamin
- § pentazocin
- …

Rules for prescription

- prescribed on prescriptions and/or order forms with an oblique blue stripe
- **very strict accounting**
- **three copies**
- **only one preparation**
- **number of doses in package**
- **14 days of validity**



Examples

Transdermal patches

Rp.

Durogesic 25 μg/h empl.
EMP 5x2,5 mg (10 cm^2)
Exp. orig No. II (duas)
D.S. …

Rp.

Injections

Dolsin inj.
INJ 10x1 ml 5%
Exp. orig No. I (unam)
D.S. …

Rp.

IPP

Morphini hydrochloridi trihydrici	0,03
Lactosi	q.s.

M.f.pulv.
D.t.d. No. XX (viginti) ad caps. gelat.
D.S. …

Drug information databases

Micromedex
EMA

Databases in Czech language:

AISLP
Pharmindex Vademecum
Pharmindex Compendium
Remedia Compendium