Introduction to Pharmacy Practice: Dispensing and Compounding

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2 May 2012
Overview

- Dispensing and compounding overview
- Examples of preparations
- What is compounding?
- Skills for compounding
- Reference sources
- Formulae/Pharmaceutical calculations
- Documentation/Storage and Expiry Dates
- Containers and labelling
- Techniques of compounding
Goals for Compounding

- By the end of this course (PHARMACY 101) you will have the basic knowledge and skills to commence compounding.

- By the end of the PHARMACY 201 course you will be competent in compounding so that you will be able to accurately compound any non-sterile pharmaceutical product e.g. cream, ointment, mixture, lotion, suppository (Aseptic compounding e.g. eye-drops, injections will be covered in Year 4).
Douglas Pharmaceuticals

- A kiwi success story: biggest pharmaceutical manufacturing company in NZ
- Founder Sir Graeme Douglas started as a community pharmacist in Auckland
- In the 60s/70s he imported or compounded pharmaceutical products not available in NZ in his pharmacy (using the techniques you are about to learn)
- Such demand he started a small manufacturing business in the 70s; moved to current site in Henderson in 1990
- Douglas now exports pharmaceuticals all over the world
- You will visit Douglas at Part III
Types of Preparations

- There are many different types of pharmaceutical products you will be able to compound
- Only a few common examples are given here
- You will get to cover them all in due course
- We are only dealing with non-sterile products now
Preparations for Oral Use

- **Capsules, Powders, Granules**
  Solid dosage forms for oral use e.g. *Digoxin Capsules* for atrial fibrillation in children

- **Solutions, Suspensions, Emulsions, Mixtures, Linctuses, Elixirs, Oral Drops**
  Liquid dosage forms for oral use: different viscosities, different solvents etc. e.g. *Chloral Elixir Paediatric* (sedative), *Liquid Paraffin Emulsion* (lubricant laxative); *Spironolactone Suspension* (diuretic)
Preparations for **External Use**

- **Applications, Colloidons, Liniments, Lotions, Paints**
  Liquid preparations for topical application, base may be aqueous, oily or alcoholic e.g. *Calamine Lotion BP* (for skin irritation); *Turpentine Liniment BP* (for muscle strain)

- **Creams, Ointments, Pastes, Gels**
  Semi-solids for topical application e.g. *Zinc and Coal Tar Ointment APF* (antipruritic for itching); *Aqueous Cream BP* (emollient cream); *Dithranol Paste BP* (for psoriasis)
Miscellaneous Preparations

- **Ear Drops, Nasal Drops**
  e.g. Ephedrine Nasal Drops (nasal decongestant)

- **Inhalations, Mouthwashes, Gargles**
  e.g. Phenol Gargle BP (antiseptic mouthwash); Menthol and Eucalyptus Inhalation BP (nasal decongestant)

- **Suppositories, Enemas, Pessaries**
  Suppositories (solid) and enemas (liquid) for rectal administration; pessaries for vaginal administration.
  e.g. Paracetamol Suppositories (analgesia)
What is Dispensing?

- **Competence Standard 6 (Dispense Medicines)** covers the supply of Prescription Medicines and Pharmacist Only Medicines, *including* extemporaneously compounded products.

- **Standard 6** covers all actions and responsibilities of the pharmacist from receipt and checking of a prescription or patient request, dispensing and labelling the product, through to counselling the patient about the use of the medicine.

- In Years 3 and 4 main emphasis is on dispensing of *pre-formulated products*.
Good Dispensing Practice

- Check prescription is legal, complete, clinically appropriate etc.
- Follow-up any queries with prescriber, check patient records
- Assess safety and appropriateness of the medicine for that patient
- Safe and disciplined dispensing process, including checking procedures (products could be *pre-formulated* or *compounded*)
- Maintain legal dispensing records
- Counsel patient appropriately
What is Compounding?

- Competence Standard 7 (Prepare Pharmaceutical Products - Non Sterile) covers the preparation of pharmaceutical products in hospital and community pharmacies.

- The pharmacist prepares small quantities of *extemporaneously compounded* products such as creams, suspensions and suppositories (i.e. small scale manufacture of medicines from bulk ingredients).

- Standard 7 can be viewed as a more specialised aspect of Standard 6.
Why do we need Compounding?

