1.0 PURPOSE

1.1 To describe the compounding of extemporaneous pharmaceutical in the Pharmacy Laboratory.

2.0 DEFINITION

2.1 **Extemporaneous Pharmaceutical Compounding**: is the process of mixing drugs by a pharmacist or modifying the concentration of a drug from that of the original manufacturer to fit the unique needs of a patient.

3.0 RESPONSIBILITY

3.1 **The pharmacist**: is responsible for

3.1.1 Making sure that the Extemporaneous Pharmaceutical Compounding Manual is available and properly referenced.

3.1.2 Making the proper calculations of the dosages and concentrations of the medicine required.

3.1.3 Checking all extemporaneous preparations before dispensing.

3.1.4 Recording the name of the materials used and the calculated amounts in the log book.

3.2 **The Physician / Pediatrician**:

3.2.1 Choose the appropriate dosage form to deliver the required dose in a safer more effective ways.

3.2.2 Consult with the pharmacist about using available therapeutic alternatives in a more suitable form.

3.2.3 Use available pharmaceutical alternatives if stability of an oral liquid cannot be assured (tablet splitting, tablet dispersion, crushing tablets/opening capsules and mixing powder with food or drinks, and giving the injectable form by the oral route).
3.3 The Nurse Staff:

3.3.1 Follow instructions for use carefully (e.g. Shake all oral preparations before the dose is given).

3.3.2 Do not use preparation beyond validated shelf life.

4.0 CROSS REFERENCES POLICY

4.1 N/A.

5.0 POLICY

5.1 The Pharmacy Laboratory follows an effective and consistent policy on the proper compounding, preparation and dispensing of topical creams, ointments, lotions, paints, disinfectants, solutions, and oral syrups and suspensions for inpatients and outpatients, according to the rules and regulations of the MOH and the CBAHI Standards.

5.2 The pharmacy department has a preparation manual (Formulation Book) that is properly referenced.

5.3 A log book is maintained to record any preparation made in the pharmacy lab in which the dosage form or concentration of any medication has been altered.

5.4 All extemporaneous preparations must be checked by a pharmacist before being dispensed. The checking pharmacist should be someone other than the person preparing the item.

5.5 The compounding area (pharmacy lab) should have a clean working bench with a smooth surface, and a sink with water supply and stainless steel surface.

6.0 PROCEDURE

6.1 The pharmacist shall make sure that the Extemporaneous Pharmaceutical Preparations Manual is available at all times in the pharmacy laboratory and properly referenced.

6.2 Only oral and topical preparations are extemporaneously prepared. Make the proper calculations of the dosages and concentrations of the medicine required by the physician order or according to the preparation book.

6.3 The pharmacist shall write down the name of the materials used and the calculated amounts in the log book.

6.4 The pharmacy lab has adequate equipment and glass ware (e.g. weighing scale, bottles, jars, mortar, filters, electric heater, thermometer, etc.).

6.5 The pharmacist shall weigh material according to the calculated amounts and carry on with the preparation and sign.
6.6 Another Pharmacist should check these preparations and co-sign.

6.7 The pharmaceutical preparations are then placed in bottles or containers and properly labeled.

6.8 The label should contain the name of the prepared medicine, strength or concentration, batch number, direction for use, preparation date and expiration date, and initials of the preparing pharmacist and checked by pharmacist.

6.9 The pharmacist shall attach any auxiliary labels that may be required to the bottle or container.

6.10 The pharmacist shall record the name of the prepared medicine, strength, prepared quantity, batch number, expiration date, and the preparation number on the log book.

6.11 The pharmacist shall check the expiration date of the raw materials, and other chemicals periodically.

6.12 The pharmacist shall check the validity of the prepared items and discard any batch that changes in color, odor, and/or appearance.

6.13 The pharmacist shall request the raw materials and chemicals weekly from the pharmacy store.

7.0 FORMS

7.1 Extemporaneous log binder

8.0 EQUIPMENT


8.2 Balances, sensitive and regular.

8.3 Mortar and pestle porcelain.

8.4 Weighing papers.

8.5 Steel spatulas.

8.6 Calibrated syringes.

8.7 Cylinders.

8.8 Beakers.

8.9 Hot plate.

8.10 Filter papers.

8.11 Jars & Bottles.

8.12 Laminar flow hood.

8.13 Heating & mixing machine.
8.15 Extemporaneous log binder.
8.16 Labels.
8.17 Gloves.
8.18 Spill Kit.

9.0 REFERENCES
   9.1 British Pharmacopoeia.
   9.2 USP.