chapter 6
Ointments, pastes and gels

Overview

Upon completion of this chapter, you should be able to:

- understand the difference between ointments, pastes and gels
- prepare an ointment from first principles
- incorporate solids and liquids into an ointment base
- select an appropriate container in which to package ointments, pastes and gels
- prepare an appropriate label for ointments, pastes and gels.

Introduction and overview of ointments, pastes and gels

This chapter will focus on the following dosage forms:

- ointments
- pastes
- gels.

Ointments

British Pharmacopoeia (BP) definition

Ointments are formulated to provide preparations that are immiscible, miscible or emulsifiable with the skin secretion. Hydrophobic ointments and water-emulsifying ointments are intended to be applied to the skin or certain mucous membranes for emollient, protective, therapeutic or prophylactic purposes where a degree of occlusion is desired. Hydrophilic ointments are miscible with the skin secretion and are less emollient as a consequence.

Definition

Ointments are preparations for external application but differ from creams in that they have greasy bases. The base is usually anhydrous and therefore most ointments are immiscible with skin secretions. Ointments usually contain a medicament or a mixture of medicaments dissolved or dispersed in the base.

Pastes

Pastes are semi-solid preparations for external use. They consist of finely powdered medicaments combined with White Soft Paraffin BP or Liquid Paraffin BP or with a non-greasy base made from glycerol, mucilages or soaps. Pastes contain a high proportion of powdered ingredients and therefore are normally very stiff. Because pastes are stiff they do not spread easily and therefore this localises drug delivery. This is particularly important if the ingredient to be applied to the skin is corrosive such as dithranol,

coal tar or salicylic acid. It is easier to apply a paste to a discrete skin area such as a particular lesion or plaque and not therefore compromise the integrity of healthy skin.

Pastes are also useful for absorbing harmful chemicals such as the ammonia which is released by bacterial action on urine and so are often used in nappy products. Also, because of their high powder content, they are often used to absorb wound exudates.

Because pastes are so thick they can form an unbroken layer over the skin which is opaque and can act as a sun filter. This makes them suitable for use for skiers as they prevent excessive dehydration of the skin (wind burn) in addition to sun blocking.

The principal use of pastes was traditionally as an antiseptic, protective or soothing dressing. Often before application the paste was applied to lint and then applied as a dressing.

Gels

Pharmaceutical gels are often simple phase, transparent semi-solid systems that are being increasingly used as pharmaceutical topical formulations. The liquid phase of the gel may be retained within a three-dimensional polymer matrix. Drugs can be suspended in the matrix or dissolved in the liquid phase.

Advantages of gels

1. Stable over long periods of time
2. Good appearance
3. Suitable vehicles for applying medicaments to skin and mucous membranes giving high rates of release of the medicament and rapid absorption.

Gels are usually translucent or transparent and have a number of uses:

- Anaesthetic gels
- Coal tar gels for use in treatment of psoriasis or eczema
- Lubricant gels
- Spermicidal gels.

General method

This section contains information on the preparation of ointments by fusion and the incorporation of both solids and liquids into ointment bases.

Fusion

This involves melting together the bases over a water bath (see Figure 5.1) before incorporating any other ingredients. The

ointment base may include a mixture of waxes, fats and oils, of which some are solid at room temperature and others are liquid.

- Hard: Paraffin BP, Beeswax BP, Cetostearyl Alcohol BP
- Soft: Yellow and White Soft Paraffin BP, Wool Fat BP
- Liquid: Liquid Paraffin BP and vegetable oils.

General method (fusion)

1. Always make excess as transference losses will always occur.
2. Determine the melting points of the fatty bases and then melt together. Starting with the base with the highest melting point, each base should be melted at the lowest possible temperature as the mixture progressively cools.
3. Add the ingredients to an evaporating basin over a water bath (see Figure 5.1) to avoid overheating – use a thermometer to check the temperature regularly.
4. As the first base cools, add the ingredients with decreasing melting points at the respective temperatures, stirring continuously to ensure a homogeneous mix before leaving to set. It is important to stir gently to avoid incorporating excess air, which could result in localised cooling and a lumpy product.

The incorporation of powders into an ointment base

- **Soluble solids** should be added to the molten fatty bases at the lowest possible temperature and the mixture stirred until cold. Alternatively, if using a pre-prepared base, soluble solids may be incorporated using the method employed for insoluble solids.
- **Insoluble solids** should be incorporated using a glass tile and spatula (see Figure 5.2). If there is more than one powder to be added, these should be mixed in a mortar using the 'doubling-up' method.

– **Coarse powders.** A minimum quantity of molten fatty base should be placed in the centre of the glass tile and used to levigate the powders. A considerable shearing force should be applied to avoid a gritty product.

The powder/fatty base mixture may then either be returned to the evaporating basin with the remaining fatty base and stirred until cold or the remaining fatty base in the evaporating basin may be allowed to cool and triturated with the powder/fatty base mixture on the tile.

– **Fine powders** may be triturated into the otherwise finished ointment on a glass tile. Small amounts of powder should be added to an equal amount of ointment, i.e. using the 'doubling-up' technique. These should be well triturated to incorporate all of the ointment base. Alternatively, a small amount of

powder may be levigated with some molten ointment base on a tile and the resulting mixture returned to the remaining molten mass and stirred to achieve a homogeneous product.

