Czech Pharmacopeia 2009 (ČL 2009)
PHARMACOPOEIA BOHEMICA MMIX (Ph. B. MMIX)

Pharmacopoeia is obligatory for all organizations and expert workers involved in preparation, manufacturing, control, evaluation, keeping, prescription and expedition of drugs and medical necessaries, listed in pharmacopeia.

These expert workers, which are pharmacists, doctors of human medicine, veterinary medicines, chemists and biologists, workers on the field of quality control, laboratory and pharmaceutical technicians, are required (if stated in law) to know the pharmacopeia content and to follow it.

The aim of ČL 2009 is a support of public health, thus it is made establish socially respected normative, which will be used by medical experts and other workers participating on drugs quality control. Such as normative should display suitable quality to be a base of safe usage of drugs by diseased people or other users. Existence of the normative allows:

- Facilitation of free movement of medicinal preparations through Europe
- Guarantee of drug quality exported/imported from/to Europe.

Law n. 129/2003 Sb., novella about drugs and about changes of some corresponding laws.

Czech Pharmacopeia 2009 (ČL 2009)
PHARMACOPOEIA BOHEMICA MMIX (Ph. B. MMIX)

ČL 2009 follows on previous edition of ČL 2002 – 5-volumed writhing with 3 appendices (Append. 2003, Append. 2004 and Append. 2005, published in bulletin of Ministry of Health only) and 3-volumed writhing ČL 2005.

Major part is constituted as translation of essays and articles of European Pharmacopeia, minor part contains so called national specifities, which were previously (ČL 2002 and appendices) concentrated in special part.

ČL 2005 and ČL 2009 contain in European part translations of new, revised or corrected articles and essays of 5th edition of European Pharmacopeia (Ph. Eur. 5) and its 1st and 2nd appendices.

Articles and essays, which did not show changes in Ph. Eur. 5 are listed with reference to ČL 2002 or its appendices.

Czech Pharmacopeia 2009

ČL 2009 contains:

1. European part (translation of Eur. Ph. 4 and Ph. Eur. Suppl. 4.1 and Ph. Eur. Suppl. 4.2); total number of general essays and articles in Eur. part of ČL 2009 is 1911.

2. National part (essays and articles not listed in Ph. Eur., needed as national specifics); total number of general essays and articles in Nat. part of ČL 2009 is 156. These are essays and articles revised and transferred from ČL 1997

- ČL 2009 posses 5 volumes + CD-ROM

Czech Pharmacopeia 2009

1st part of ČL 2009

I Foreword

II Introduction

III Composition of European Pharmacopeia Commission, list of experts and composition of secretary apparatus to 31. 12. 2007

IV Texts
- New texts
- Revised texts and fast revisions
- Corrected and converted texts
- Deleted texts

Czech Pharmacopeia 2009 1st part

GENERAL ESSAYS AND GENERAL ARTICLES

1. General Principles

- General regulations
  („certified authority" – national, supranational or international authority or organization, which has the power to resolve relevant problems. In Czech Republic: State Institute for Drug Control, Ministry of Health, Institute for State Control of Veterinary bio-preparations and Drugs, Ministry of Agriculture, Ministry of Defense)
- Further regulations touching general essays and articles
  (weights and volumes; apparatus and procedures; water bath; drying, annealing; concentration)
- General essays (envelopes and packing material)
- Pharmacopeia articles (monographs)
  (Latin name, Czech name; definition; characteristics; proofs of identity, proofs of purity and content determination; storage; marking; warnings; impurities; referential compounds)
- Marks and symbols
- International System of Units (SI) used in Pharmacopeia and their relation to other units

Czech Pharmacopeia 2009 1st part

2. EXPERIMENTAL METHODS

2.1. Apparatus and other requisites for testing
2.2. Physical and physico-chemical methods
2.3. Proofs of identity (quality)
2.4. Limit assays
2.5. Content determination (quantity)
2.6. Biologic assays
2.7. Methods of effectiveness determination
2.8. Pharmacognostic methods
2.9. Methods of pharmaceutical technology

Czech Pharmacopeia 2009 1st part

General Articles
Anticorpora monoclonalia ad usum humanum; Corpora ad usum pharmaceuticum (Etherolea, Extracta, Olea plantarum pinguia, Plantae medicinales, Plantae medicinales ad potionem aquosam, Plantarum medicinalium praeparata,…)

General articles of drug forms
(Auricularia, Capsulae, Emplastra transcutanea, Inhalanda, Liquida, Sirupi, Ocularia, Gargarismata, Parenteralia, Injectiones, Implantata, Unguenta, Tabulettae, ...)

Czech Pharmacopoeia 2009 1st part

2. Experimental methods

- Melting point
- Spectrophotometry, NMR, CD, mass spectrometry
- Chromatography: paper (ascendant, descendent), thin layer, gas, liquid, size exclusion, electrophoresis)
- Loss of weight with drying
- Proofs of identity (quality)
- Limit assays
- Content determination (quantification) (number of acidity, ester, hydroxyl, iodine, peroxide, saponification)
- Biological assays (Test of sterility …)
- Methods for effectiveness determination
- Pharmacognostic methods
- Methods of pharmaceutical technology

Czech Pharmacopoeia 2009 1st part
Pharmacognostic methods

- Ashes insoluble in hydrochloric acid
- Strange admixtures
- Stomata and stomatal index
- Number of swelling
- Pesticide residues
- Quantification of tannins in plant drugs
- Number of bitterness (quinine HCl; group of 6 persons)
- Residue after drying of extracts
- Loss of weight by drying
- Quantification of aflatoxine B_1 in plant drugs
- Plant drugs: sampling and sample preparation

Czech Pharmacopoeia 2009 1st part
Pharmacognostic methods

- Water in essential oils
- Strange esters in essential oils
- Fatty oils and resinous essential oils in essential oils
- Odour and taste of essential oils
- Residue after essential oils evaporation
- Solubility of essential oils in ethanol
- Quantification of cineol in essential oils
- Quantification of essential oils in plant drugs

Czech Pharmacopoeia 2009

2nd and 3rd part contain articles (monographs)

Design of monograph with FGN content

1. Latin name of drug, Czech name of drug
2. Description
3. Characteristics
4. Proofs of identity
   a) macro- and microskopic description
   b) Chromatography
5. Proofs of purity
   a) Strange admixtures
   b) Loss of weight by drying
   c) Total ash, Ash insoluble in hydrochloric acid
6. Quantification
7. Storage

Czech Pharmacopoeia 2009

5th part (National)

General essays and tables

- Narcotics and psychotropic compounds
- Separanda
- Venena
- Recommended therapeutical doses for adults
- Recommended therapeutical doses for children
- Recommended doses of chosen officinal drugs used at animals
- Dependence of relative density on ethanol content
- Isotonization of aqueous solutions of drugs prepared in pharmacies
- Latin, English and Czech names of general essays and monographs ČL 2002
- Standard names of drug forms, ways of dosage and packages
- Relative atom mass of elements

Special part

Medicinal compounds and additives
Medicinal preparations