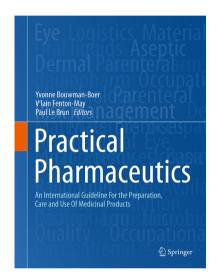
# **Practical Pharmaceutics**

An international guideline for the preparation care and use of medicinal products. *Additional information on purpose and contents* 



#### Reason

The importance of maintaining the pharmaceutical science in the practice of pharmacy is paramount for the sake of the patient and the profession. In some Countries pharmaceutics in practice is being side-lined due to the surge in the popularity of Clinical pharmacy. However, we believe that a fundamental understanding of the design and manufacturing is an unique added value for a professional in daily clinical

practice. This is a book in which the science that lies behind the preparation and manufacture of medicines is in one place.

#### **Back cover text**

This book contains essential knowledge on the preparation, control, logistics, dispensing, and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will

help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients, and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary, and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured.

The basic and practical knowledge on the design, preparation and quality management of medicines can be directly applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate students as well as pharmacy graduates will find knowledge and backgrounds in a fully coherent way and fully supported with examples.

#### **Unique Selling Points**

- Features many modern and relevant formulations and cases that will help readers better understand theory and practice.
- Includes natural links between industrial production and preparation in pharmacies.
- Provides unique knowledge of medicinal products, which is necessary to support the right use by patients.

### **Development of Practical Pharmaceutics**

For several years pharmacists in many European countries have felt the need for knowledge, information and guidelines on the practice of preparation in the pharmacy. This was clearly put forward by experts from many European countries at the EDQM symposium on European Co-operation & Synergy and at the BEAM compounding course in 2010. During this course it was agreed that the knowled ge for the preparative pharmacist were contained in the Dutch book 'Recepteerkunde' and that this book could be used as a base for a European wide textbook on preparation in pharmacies.

The first principal was that "Recepteerkunde" would form the basis of the book. Secondly the principal was retained of using experienced practising pharmacists from hospital and academia as authors to the Chapters. In order to ensure that the book reflected the practice from across Europe, experts in the specific fields were chosen from all quarters of Europe. An editorial advisory group with pharmacists from all over Europe has dutifully answered many questions about the actual situation in their Countries.

The editors have tried to involve as many different nationalities, as authors or advisory group members, as was feasible. In the end out of 58 authors there are still 28 Dutch authors most of whom were involved in the original text.

The project has been financed by EAHP and both the Dutch pharmacists associations KNMP and NVZA. They invested in the book and will receive the royalties generated by the book.

## Hard copy and eBook

The question "Book or Web based structure" has been considered since the start of the project. For a start the advantages of a book, which requires a logical and quickly referenced relationship between many chapters, tables and figures, seem to outweigh those of a Wiki-like approach. Springer International makes Practical Pharmaceutics available in all feasible formats, be it as an eBook, a hardcover printed copy, a Kindle edition or a low priced printed MyCopy for eBook licensees.

However the question of whether a knowledge base type or paper publication is preferred remains to be answered.

#### **Extensions**

Another question that is asked is whether to attach to the main information: working procedures, formulations, preparation sheets and other documents. A vision on this aspect is still to be developed. An indication for the usefulness of extensions will be concluded from the comments of the readers.

# PATIENTS' NEEDS

- Prescription assessment.
- Availability of medicines

# **DISPENSING**

- Logistics
- · Instructions for the use of medicines
- · Impact on environment

### **PRODUCTION**

- Raw materials
- Containers
- Human resources
- · Occupational safety and health
- Premises
- Equipment
- Basic operations
- · Sterilisation methods
- · Aseptic handling
- Quality requirements and analysis

### In control

- Documentation
- Production, Validation and Quality Control
- · Quality systems

## PRODUCT DESIGN

- Oral solids
- Oral liquids
- Pulmonary
- Oropharynx
- Nose
- Ear
- Eye
- Rectal and vaginal
- Dermal
- Parenteral
- Irrigation and dialysis
- Radiopharmaceutics

#### Basics

- Biopharmaceutics
- Product design
- Physical chemistry
- Microbiology
- Statistics
- · Quality risk management
- Stability

#### **Editors' experiences**

### European standards

As European pharmacists we may be very happy with the European Pharmacopoeia. It standardises the active substances and excipients: their quality as well as their names and even covers preparation in the pharmacy now in a separate monograph. Routes of administration and packaging have been standardised as well, by EDQM. Practical Pharmaceutics may contribute to the standardisation of other terms used in preparation of medicines, as is explained in Chapter 1. Introduction.

EDQM has also issued valuable documents that elaborate on other pharmaceutical topics, such as analytical validation. The editors' impression is however that the familiarity of pharmacists with the European standards could be much improved. Many pharmacists seem to be more acquainted with the USP than the European standards, not because of any perceived superiority but due to the preponderance and easy availability of literature from that area.