The incorporation of liquids into an ointment base

- **Non-volatile, miscible liquids** may be mixed with the molten fat in the evaporating basin. Alternatively, if a pre-prepared base is used, then incorporate as for volatile or immiscible liquids.
- **Volatile or immiscible liquids,** e.g. coal tar solutions, should be triturated with the ointment on the glass tile.

  A very small amount of the ointment should be placed on the glass tile and a 'well' made in the centre. Traditionally, small quantities of liquid should be gently folded in to avoid splashing. An alternative method is to spread a small amount of the ointment on the tile and then score it with a spatula. Then add small quantities of the liquid and fold into the base gently.

  If using coal tar or other volatile ingredients, these should not be weighed until immediately before use and the beaker in which it has been weighed should be covered with a watch glass to prevent evaporation. In addition, always remember that volatile ingredients should not be added to molten bases.

Worked examples

Example 6.1

The preparation of Simple Ointment BP

You receive a prescription in your pharmacy with the following details:

Patient:	Mr Martin Ally, 5 Longmeadow, Astonbury
Age:	56
Prescription:	Simple Ointment BP
Directions:	Mdu
Mitte:	30 g

1. **Use of the product**
   The product is used as an emollient (*Martindale* 33rd edn, p 1408).
2. **Is it safe and suitable for the intended purpose?**
   This is an official formula for an emollient, therefore the formula and frequency of application are safe.
3. **Calculation of formula for preparation**
   Prepare 30 g Simple Ointment BP.

Product formula
(from the *British Pharmacopoeia* 1988, p 713)

	Master	100 g	10 g	40 g
Cetostearyl Alcohol BP	50 g	5 g	0.5 g	2 g
Hard Paraffin BP	50 g	5 g	0.5 g	2 g
Wool Fat BP	50 g	5 g	0.5 g	2 g
White/Yellow Soft Paraffin BP	850 g	85 g	8.5 g	34 g

4. Method of preparation

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
White/Yellow Soft Paraffin BP is used as the diluent as per the product formula.

c. Preservative
There is no preservative included as per the product formula.

d. Flavouring when appropriate
Ointments are for external use and so no flavouring is required.

The following method would be used to prepare 40 g of Simple Ointment BP from the formula above:
Noting that the melting points of the ingredients are:
Cetostearyl Alcohol BP: 49–56°C (*British Pharmacopoeia* 1988, p 111)
Hard Paraffin BP: 50–61°C (*British Pharmacopoeia* 1988, p 415)
White/Yellow Soft Paraffin BP: 38–56°C (*British Pharmacopoeia* 1988, p 416)
Wool Fat BP: 38–44°C (*British Pharmacopoeia* 1988, p 601)

1. Weigh 2 g Hard Paraffin BP on a Class II or electronic balance.
2. Weigh 2 g Cetostearyl Alcohol BP on a Class II or electronic balance.
3. Weigh 2 g Wool Fat BP on a Class II or electronic balance.
4. Weigh 34 g Yellow/White Soft Paraffin BP on a Class II or electronic balance.
5. Place the Hard Paraffin BP into an evaporating dish and melt over a water bath.
6. Remove from the heat and add the other ingredients in descending order of melting point until all are melted in

Tips

The exact quantity cannot be prepared for an ointment: a suitable overage must be produced in order to dispense the required amount.

Yellow or White Soft Paraffin BP may be used when making this ointment, which is often used as a base for other ointments. As a general rule, if it is to be used as a base and the ingredients to be added are coloured (e.g. Coal Tar Solution BP), Yellow Soft Paraffin BP would be used. If the ingredients to be added are white or pale in colour (e.g. Zinc Oxide BP or Calamine BP), White Soft Paraffin BP would be used to produce a more pharmaceutically elegant product.

(return to the heat if necessary to ensure even melting but take care not to overheat).
7. Stir until cold.
8. Weigh 30 g and pack into a collapsible tube or amber glass jar. Label and dispense.

5. Choice of container
A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title
The product is official, therefore the following title would be suitable: 'Simple Ointment BP'

b. Quantitative particulars
Quantitative particulars are not required as the product is official.

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is an ointment for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply as directed.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is an ointment and so will attract a 3-month discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Simple Ointment BP		**30 g**
	Apply as directed.	
	For external use only	
	Do not use after (3 months)	
Mr Martin Ally		Date of dispensing

7. Advice to patient
The patient would be advised to apply the ointment as directed. In addition, the discard date and the fact that the product is for external use only would be highlighted to the patient. If further direction for use is requested, the patient could be advised to apply the ointment frequently as the product is an emollient.

Example 6.2

The preparation of Calamine and Coal Tar Ointment BP

You receive a prescription in your pharmacy with the following details:

Patient:	Mr Kenny Doyle, 13 Acres Street, Astonbury
Age:	38
Prescription:	Calamine and Coal Tar Ointment BP
Directions:	Apply once or twice daily
Mitte:	20 g

1. **Use of the product**
   The product is used to treat psoriasis and occasionally chronic atopic eczema (*British National Formulary* 51st edn, p 582).
2. **Is it safe and suitable for the intended purpose?**
   This is an official preparation, therefore the formula is safe and suitable for purpose. The *British National Formulary* (51st edn, p 582) suggests an application frequency of 1–2 times daily, which corresponds to the prescribed frequency.
3. **Calculation of formula for preparation**
   Prepare 20 g Calamine and Coal Tar Ointment BP.

