

**OTC Compounding
Policy and Procedure # 133**

The minimum guidelines for pharmacists who are doing over-the-counter (OTC) compounding are:

1. Component products used in OTC compounding should be available to the public.
2. Compounded product should be made on a patient-specific need and kept behind the pharmacy counter under supervision of the pharmacist.
3. Compounded product labels should include: active ingredients; strength; dosage; directions for use; expiration date; and one of the following: a) lot number b) batch number c) control number, or d) identification number; as well as, appropriate auxiliary labels.
4. Patients should receive detailed written or verbal information and counseling with all compounded products.
5. Records of products provided to patients must be maintained in a readily retrievable manner.