### European practices

From a first impression, from only a part of all European countries, it may be concluded that the practice of pharmacy preparation differs quite a lot throughout Europe. Differences seem to be smallest at stock preparation in hospital pharmacies. Differences are mainly nationally determined: influenced by the Inspectorate, legislation, preference for specific dosage route e.g. rectal, reactions to local disasters and generally by the level of wealth and quality investigations having been performed.

Friction between pharmacy preparation and manufacturing It is easily assumed by many pharmacists, even contributors to the book, that practices and quality of production of medicines by pharmacy preparation as compared to that from industry are incomparable and unbridgeable. This book may prove their basic similarity. It brings together preparation in pharmacies and industrial production in principally the same system. It shows the similarities of the different scales of preparation as well as the specific qualities when applicable.

#### *Practical problems*

The need for pharmacy preparation is generally accepted, not only because medicines shortages are overwhelming in the market at the moment, but also because a series of medicines will not become available due to small patient groups. For pharmacy preparation as such, knowledge could be improved (this book may help) but also the availability of very practical provisions such as raw materials and appropriate containers. It was striking that adapting licensed tablets seems to provide the only source of active substances for pharmacy prepared capsules in many countries. An analogous case refers to the handling of medicines by care personnel if the product doesn't fit the demands of the patient.

The need for validated formulations for pharmacy preparations is quite obvious. This book uses formulations as illustrations of principles described in the chapters. They may however give insufficient directions for the actual preparation. The translation of the principal European formularies – the German DAC/NRF and the Dutch FNA – would definitely meet needs.

Chapters	Authors
Preface	V'Iain Fenton-May, Yvonne Bouwman, Paul Le Brun
1. Introduction	Yvonne Bouwman, V'Iain Fenton-May
2. Prescription assessment	Andrew Lowey (UK), Stefanie Melhorn (DE)
3.Availability of medicines	Helena Jenzer (CH), V'lain Fenton-May (UK)
4.Oral solids	Minna Helin-Tanninen (FI), João Pinto (PT)
5.Oral liquids	Antje Lein (DE), Shiwai Ng (NL)
6.Pulmonary	Anne de Boer (NL), Ernst Eber (AT)
7.Oropharynx	Suzy Dreijer (NL)
8.Nose	Suzy Dreijer (NL, Anita Hafner (HR)
9.Ear	Suzy Dreijer (NL), Monya Gantumur (HR)
10.Eye	Annick Ludwig (BE), Holger Reimann (DE)
11.Rectal and vaginal	Stineke Haas (NL), Herman Woerdenbag (NL), Małgorzata Sznitowska (PL)
12.Dermal	Antje Lein (DE), Christien Oussoren (NL)
13.Parenteral	Marija Tubic (DE), Irene Krämer (DE)
14.Irrigation and dialysis	Daan Touw (NL), Olga Mucicova (CZ)
15.Radiopharmaceutics	Rogier Lange (NL), Marco Prins (NL), Adrie de Jong (NL)
16.Biopharmaceutics	Erik Frijlink (NL), Daan Touw (NL), Herman Woerdenbag (NL)
17.Product design	Herman Vromans (NL), Giovanni Pauletti (US)
18.Physical chemistry	Wouter Hinrichs (NL), Suzy Dreijer (NL)
19.Microbiology	Hans van Doorne (NL), Alexandra Staerk, David Roesti (CH)

20. Statistics	Herman J Wijnne (NL), Hans van Rooij (NL)
21.Quality risk management	Yvonne Bouwman (NL), Lilli Møller Andersen (DK)
22.Stability	DaanTouw (NL), Jean Vigneron (FR)
23.Raw materials	Roel Bouwman (NL), Richard Bateman (UK)
24.Containers	Jan Dillingh (NL), Julian Smith (UK)
25.Human resources	Jan de Smidt (NL), Hans van Rooij (NL)
26.Occupational safety and health	Yvonne Bouwman (NL), Shiwai Ng (NL), Sylvie Crauste-Manciet (FR)
27.Premises	Willem Boeke (NL), Paul Le Brun (NL)
28.Equipment	Marco Prins (NL), Willem Boeke (NL)
29.Basic operations	Herman Woerdenbag (NL), Małgorzata Snitowska (PL), Yvonne Bouwman (NL)
30.Sterilisation methods	Marco Prins (NL), Mattias Paulsson (SE)
31.Aseptic handling	Frits Boom (NL), Alison Beaney (UK)
32.Quality requirements and Analysis	Oscar Smeets (NL), Mark Santillo (UK), Hans van Rooij (NL)
33.Documentation	Rik Wagenaar (NL), Mark Santillo (UK)
34.Production, Quality Control and Validation	Rogier Lange (NL) Lilli Møller Andersen (DK)
35.Quality systems	Yvonne Bouwman (NL), Lilli Møller Andersen (DK)
36.Logistics	V'Iain Fenton May (UK), Hana Snajdrova (CZ)
37.Instructions for the use of medicines	Suzy Dreijer (NL), Anthony Sinclair (UK)
38.Impact on Environment	Bengt Mattson (SE), Tessa Brandsema (NL)
39.Information sources	Doerine Postma (NL), Sin Ying Chuah (NL)