Product formula (from the *British Pharmacopoeia* 2004, p 2233):

	Master	100 g	10 g	30 g
Calamine BP	125 g	12.5 g	1.25 g	3.75 g
Strong Coal Tar Solution BP	25 g	2.5 g	0.25 g	0.75 g
Zinc Oxide BP	125 g	12.5 g	1.25 g	3.75 g
Hydrous Wool Fat BP	250 g	25 g	2.5 g	7.5 g
White Soft Paraffin BP	475 g	47.5 g	4.75 g	14.25 g

4. **Method of preparation**

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
White Soft Paraffin BP is used as the diluent as per the product formula.

c. Preservative
There is no preservative included as per the product formula.

d. Flavouring when appropriate
Ointments are for external use and so no flavouring is required

Tips

The exact quantity cannot be prepared for an ointment, a suitable overage must be produced in order to dispense the required amount.

Note that the quantity of Strong Coal Tar Solution BP is in grams and so must be weighed.

The following method would be used to prepare 30 g of Calamine and Coal Tar Ointment BP from the formula above:
Noting that the melting points of the ingredients are as follows:
Hydrous Wool Fat BP: 38–44°C (*British Pharmacopoeia* 1988, p 602).
White/Yellow Soft Paraffin BP: 38–56°C (*British Pharmacopoeia* 1988, p 416).

1. Weigh 3.75 g Calamine BP on a Class II or electronic balance.
2. Weigh 3.75 g Zinc Oxide BP on a Class II or electronic balance.
3. Transfer the Calamine BP and the Zinc Oxide BP to a porcelain mortar and triturate together with a pestle.
4. Weigh 14.25 g White Soft Paraffin BP on a Class II or electronic balance.
5. Weigh 7.5 g Hydrous Wool Fat BP on a Class II or electronic balance.
6. Place the White Soft Paraffin BP into an evaporating dish and melt over a water bath.
7. Remove from the heat and add the Hydrous Wool Fat BP. Stir until melted to ensure an even well-mixed base.
8. Transfer the powders to a glass tile and levigate with some of the molten base.
9. Transfer the powder/base mix to the rest of the molten base and stir until homogeneous.
10. Weigh 0.75 g Strong Coal Tar Solution BP on a Class II or electronic balance.
11. Allow the base/powder mixture to cool and add the Strong Coal Tar Solution BP and stir until homogeneous.
12. Weigh 20 g of the product and pack into a collapsible tube or amber glass jar. Label and dispense.

Tips

The Strong Coal Tar Solution BP cannot be added until the bases are quite cool (less than 40°C) as it is a volatile preparation. This method would also avoid heating the Strong Coal Tar Solution BP and therefore reduce the volatilisation of some of the coal tar constituents and reduce the risk of sedimentation.

5. Choice of container
A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title
The product is official therefore the following title would be suitable: 'Calamine and Coal Tar Ointment BP'.

b. Quantitative particulars
Quantitative particulars are not required as the product is official.

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is an ointment for external use.

In addition, the product contains coal tar and so the following warning should be added to the label: 'Caution: may stain hair, skin and fabrics'.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply ONCE or TWICE a day.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is an ointment and so will attract a 3-month discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Calamine and Coal Tar Ointment BP	**20 g**
Apply ONCE or TWICE a day.	
For external use only	
Caution: may stain hair, skin and fabrics	
Do not use after (3 months)	
Mr Kenny Doyle	Date of dispensing

7. Advice to patient
The patient would be advised to apply the ointment once or twice a day. In addition, the discard date, the fact that the product is for external use only and that it may stain hair, skin and fabrics would be highlighted to the patient.

Example 6.3

The preparation of Zinc Ointment BP

You receive a prescription in your pharmacy with the following details:

Patient:	Master John Pike, 234 High Street, Astonbury
Age:	2
Prescription:	Zinc Ointment BP
Directions:	paa qds
Mitte:	20 g

1. Use of the product
For nappy and urinary rash and eczematous conditions (*British National Formulary* 51st edn, p 571).

2. Is it safe and suitable for the intended purpose?
This is an official preparation, therefore the formula is safe

and suitable for purpose. External products which do not contain potent ingredients are normally applied liberally when required. Therefore, an application frequency of four times a day would be suitable for the treatment of nappy rash.

3. **Calculation of formula for preparation**
Prepare 20 g of Zinc Ointment BP.

Product formula (from the *British Pharmacopoeia* 2004, p 2809):

	Master	100 g	10 g	30 g
Zinc Oxide BP	150 g	15 g	1.5 g	4.5 g
Simple Ointment BP	850 g	85 g	8.5 g	25.5 g

Tips

The exact quantity cannot be prepared for an ointment as losses will be experienced on transfer. Therefore, a suitable overage must be produced in order to dispense the required amount.