- Traditionally a major component of pharmacy practice
- From 1950s onwards a shift towards **pre-manufactured products** from industry (e.g. tablets, capsules, inhalers, creams etc.)
- 1980s and 1990s introduction of **Code of Good Manufacturing Practice (GMP) to pharmacy**: stringent standards for compounding
- Further decline in compounding especially in community pharmacy
- However, resurgence in recent years – why?
Some Reasons for Compounding

- Unavailability of dosage forms for selected patient groups e.g. children or elderly (a particular issue in NZ with PHARMAC restrictions)
- Products may not be licensed in NZ
- Many hospitalised patients are ‘nil by mouth’
- Some patients unable to take standard dose forms e.g. if vomiting, difficulty swallowing, short gut (following surgery)
- Palliative care patients – may need to administer medicines in unconventional ways
Some Reasons for Compounding cont.

- Intravenous nutrition patients (unable to take food by mouth)
- Patient may be allergic to some ingredients in commercial products e.g. arachis (peanut) oil or colouring agents
- Specialist veterinary products
- Marketing?: Many patients like the thought of something made individually for them or a ‘boutique’ brand of a medicine
- Emergence in recent years of specialist compounding pharmacies
Compounding cont.

- Items usually (but not always) individually prescribed for a patient on a prescription from a medical practitioner
- Usually manufactured according to an **official** (e.g. BP, APF, BNF) or a **local** formula (e.g. Auckland Hospital Formulary)
- Strict protocols employed (equipment, documentation, personnel etc.)
- Intended to be used **within a specific period**
Skills for Compounding

- Reading and interpreting prescriptions
- Using pharmaceutical reference sources
- Finding formulae and performing pharmaceutical calculations
- Following documentation procedures
- Following Standard Operating Procedures (SOP’s)
- Using generic skills - weighing, measuring etc.
- Using specific compounding skills - mixing, diluting etc.
Skills for Compounding cont.

- Checking doses
- Selection of containers
- Labelling - standard and additional information
- Storage and expiry
- Medication counselling
- General awareness of accuracy, organisation, hygiene, cleanliness, professionalism
Your First Prescription

Dr A Jolly  
Grafton Medical Centre  
Auckland Ph 09 123 4567  
2 May 2012

for Mr Brad Pits  
20 Grafton Gully, Auckland

Rx  
Potassium Citrate Mixture BP  
mitte: 200 mL  sig: 10 mL ex aq tds

A.Jolly
Common Reference Sources (for formulae)

- British Pharmacopoeia (BP)
- British Pharmaceutical Codex (BPC) or Pharmaceutical Codex (PC)
- British National Formulary (BNF)
- Martindale’s Extra Pharmacopoeia
- Australian Pharmaceutical Formulary (APF)
- United States Pharmacopoeia (USP)
Potassium citrate mixture is a ‘urinary alkaliniser’ used to relieve stinging discomfort of cystitis and mild urinary tract infection.

*in NZ, a different preservative may be used
## Potassium Citrate Mixture BP

<table>
<thead>
<tr>
<th>BP Formula</th>
<th>For 200 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium citrate</td>
<td>3 g</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>0.5 g</td>
</tr>
<tr>
<td>Lemon spirit</td>
<td>0.05 mL</td>
</tr>
<tr>
<td>Quillaia tincture</td>
<td>0.1 mL</td>
</tr>
<tr>
<td>Syrup</td>
<td>2.5 mL</td>
</tr>
<tr>
<td>Chloroform water (double strength)*</td>
<td>3 mL</td>
</tr>
<tr>
<td>Purified water</td>
<td>to 10 mL</td>
</tr>
</tbody>
</table>

*in NZ, a different preservative may be used
Pharmaceutical Calculations

- Basic Information:

  1 kg = 1000 g
  1 g = 1000 mg
  1 mg = 1000 micrograms
  1 litre = 1000 mL
Expressions of strength in pharmaceutical products

- Ratio of 1:10 = 1 part in 10 parts

  e.g. 1 g in 10 g; or 1 g in 10 mL; or 1 mL in 10 mL; or 1 mL in 10 g

- For example, if 1 g of sodium chloride is in 10 mL of solution this can be expressed as a percentage strength: 10% w/v
% Concentration

- **Solids in solids (weight in weight)**
  1% w/w = 1 g in 100 g of product

- **Solids in liquids (weight in volume)**
  1% w/v = 1 g in 100 mL of product

- **Liquids in liquids (volume in volume)**
  1% v/v = 1 mL in 100 mL of product

- **Liquids in solids (volume in weight)**
  1% v/w = 1 mL in 100 g of product
Example Calculations

- Express as a percentage:
  a. 10 mg of drug in 200 mL of solution
  b. 300 mg drug in 200 g base

- Indicate amount of drug present:
  a. 30 mL of a 10% w/v preparation
  b. 15 g of a 0.1% w/w preparation
Answers: Express as percentage

- a.
- b.
Answers: Amount of drug present

- a.
- b.
Calculations wisdom

- **Always approximate** your answer before reaching for your calculator!

