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INTRODUCTION TO THE STUDY OF PHARMACOLOGY

Notes for Students

This study material is exclusively for students of general medicine and densistry in Pharmacology I course. It contains only basic notes of discussed topics, which should be completed with more details and actual information during practical courses to make a complete material for test or exam studies. Which means that without your own notes from the lesson this presentation IS NOT SUFFICIENT for proper preparation for neither tests in practicals nor the final exam.

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Literature

Rang, H.P. a kol. Rang and Dale‘s pharmacology 8th ed.(2016)

http://web.b.ebscohost.com/ehost/ebookviewer/ebook/bmxlYmtfXzExNjA0OTNfX0FO0?sid=82e7fdcf-dd4c-43d3-b3a3-7b4b24c21b8e@sessionmgr103&vid=0&format=EB&lpid=lp_1&rid=0

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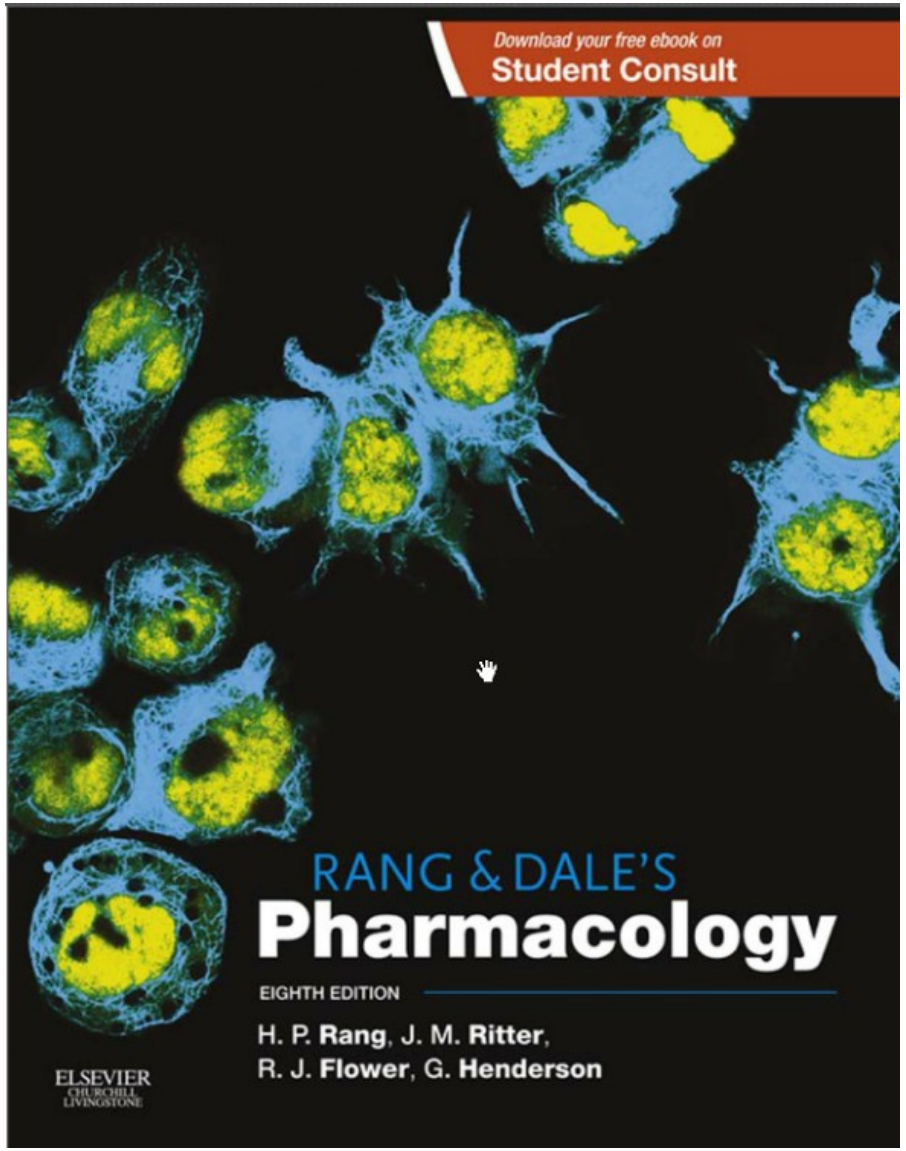
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RANG & DALE'S
Pharmacology
EIGHTH EDITION
H. P. Rang, J. M. Ritter,
R. J. Flower, G. Henderson
ELSEVIER
CHURCHILL
LIVINGSTONE