Tips

The Zinc Oxide BP is transferred to a mortar so that the size of any lumps can be reduced enabling a smooth product to be made.

Tips

To triturate means to mix. A smooth product will be produced if the Zinc Oxide BP is finely sifted and then just mixed with the base. The particle size reduction of the Zinc Oxide BP in this example has only been achieved by mixing in a mortar, rather than sifting with a sieve. In order to achieve a smooth product, considerably more lateral shearing force will need to be applied to the powder and we suggest that the process employed would be more akin to levigation (wet grinding), but in this case using a semi-solid base rather than a molten base.

4. **Method of preparation**

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
Simple Ointment BP is used as the diluent as per the product formula.

c. Preservative
There is no preservative included as per the product formula.

d. Flavouring when appropriate
Ointments are for external use and so no flavouring is required.

The following method would be used to prepare 30 g of Zinc Ointment BP from the formula above:

1. Weigh 4.5 g Zinc Oxide BP on a Class II or electronic balance.
2. Transfer to a porcelain mortar and stir with a pestle.
3. Transfer the Zinc Oxide BP to a glass tile.
4. Weigh 25.5 g Simple Ointment BP on a Class II or electronic balance.
5. Transfer the Simple Ointment BP to the glass tile.
6. Triturate the Zinc Oxide BP with the Simple Ointment BP until a smooth product is formed.
7. Weigh 20 g of the product and pack into a collapsible tube or amber glass jar. Label and dispense.

5. **Choice of container**
   A collapsible tube or plain amber jar would be most suitable.
6. **Labelling considerations**

a. Title
The product is official, therefore the following title would be suitable: 'Zinc Ointment BP'.

b. Quantitative particulars
Quantitative particulars are not required as the product is official.

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is an ointment for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply to the affected areas FOUR times a day.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is an ointment and so will attract a 3-month discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Zinc Ointment BP	**20 g**
Apply to the affected areas FOUR times a day.	
For external use only	
Do not use after (3 months)	
Master John Pike	Date of dispensing

7. **Advice to patient**
   The parent/guardian would be advised to apply the ointment to the affected areas four times a day. In addition, the discard date and the fact that the product is for external use only would be highlighted to the parent/guardian.

Example 6.4

Unofficial ointment request from local doctor

You receive a prescription in your pharmacy with the following details:

Patient:	Mr David Raymond, 13 Gas Street, Astonbury
Age:	38
Prescription:	CCS & S Ointment
Directions:	Apply mdu
Mitte:	20 g

1. **Use of the product**
   The product is used to treat psoriasis (*Martindale* 33rd edn, pp 1122 and 1124).
2. **Is it safe and suitable for the intended purpose?**
   This is an unofficial formula, therefore the formula and frequency of application need to be checked. The formula has originated from a specialist dermatological clinic (see below) and they advise a frequency of application for CCS & S ointment of once to twice daily depending on severity of the condition being treated. The product is therefore safe and suitable for use.
3. **Calculation of formula for preparation**
   Prepare 20 g of CCS & S Ointment.
   The local dermatology clinic has a formulary which gives the following formula:

Salicylic Acid BP	3%
Camphor BP	3%
Sulphur BP	3%
Phenol BP	3%
White Soft Paraffin BP	to 100%

Product formula

	100 g	10 g	30 g
Salicylic Acid BP	3 g	300 mg	900 mg
Camphor BP	3 g	300 mg	900 mg
Sulphur BP	3 g	300 mg	900 mg
Phenol BP	3 g	300 mg	900 mg
White Soft Paraffin BP	88 g	8.8 g	26.4 g

4. **Method of preparation**

a. Solubility where applicable
A liquid is formed when Camphor BP and Phenol BP are mixed together (*Martindale* 33rd edn, p 1589).

b. Vehicle/diluent
White Soft Paraffin BP is used as the diluent as per the product formula.

c. Preservative
Phenol BP would act as a preservative in addition to acting as an antiseptic.

d. Flavouring when appropriate
Ointments are for external use and so no flavouring is required.

The following method would be used to prepare 30 g of CCS & S Ointment from the formula above:

Note that when phenol is combined with camphor, a liquid mixture results.

1. Weigh 900 mg Salicylic Acid BP on a Class II or electronic balance.
2. Weigh 900 mg Sulphur BP on a Class II or electronic balance.
3. Transfer the Salicylic Acid BP to a glass mortar and grind with a pestle to reduce particle size.
4. Add the Sulphur BP and continue mixing.
5. Transfer the mixed powders to a glass tile.
6. Weigh 26.4 g White Soft Paraffin BP on a Class II or electronic balance.
7. Transfer the White Soft Paraffin BP to the glass tile.
8. Triturate the powders with the White Soft Paraffin BP until a smooth product is formed.
9. Weigh 900 mg Camphor BP on a Class II or electronic balance.
10. Transfer to a clean dry glass mortar.
11. Weigh 900 mg of Phenol BP on a Class II or electronic balance.
12. Add the Phenol BP to the Camphor BP and mix together with a pestle.
13. Make a well in the ointment mass and add the liquid mixture.
14. Triturate until all the liquid is incorporated and a homogeneous product is formed.
15. Weigh 20 g of product and pack into a collapsible tube or amber glass jar and label.