- You should know roughly what you are expecting e.g. about 2 mL, or about 50 mg etc. before you start tapping in the figures.

- Calculators are great for checking your answer is correct and getting exact amount e.g. 2.2 mL or 55 mg.

- Always do the calculation twice to double check.

- Always remember Prof Shaw’s famous saying: “A decimal point can kill your patient!!!!”
Very important: Full documentation is required for all extemporaneously prepared products.

Requires record of formula, batch no., calculations, methods, expiry dates etc.

Often use a **Standard Operating Procedure (SOP)** for a specific product.

An example of our documentation system is shown.
Dose and Dosage

- Dose is the amount of medicine taken or given at one time
- Dosage is the amount of medicine to be taken or given in a period of time
- e.g. Paracetamol 500 mg tablets, Take two tablets four times a day
  Dose = 1 g (two tablets at one time)
  Dosage = 4 g per day (eight tablets in one day)
Dose and Dosage cont.

- Sometimes the formula recommends an amount per day in **divided doses** e.g. Pholcodine Linctus BP, 20-40 mL daily in divided doses.

- The number of doses needs to be decided by the prescriber or you the pharmacist.

- You might see directions for this product as 5 to 10 mL four times a day.
Dose and Dosage cont.

- Most doses in standard texts are given as ranges for a particular condition at a particular age.

- At this stage you are not expected to know all the specific details of dosing.

- However, when working from a formula always check that the dose range is right for your patient: especially for children and elderly.
Storage and Expiry Dates

- It is a legal requirement that extemporaneously prepared products have an **expiry date**

- The difficulty is that for many preparations stability data and microbiological data is not known

- Standard texts don’t always agree

- PSNZ has some recommendations, largely based on ‘common sense’
Recommended Expiry Dates

- Internal preparations without a preservative: 7 days
- Internal preparations with a preservative: 14 days
- External preparations diluted from a pre-formulated product: 14 days
- External preparations compounded extemporaneously: 1 month (28 days)
Your First Prescription (again)

Dr A Jolly
Grafton Medical Centre
Auckland Ph 09 123 4567
2 May 2012

for Mr Brad Pits
20 Grafton Gully, Auckland

Rx
Potassium Citrate Mixture BP
mitte: 200 mL sig: 10 mL ex aq tds

A.Jolly
John’s Drugs R’Us Pharmacy
685 Grafton Boulevard
Auckland, Ph 09 765 4321

SHAKE THE BOTTLE

200 mL Potassium Citrate Mixture BP

Take TWO  5 mL spoonfuls THREE times a day with water

2 May 2012         Mr Brad Pits
                     Dr A Jolly         JPS 2761

Discard mixture after 16 May 2012
Abbreviations

- A complete list is given in the APF
- Many of these you will never come across
- A list of common abbreviations is attached
- The BNF discourages the use of Latin abbreviations and recommends that prescriptions be written in English
Abbreviations?

- i tab nocte prn
- 5 - 10 mL qqh ex aq
- ii caps tds ac
- i suppos pr mane
- i tab qds pc for 5/7
Preservatives

- Preservatives used to prevent contamination and spoilage
- Chloroform water is used in many official formulae as a preservative
- It is now thought it may be a carcinogen if ingested in high amounts
- PSNZ recommends that it is not used for internal medicines (but still used in UK)
- PSNZ (and PSA) recommend Compound Hydroxybenzoate Solution APF 0.1% (known as Parabens) as an alternative
Containers

- A variety of containers available according to the type of product. Covered in much more detail next year.
- For internal liquid preparations a standard medicines bottle is used.
- Can be glass or plastic, clear or amber.
- For internal use, smooth external surface (i.e. non-ribbed).
Standard Techniques

- The **generic skills** of compounding are weighing and measuring.

- **Accuracy** and **precision** are fundamental to good practice.

- Specific techniques such as diluting, using mortar and pestle etc. will be done mostly in Pharmacy Practice 201.
Weighing Solids

- **Class B Beam Balance**
  
  This is the traditional pharmacy weighing balance and many pharmacies will still use this.

- **Electronic Top Loading Balance**
  
  Sometimes called top-pan balance: digital readout and different levels of sensitivity. Pharmacies increasingly switching to this type.
Measuring Liquids

- **Measuring Cylinder (Straight)**

- **Measuring Cylinder (Conical)**
  The conical type, in a range of volumes, is preferred. A glass stirring rod can be used to dissolve solids

- **Pipette, Syringe, Dropper**
  Used to measure small volumes, particularly for adding to a bulk solution, or making up to volume
Summary

- Standard 7 encompasses the compounding of non-sterile pharmaceutical products

- It remains an essential pharmacist competency and includes a number of generic skills such as calculations, documentation etc.

- Happy compounding!