How to use a Batch Record

1. The Information given in the MBR's, all formulas and procedures are tentative and need to be controlled and approved by local regulations. After downloading the MBR is called Batch Record (BR).
2. The BR is intended to document the compounding process to ensure the quality of the final product. On the BR all processing information need to fill in.
3. The BR normally contains the compounding information on the first site, including composition (ingredients, materials) and the processing. A proposed label for the final container is placed in the upper right corner (compare with Illustration under Method or see any MBR), where furthermore a pharmacy name and a batch number must be added. When a production date is inserted, an expiration date (column M8) occur considering the proposed shelf life (column C8).
   The ingredients are defined by corresponding CAS number, if possible. The product numbers of other materials are proposed, and need to be modified to local needs.
4. The BR contains the quantities of factor 1. You may change this factor to calculate with the formula for another batch size. Please check the calculated quantities and assure that the proposed weight is correct.
5. Note that column (H) is hidden for printing. In column (H) the amount with factor 1 is given. If you change the factor the newly calculated amounts are shown in column (I).
6. The second page of the BR contains the proposed quality and identity tests with expected values and results to be filled in.
7. Under References is all related information corresponding to the product given.

Good Processing Practice

1. Before starting of any compounding process, please inspect the area, the batch record, the ingredients, the materials and labels.
2. The weighing process of the active pharmaceutical ingredient (API) should be supervised or controlled by a responsible professional pharmacist and the removed weight is to be written on the label of the storage container.
3. Give a batch number on every compounding, for easy identification of the batch
4. If more than one product/batch is compounded at the same time and/or same day caution has to be taken so no confusion on the compounding parts occur.
5. For sterile products that are in an autoclaving phase, never process more than one product with the same volume/sizes or type of container.
6. Ophthalmic solutions may be sterilized in plastic bags for infusion solutions and later transferred under aseptically conditions into sterile eye drop bottles
7. Some API's are unstable in solution at room temperature. These solution may be stored for a prolonged period of tim at -20°C. Prepared solution (for example urea, antibiotics) ca be stored in glass containers and frozen in inclined position for several months (not suitable for biologics and barbitones).
8. Quality control – Whenever possible use simple methods such as physical characteristics (refractive index, conductivity, pH-value, etc), spot tests on a glass plate (see WHO basic identity test in the references section). Whenever possible make further chemical tests (determination of kations, IR-spectrometry) and microbiological test (sterile tests, etc).
9. Consider reusable storage container materials, such as glass or polypropylene that can be autoclaved. Check if further materials like textiles, glass syringes, metallic needles can be reused after appropriate cleaning and sterilization.

Further information for compounding or Good Processing Practice can be found under Links and References