Tips

Note that a vulcanite spatula would be the spatula of choice as traditional stainless steel spatulas may react with acids, tannins, iodine and mercury salts etc.

Vulcanite (also called ebonite) is a hard, usually black, rubber produced by vulcanising natural rubber with sulphur. Such spatulas are used for making ointments containing corrosive substances or substances that react with steel.

Tips

The Camphor BP and Phenol BP are weighed and mixed at the final stage of preparation of the product as both are volatile ingredients.

5. Choice of container

A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title

The product is unofficial, therefore the following title would be suitable: 'CCS & S Ointment'.

b. Quantitative particulars

Quantitative particulars are required as the product is unofficial. As the product is for external use, the quantitative particulars would be expressed per container:

The product contains:	
Salicylic Acid BP	3%
Camphor BP	3%
Sulphur BP	3%
Phenol BP	3%
White Soft Paraffin BP	to 100%

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is an ointment for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply as directed.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is an ointment and so will attract a 3-month discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

CCS & S Ointment		**20 g**
	Apply as directed.	
	For external use only	
	Do not use after (3 months)	
The product contains:		
Salicylic Acid BP	3%	
Camphor BP	3%	
Sulphur BP	3%	
Phenol BP	3%	
White Soft Paraffin BP	to 100%	
Mr David Raymond		Date of dispensing

7. Advice to patient
The patient would be advised to apply the ointment as directed. In addition, the discard date and the fact that the product is for external use only would be highlighted to the patient. If further direction for use is requested, the patient could be advised to apply the cream once or twice a day as, although the concentration of Salicylic Acid BP is quite low when compared to preparations used in the treatment of warts and hard skin, it will act as a keratolytic and so a maximum application frequency of once or twice a day would be appropriate.

Example 6.5

Unofficial ointment request from local doctor

You receive a prescription in your pharmacy with the following details:

Patient:	Ms Daphne Stokes, 74 Fish Street, Astonbury
Age:	42
Prescription:	Salicylic Acid 2% in Betnovate Ointment
Directions:	Apply mdu
Mitte:	40 g

1. **Use of the product**
   Used to treat psoriasis (Salicylic Acid: *Martindale* 33rd edn, p 1122; Betnovate Ointment: *British National Formulary* 51st edn, p 576).
2. **Is it safe and suitable for the intended purpose?**
   The suitability of the product formula must be decided by the compounder. Refer to a diluent directory which in this case states that up to 5% of Salicylic Acid BP can be added to Betnovate Ointment. Had the formula requested Betnovate Cream, this would have been unsuitable as the Salicylic Acid BP causes the cream to crack. The suggested frequency of application for Betnovate Ointment is to apply thinly 1–2 times daily (*British National Formulary* 51st edn, p 576). Therefore, the product is safe and suitable for use.
3. **Calculation of formula for preparation**
   Prepare 40 g of Salicylic Acid BP 2% in Betnovate Ointment.
   Note: Suitable sources to provide information on the dilution of creams and ointments would be:
   - National Pharmacy Association *Diluent Directory*
   - product data sheet (Summary of Product Characteristics – SPC)
   - reports in the pharmaceutical literature
   - personal contact with product manufacturer.

Product formula

	Master	100 g	10 g	50 g
Salicylic Acid BP	2 %	2 g	200 mg	1 g
Betnovate Ointment	98 %	98 g	9.8 g	49 g

4. **Method of preparation**

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
Betnovate Ointment is used as the base as per the product formula.

c. Preservative
The product contains no additional preservative (apart from any preservative already present within the Betnovate Ointment).

d. Flavouring when appropriate
Ointments are for external use and so no flavouring is required.

The following method would be used to prepare 50 g of Salicylic Acid BP 2% in Betnovate Ointment from the formula above:

1. Weigh 1 g Salicylic Acid BP on a Class II or electronic balance.
2. Transfer to a glass mortar and grind with a pestle to reduce any lumps in the powder.
3. Transfer the powder to a glass tile.
4. Weigh 49 g Betnovate Ointment.
5. Transfer to the tile.
6. Triturate the Salicylic Acid BP and the Betnovate Ointment together, remembering the 'doubling-up' technique for adequate mixing.
7. Weigh 40 g of the resultant ointment, pack into a collapsible tube or amber glass jar, label and dispense.

5. Choice of container
A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title
The product is unofficial, therefore the following title would be suitable: 'Salicylic Acid 2% in Betnovate Ointment'.

b. Quantitative particulars
Quantitative particulars are required as the product is unofficial. As the product is for external use, the quantitative particulars would be expressed per container:

The product contains:

Salicylic Acid BP	2%
Betnovate Ointment	98%

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is an ointment for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply as directed.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is an ointment and so would normally attract a 3-month discard date. However, as the product is a diluted proprietary ointment, it is common to assign a shorter 2-week discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Salicylic Acid 2% in Betnovate Ointment		**40 g**
	Apply as directed.	
	For external use only	
	Do not use after (2 weeks)	
The product contains:		
Salicylic Acid BP	2%	
Betnovate Ointment	98%	
Ms Daphne Stokes		Date of dispensing

7. Advice to patient
The patient would be advised to apply the ointment as directed. In addition, the discard date and the fact that the product is for external use only would be highlighted to the patient. If further direction for use is requested, as the preparation contains Betnovate Ointment the patient could be advised to apply the ointment thinly 1–2 times daily (*British National Formulary* 51st edn, p 576). In addition, although the concentration of Salicylic Acid BP is quite low when compared to preparations used in the treatment of warts and hard skin, it will act as a keratolytic and so a maximum application frequency of once or twice a day would also be appropriate.