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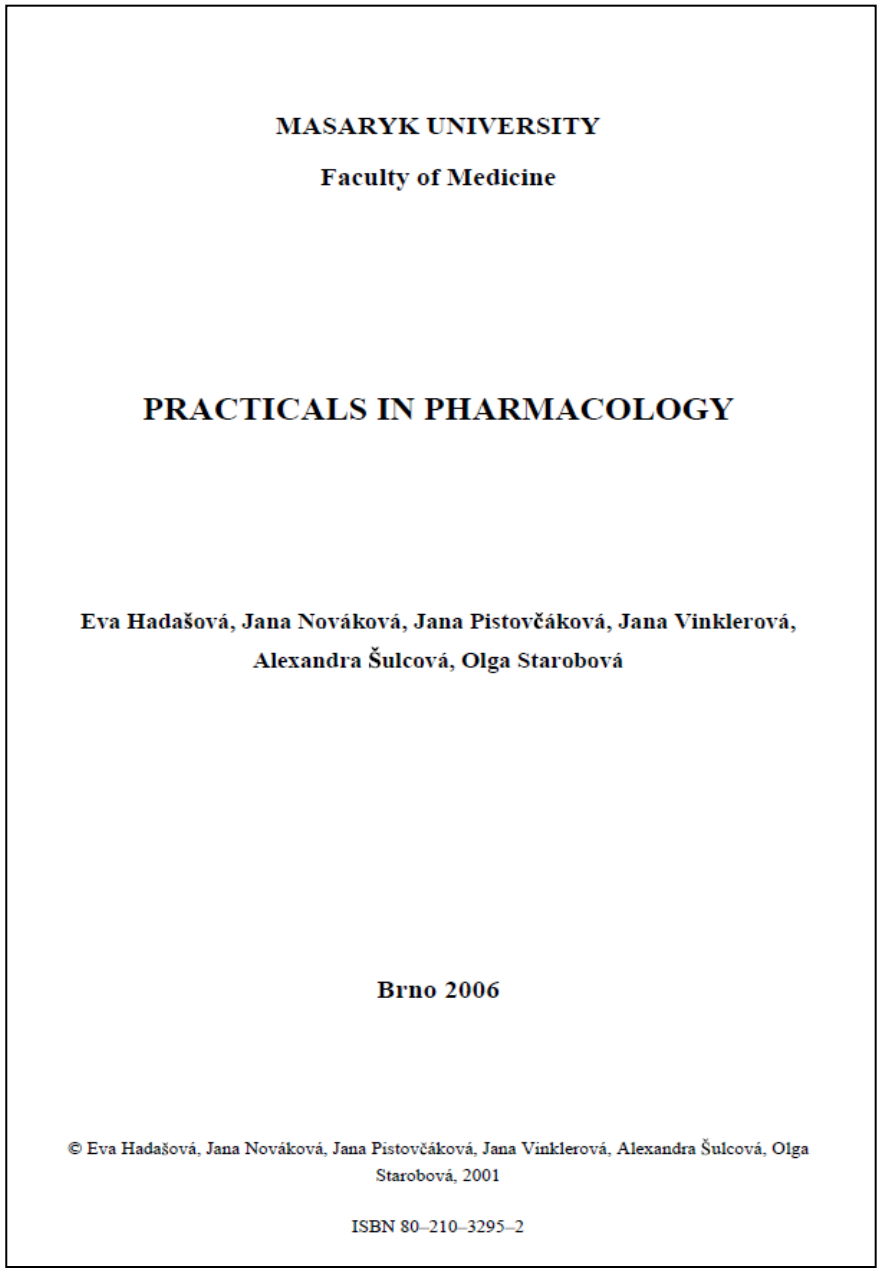
Literature

Practicals in Pharmacology, 2006

Hadasova, Novakova, Pistovcakova,

Vinklerova, Sulcova, Starobova

Pdf available at: IS.muni.cz



MASARYK UNIVERSITY

Faculty of Medicine

PRACTICALS IN PHARMACOLOGY

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„GENERICS“

Drug which is produced and distributed after ending of patent protection - mostly manufactured by other company which has not developed the original drug (the same active substance!)

Mostly cheaper than original preparation

Assumed to be identical in dose, strength, route of administration, safety, efficacy, and intended use

Bioequivalent trials are needed before registration

Registration procedures are much easier than in orig. preparation

Drug patents give 10 years of protection, but they are applied for before clinical trials begin, so the *effective* life of a drug patent tends to be between 7 and 12 years

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„GENERIC PRESCRIPTION“

prescription of the generic name (INN) on Rx formulary
+ dose, number of doses

Pharmacist will chose apropriate ready-mady preparation after consultation with the patient

„ GENERIC SUBSTITUTION“

substitution of the prescribed preparation with another one (generic)

