Procedures for extemporaneous dispensing

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Process for supplying extemporaneously prepared medicines

The intern is required to complete the following each time an extemporaneous prescription is attempted.

1. Establish the validity of the prescription
2. Check the patient details including age and weight if applicable
3. Check the appropriateness of the prescription including correct dose or strength of medicaments
4. Complete the necessary recording of the prescription
5. Prepare a suitable label including extra warning and/or cautionary and advisory labels, appropriate shelf life and storage conditions
6. Select the appropriate container
7. Prepare the product suitably
8. Check the final product including the label
9. Provide appropriate advice and counselling to the patient

Assessment of the Preparation of Specific Products

Each time an extemporaneous product is prepared the intern must satisfy the following criteria. It is the duty of the preceptor to establish that criteria appropriate to the preparation have been met.

Criteria:

1. Correct quantities calculated
2. Medicaments weighed accurately with regard to balance sensitivity and minimum weighable mass
3. Appropriate preparation technique exercised
4. Stability and shelf life of final product determined (by reference or precedent)
5. Product labelled appropriately

Some Specific Examples:

The requirements of the relevant occupational health and safety laws are to be observed at all times to minimise exposure of dispensary personnel to any hazard.

Creams and Ointments

e.g. Salicylic Acid and Sulfur Cream Aqueous APF 22
1. Ensure that the two actives (salicylic acid and sulfur) are weighed accurately
2. Ensure that the salicylic acid and sulfur are in a form which is readily dispersible in the base (e.g. wet sulfur with a few drops of glycerol and dissolve salicylic acid in a few drops (minimal amount) of alcohol)
3. The correct amount of base cream must be used
4. Triturate with a small quantity of base followed by dilution with base to ensure uniform mixing
5. Ensure appropriate cleanliness
6. Transfer to the container must be complete
7. Packing of the jar must be elegant
8. Labelling must include “For External Use Only”, “Store below 25°C” and an expiry date of 28 days (APF requirements).
9. Appropriate counselling for safe use.

**Lotions and Paints**

e.g. Salicylic Acid and Coal Tar Lotion APF 22
1. Ensure that the ingredients are measured or weighed accurately and safely
2. The product should be made to volume in a measure or a calibrated bottle.
3. A coloured fluted bottle (poisons bottle) is generally used and should be labelled “For External Use Only” and “Store below 25°C”. The expiry date is 28 days.
4. Appropriate counselling for safe use.

**Pastes**

e.g. Trichloracetic Acid Paste (Upton’s Paste) APF 22
1. Ensure that the two powders are weighed accurately and safely
2. The glycerol must be weighed into a container
3. Trituration must ensure uniform mixing
4. The paste should be packed into an ointment jar
5. Labelling must include “For External Use Only” and an expiry date of 28 days.

**Mixtures**

e.g. Propranolol Mixture CF – 5mg/mL APF 22
1. Propranolol hydrochloride tablets may be used (do not use brands of propranolol tablets containing calcium carbonate as an excipient) (APF)
2. Crush the required number of tablets in a mortar
3. Add the citric acid. This stabilises the propranolol in aqueous solution.
4. Add the sodium benzoate (preservative)
5. Add the syrup gradually with adequate trituration
6. Slowly add most of the water with mixing
7. Transfer to a measure or calibrated bottle
8. Rinse the mortar with successive small portions of water to achieve total transfer
9. Add rinsings to the product and make to volume with water
10. Label “Store at 2-8°C” (Label 6), “Protect from light” and “Shake the bottle” (Brown glass bottle).
11. Expiry date is 30 days from date of preparation (APF)

**Remember:**

- All suspensions must be made in a mortar
- Products must be made to volume accurately (Remove the stirring rod!)
- Complete transfer must be obtained in order to maintain the correct concentration of active ingredient/s
- Cleanliness is of paramount importance
- Labels must be accurate and fulfil ALL requirements. “Shake the bottle” is always needed for products that settle on standing
- The final product, including the label, must be checked carefully
- The patient must be counselled appropriately