Example 6.6
The preparation of Compound Zinc Paste BP

You receive a prescription in your pharmacy with the following details:

Patient:	Mrs Sandra Jones, 6 Summet Drive, Astonbury
Age:	56
Prescription:	Compound Zinc Paste BP
Directions:	paa tds
Mitte:	20 g

1. Use of the product
Mild astringent (*Martindale* 33rd edn, p 1128).

2. **Is it safe and suitable for the intended purpose?**
   This is an official preparation, therefore the formula is safe and suitable for purpose.
3. **Calculation of formula for preparation**
   Prepare 20 g Compound Zinc Paste BP.

Product formula (from the *British Pharmacopoeia* 2004, p 2809):

	Master	100 g	10 g	30 g
Zinc Oxide BP	250 g	25 g	2.5 g	7.5 g
Starch BP	250 g	25 g	2.5 g	7.5 g
White Soft Paraffin BP	500 g	50 g	5 g	15 g

4. **Method of preparation**

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
White Soft Paraffin BP is used as the diluent as per the product formula.

c. Preservative
There is no preservative included as per the product formula.

d. Flavouring when appropriate
Pastes are for external use and so no flavouring is required.

The following method would be used to prepare 30 g of Compound Zinc Paste BP from the formula above:
Noting the melting point of the base:
White/Yellow Soft Paraffin BP 38–56°C (*British Pharmacopoeia* 1988, p 416)

1. Weigh 7.5 g Zinc Oxide BP on a Class II or electronic balance.
2. Weigh 7.5 g Starch BP on a Class II or electronic balance.
3. Weigh 15 g White Soft Paraffin BP on a Class II or electronic balance.
4. Transfer the Zinc Oxide BP to a porcelain mortar.
5. Add the Starch BP to the mortar and triturate with the pestle to form an evenly mixed powder.
6. Transfer the powder to a glass tile.
7. Transfer the White Soft Paraffin BP to the glass tile.
8. Mix the powders with the White Soft Paraffin BP using a metal spatula and remembering the principle of 'doubling-up' when mixing.

Tips

A porcelain mortar is used because of the volume of powder involved.

9. Triturate until a smooth product is formed.
10. Weigh 20 g and pack into a collapsible tube or amber glass jar. Label and dispense.

Tips

An alternative way to prepare this paste would involve melting the base then combining the powders with the molten base and stirring until cooled.

5. Choice of container
A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title
The product is official, therefore the following title would be suitable: 'Compound Zinc Paste BP'.

b. Quantitative particulars
Quantitative particulars are not required as the product is official.

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is a paste for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply to the affected areas THREE times a day.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is a paste and so will attract a 3-month discard date.

g. Sample label (You can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Compound Zinc Paste BP	**20 g**
Apply to the affected areas THREE times a day.	
For external use only	
Do not use after (3 months)	
Mrs Sandra Jones	Date of dispensing

7. Advice to patient
The patient would be advised to apply the ointment to the affected areas three times a day. In addition, the discard date and the fact that the product is for external use only would be highlighted to the patient.

Example 6.7

The preparation of Zinc and Coal Tar Paste BP

You receive a prescription in your pharmacy with the following details:

Patient:	Mr Scott Bird, 24 Fleet Drive, Astonbury
Age:	38
Prescription:	Zinc and Coal Tar Paste BP
Directions:	Apply bd mdu
Mitte:	20 g

1. **Use of the product**
   Used to treat psoriasis (and occasionally chronic atopic eczema) (*British National Formulary* 51st edn, pp 582–583).
2. **Is it safe and suitable for the intended purpose?**
   This is an official preparation, therefore the formula is safe and suitable for purpose. The *British National Formulary* (51st edn, p 583) suggests an application frequency of 1–2 times daily which is consistent with the prescription).
3. **Calculation of formula for preparation**
   Prepare 20 g Zinc and Coal Tar Paste BP.

Product formula (from the *British Pharmacopoeia* 2004, page 2810)

	Master	100 g	10 g	30 g
Emulsifying Wax BP	50 g	5 g	500 mg	1.5 g
Coal Tar BP	60 g	6 g	600 mg	1.8 g
Zinc Oxide BP	60 g	6 g	600 mg	1.8 g
Starch BP	380 g	38 g	3.8 g	11.4 g
Yellow Soft Paraffin BP	450 g	45 g	4.5 g	13.5 g

4. **Method of preparation**

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
Yellow Soft Paraffin BP is used as the diluent as per the product formula.

c. Preservative
There is no preservative included as per the product formula.

d. Flavouring when appropriate
Pastes are for external use and so no flavouring is required.