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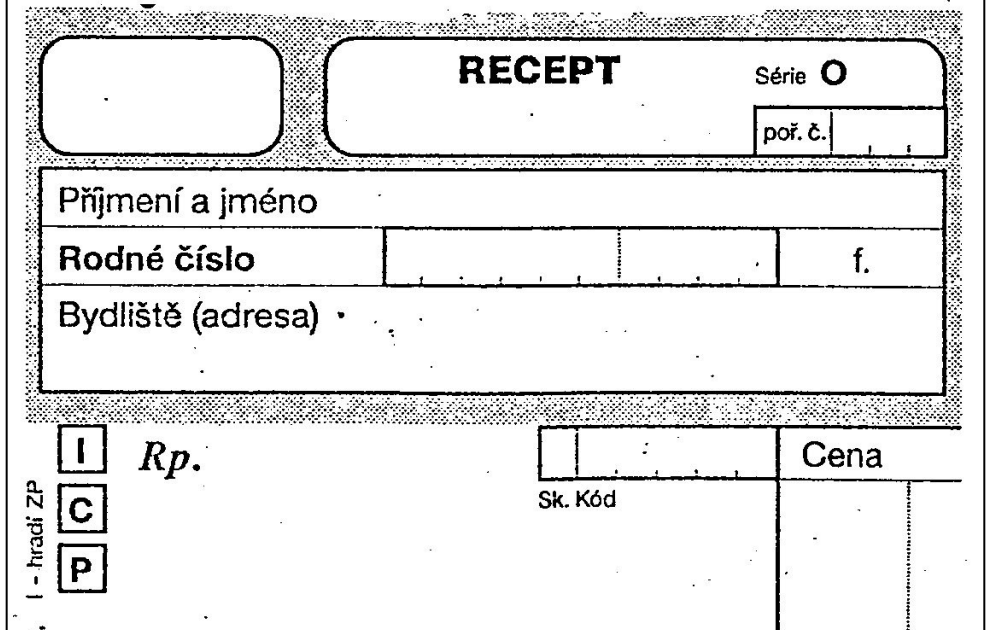
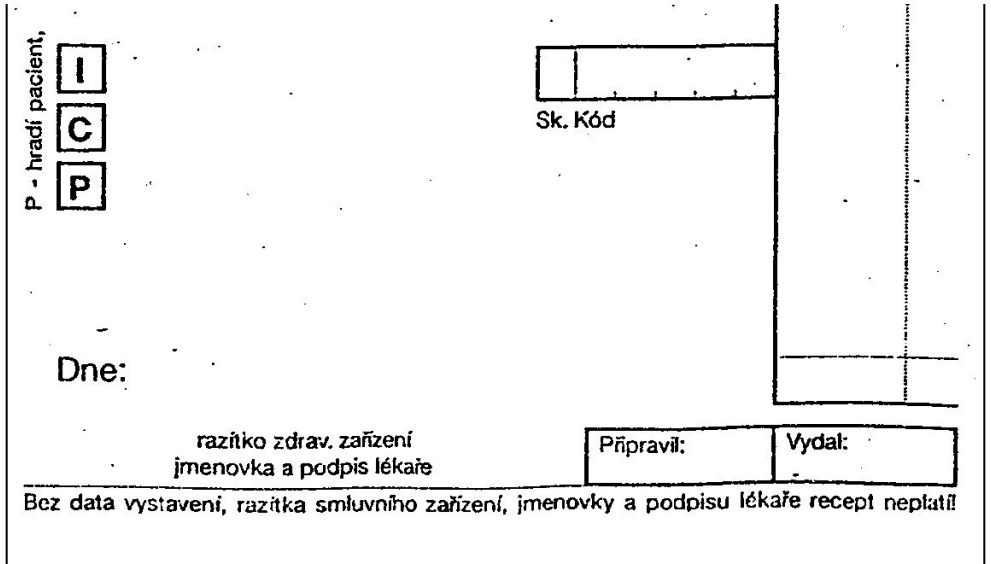


Latin terminology in drug prescription



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Pharmacopoeia

pharmacon = drug
poieo = prepare

Substances in pharmacopoeia- called **officinal** drugs

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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

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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*

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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

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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*

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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]*

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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**

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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

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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

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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*

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PHARMACOPOEIA BOHEMICA

- 3 volumes + CD, 2017
- Translation of 7th ed. of Eur. Pharmacopoeia
- Issued by The Czech Ph. Comm. Of Ministry of Health

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- **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

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PHARMACOPOEIA

WHAT we can not find there !

pharmacological properties of drugs, their pharmacodynamics, pharmacokinetics

indications, contra-indications
toxic effects

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Drug dosology in paediatrics