The following method would be used to prepare 30 g of Zinc and Coal Tar Paste BP from the formula above:

Noting the melting points of the ingredients:

Emulsifying Wax BP	52°C
White/Yellow Soft Paraffin BP	38–56°C

1. Weigh 1.8 g Zinc Oxide BP on a Class II or electronic balance.
2. Transfer to a porcelain mortar.
3. Weigh 11.4 g Starch BP on a Class II or electronic balance.
4. Add the Starch BP to the Zinc Oxide BP in the porcelain mortar and stir with the pestle.
5. Weigh 1.5 g Emulsifying Wax BP on a Class II or electronic balance.
6. Weigh 1.8 g Coal Tar BP on a Class II or electronic balance.
7. Weigh 13.5 g Yellow Soft Paraffin BP on a Class II or electronic balance.
8. Place the Emulsifying Wax BP into an evaporating dish and melt over a water bath at 70°C.
9. Add the Coal Tar BP and half of the Yellow Soft Paraffin BP to the evaporating basin.
10. Stir at 70°C until melted.
11. Add the remaining Yellow Soft Paraffin BP stir until melted.
12. Cool to approximately 30°C and add the powders and stir constantly until cold.
13. Weigh 20 g of the paste transfer to a collapsible tube or amber glass jar, dispense and label.

Tips

The powders must be mixed, remembering the principle of 'doubling-up' in order to ensure even mixing of the powders.

Tips

The above method is as recommended by the *British Pharmacopoeia*. An alternative method would be:

- Melt the Yellow Soft Paraffin BP and Emulsifying Wax BP together at the lowest possible temperature, stirring until cool, to make a homogeneous product.
- Mix the powders as before but transfer them to a glass tile and incorporate the powders into the base using a spatula.
- Finally, using a spatula (preferably ebonite), incorporate the Coal Tar BP.

This method may be preferred because of the possible problem of toxicity associated with Coal Tar BP. This method would avoid heating the Coal Tar BP and therefore reduce the volatilisation of some of the coal tar constituents and reduce the risk of sedimentation.

5. Choice of container

A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title

The product is official, therefore the following title would be suitable: 'Zinc and Coal Tar Paste BP'.

b. Quantitative particulars

Quantitative particulars are not required as the product is official.

c. Product-specific cautions (or additional labelling requirements)

'For external use only' will need to be added to the label as the product is a paste for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply TWICE a day as directed.'

e. Recommended *British National Formulary* cautions when suitable
Not applicable.

f. Discard date
The product is a paste and so will attract a 3-month discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Zinc and Coal Tar Paste BP	**20 g**
Apply TWICE a day as directed.	
For external use only	
Do not use after (3 months)	
Mr Scott Bird	Date of dispensing

7. Advice to patient
The patient would be advised to apply the ointment twice a day as directed. In addition, the discard date and the fact that the product is for external use only would be highlighted to the patient.

Example 6.8

The preparation of Dithranol Paste BP

You receive a prescription in your pharmacy with the following details:

Patient:	Miss Amy Smith, 12 Ash Drive, Astonbury
Age:	30
Prescription:	Dithranol Paste BP 0.1%
Directions:	Apply mdu
Mitte:	40 g

1. Use of the product
Used in treatment of subacute and chronic psoriasis (*British National Formulary* 51st edn, p 583).

2. Is it safe and suitable for the intended purpose?
This is an official preparation, therefore the formula is safe and suitable for purpose.

3. Calculation of formula for preparation
Prepare 40 g of Dithranol Paste BP 0.1%.
(Note: the strengths of dithranol paste can vary between 0.1% and 1%.)

Product formula (from the *British Pharmacopoeia* 2004, p 2372)

	Master	100 g	10 g	50 g
Dithranol BP	1 g	100 mg	10 mg	50 mg
Zinc and Salicylic Acid Paste BP	999 g	99.9 g	9.99 g	49.95 g

4. Method of preparation

a. Solubility where applicable
Not applicable.

b. Vehicle/diluent
Zinc and Salicylic Acid Paste BP is used as the diluent as per the product formula.

c. Preservative
There is no preservative included as per the product formula.

d. Flavouring when appropriate
Pastes are for external use and so no flavouring is required.

The following method would be used to prepare 50 g of Dithranol paste BP 0.1% from the formula above:

1. Weigh 50 mg Dithranol BP on a Class I or sensitive electronic balance.
2. Transfer to a glass tile.
3. Weigh 49.95 g Zinc and Salicylic Acid Paste BP on a Class II or electronic balance.
4. Transfer the Zinc and Salicylic Acid Paste BP to the glass tile.
5. Triturate Dithranol BP with the Zinc and Salicylic Acid Paste BP, remembering the principle of 'doubling-up' until a smooth product is formed.
6. Weigh 40 g of the product and pack into a collapsible tube or amber glass jar. Label and dispense.

Tips

Dithranol BP is extremely irritant and care should be taken when handling. If large quantities are to be made, anecdotal evidence suggests that using Liquid Paraffin BP to dissolve the powder prior to addition to the paste reduces the likelihood of dispersal of the powder when admixing with the paste. If used, the formula would need to be slightly adjusted to allow for the weight of Liquid Paraffin BP used.

5. Choice of container
A collapsible tube or plain amber jar would be most suitable.

6. Labelling considerations

a. Title
The product is official, therefore the following title would be suitable: 'Dithranol Paste BP 0.1%'.

b. Quantitative particulars
Quantitative particulars are not required as the product is official.

c. Product-specific cautions (or additional labelling requirements)
'For external use only' will need to be added to the label as the product is a paste for external use.

d. Directions to patient – interpretation of Latin abbreviations where necessary
'Apply as directed.'

e. Recommended *British National Formulary* cautions when suitable
The *British National Formulary* (51st edn, p 584) recommends the following cautions:
Label 28 – 'To be spread thinly…'

f. Discard date
The product is a paste and so will attract a 3-month discard date.

g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label):

Dithranol Paste BP 0.1%	**40 g**
To be spread thinly as directed.	
For external use only	
Do not use after (3 months)	
Miss Amy Smith	Date of dispensing

7. Advice to patient
The patient would be advised to apply the paste thinly as directed. In addition, the discard date and the fact that the product is for external use only would be highlighted to the patient. If further direction for use is requested, the patient could be advised to apply the paste once or twice a day as, although the concentration of Salicylic Acid BP is quite low when compared to preparations used in the treatment of warts and hard skin, it will act as a keratolytic and so a maximum application frequency of once or twice a day would be appropriate.

Self-assessment

Questions

1. You are asked to prepare 25 g of a 1 in 5 dilution of Hydrocortisone 1% Ointment BP in White Soft Paraffin BP. What quantity of Hydrocortisone 1% Ointment BP would be required (the 25 g includes an overage)?

a. 4 g
b. 4.166 g
c. 5 g
d. 5.166 g

2. You are asked to prepare 15 g of an ointment containing 25% Salicylic Acid BP in White Soft Paraffin BP. What quantity of powder is required (the 15 g includes an overage)?

a. 2.5 g
b. 2.75 g
c. 3.75 g
d. 5.75 g

3. How much White Soft Paraffin BP would be used when making the ointment outlined in question 2?

a. 9.35 g
b. 11.25 g
c. 12.25 g
d. 12.5 g

4. You are asked to prepare 50 g of an ointment containing 0.75% Salicylic Acid BP in White Soft Paraffin BP. What quantity of powder is required (the 50 g includes an overage)?

a. 75 mg
b. 375 mg
c. 3.75 g
d. 7.5 g

5. You are presented with the following prescription: Hydrocortisone BP 2.5 g White Soft Paraffin BP ad 50 g. What is the percentage w/w of Hydrocortisone BP?

a. 1%
b. 2.5%
c. 4.75%
d. 5%

6. You are asked to prepare the following ointment:

Calamine BP	15%
Strong Coal Tar Solution BP	2.5%
Zinc Oxide BP	12.5%
Hydrous Wool Fat BP	25%
White Soft Paraffin BP	ad 100%

How much Strong Coal Tar Solution BP would be required to produce 20 g of this product?

a. 0.5 ml
b. 0.5 g
c. 2.5 ml
d. 0.25 g

7. How much White Soft Paraffin BP would be in 20 g of the product in question 6?
a. 1.8 g
b. 4.5 g
c. 9 g
d. 18 g

8. The most suitable way to incorporate a coarse insoluble powder into a molten ointment base is by:
a. trituration
b. fusion
c. levigation
d. titration

9. A suitable discard date for an extemporaneously prepared ointment would be:
a. 2 weeks
b. 4 weeks
c. 1 month
d. 3 months

10. The directions on the prescription for an ointment include the instruction 'paa'. How will this be written on the label?
a. 'Apply when required.'
b. 'Apply to the vagina.'
c. 'Apply after food.'
d. 'Apply to the affected area.'

11. Describe the major differences between ointments and creams:
a. as pharmaceutical formulations
b. as products used by a patient.

Formulation questions

This section contains details of extemporaneous products to be made in the same way as the examples earlier in this chapter. For each example, provide answers using the following sections:

1. **Use of the product**
2. **Is it safe and suitable for the intended purpose?**
3. **Calculation of formula for preparation**
4. **Method of preparation**
   a. Solubility where applicable
   b. Vehicle/diluent
   c. Preservative
   d. Flavouring when appropriate
5. **Choice of container**
6. **Labelling considerations**

a. Title
b. Quantitative particulars
c. Product-specific cautions (or additional labelling requirements)
d. Directions to patient – interpretation of Latin abbreviations where necessary
e. Recommended *British National Formulary* cautions when suitable
f. Discard date
g. Sample label (you can assume that the name and address of the pharmacy and the words 'Keep out of the reach of children' are pre-printed on the label)

7. **Advice to patient**

12. You receive a prescription in your pharmacy with the following details:

Patient:	Mr Amarjit Singh, 6 Summet Dive, Astonbury
Age:	44
Prescription:	Cetrimide Emulsifying Ointment BP
Directions:	Use three times a day
Mitte:	30 g

13. You receive a prescription in your pharmacy with the following details:

Patient:	Mrs Helen Preston, 21 Elm Road, Astonbury	
Age:	40	
Prescription:	Salicylic Acid	2%
	Sulphur ppt	3%
	Hydrous oint	qs
Directions:	Apply bd to patches	
Mitte:	15 g	