Doses divided into 3 age groups

0-1 1-6 6-15

<u>Calculation according to the body surface</u>

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

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

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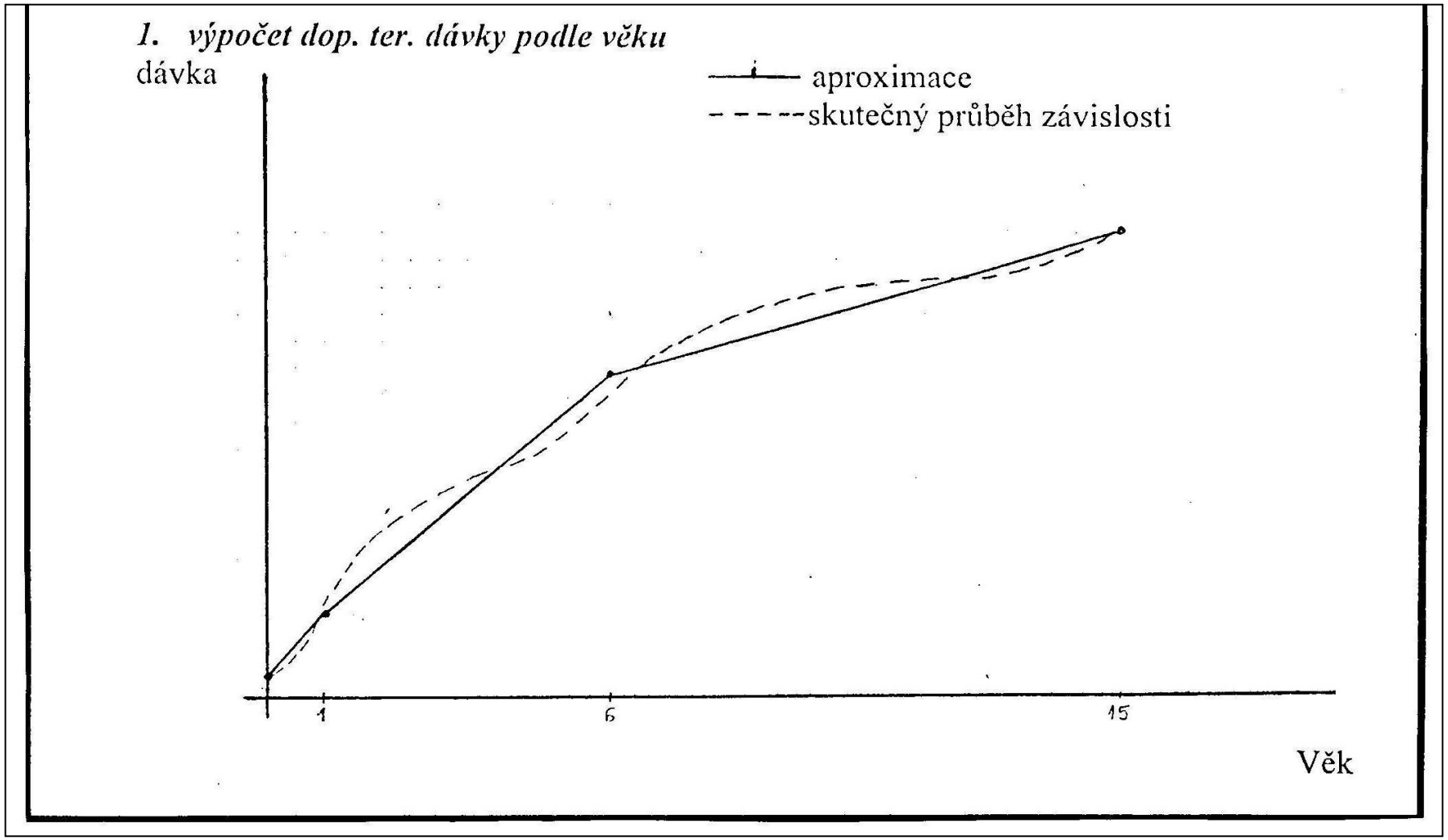
1. výpočet dop. ter. dávky podle věku
dávka
aproximace
skutečný průběh závislosti
1
6
15
Věk

Doses for children

Interpolation

$$d = d_1 + \frac{d_2 - d_1}{n} . n_d$$

d…..recommended dose for the given age

d_1….recommended dose for lower limit of the age interval

d_2 … recommended dose for upper limit of the age interval

n…..number of year intervals within the range of age

n_d….number of year intervals from the beginning of range of age to the age of the given child

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Calculate the DTS of a substance X for 10 years old child,
if the dose interval from 6 to 15 years of age is 0,7-1,5 g.

$$d = d1 + \frac{d2 - d1}{n}. nd$$

d1 = 0,7

d2 = 1,5

n = 9

nd = 4

$$d = 0,7 + \frac{1,5 - 0,7}{9}. 4 = 0,7 + 0,088*4 = \underline{1,05\ g}$$

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