General guidance for compounding oral liquids

1. **Funded proprietary oral liquid medicines**

   When a funded commercial preparation is available this must be used. Extemporaneous compounding increases the risk of error that could harm the patient through overdosing or underdosing. Using a commercial preparation reduces the risk by removing compounding error.

   However, in many instances proprietary oral liquids are not available and extemporaneous compounding is unavoidable. With this in mind, the Health and Quality Safety Commission's Compounding Working Group have developed standardised oral formulation batch sheets for the more commonly compounded oral liquid medicines. These are evidence-based guidelines designed to reduce the risks involved in extemporaneous compounding across New Zealand. General guidance and explanatory notes for using these batch sheets are included below.

2. **Preparing a different strength to the standard formulation**

   Where there is a standard formulation, this should be used, as any deviation from this may be unsafe or unstable. The strengths have been standardised to avoid confusion and mix-ups if different strengths are prepared by different pharmacies – this can lead to overdosing or underdosing when the medicine is given. The stability of the preparation is specific for the strength studied and this should not normally be modified.

3. **Substituting Ora Sweet SF or Ora Blend SF for *Ora Sweet or *Ora Blend (*sugar containing Ora products) and vice-versa**

   Information on substituting bases is provided on the batch sheets. It is generally considered acceptable to substitute sugar-containing Ora products with sugar-free Ora products. For example, replacing *Ora-Blend with Ora-Blend SF or replacing *Ora-Sweet with Ora-Sweet SF. However, it is ***not advisable*** to use sugar-containing Ora products if a study has been performed using sugar-free products (i.e. Ora Sweet SF or Ora Blend SF). This is because sugar can cause chemical stability problems or discoloration with some drugs (e.g. the Maillard reaction).

   Note: We have recently been made aware that using Ora SF products instead of *Ora Sweet may cause physical incompatibility with some specific formulations. This may be brand specific. Where we are aware of a problem (e.g. with vancomycin) this is indicated on the batch sheet. As with all compounded formulations, practitioners are requested to be vigilant for any physical changes (clumping, caking, colour changes etc.) and report these to the Pharmaceutical Society (email practice@psnz.org.nz).

4. **Using different brands**

   Unless otherwise indicated, the standard formulation uses the funded tablet brand. Chemical and physical stability can be altered if alternative brands are used. If specific problems have been reported with the use of specific brands this is noted on the batch sheet. When the funded brand changes, please be aware of possible changes such as precipitation, clumping, discolouration or excessive thickness, and report these to the Pharmaceutical Society (email practice@psnz.org.nz).

5. **Storage conditions**

   In general, when published chemical stability has been reported both in a refrigerator and at room temperature, then the recommended storage condition is refrigeration (2-8°C). The exception to this is if stability problems have been identified (usually physical instability such as precipitation) if the product is refrigerated. When the product is chemically and physically stable at room temperature and in a refrigerator, the latter is recommended as this reduces the risk of problems associated with storage at excessive heat or light and microbial growth in-use (these are rarely adequately assessed in published studies). Pharmacists can use their discretion to indicate that storage at room temperature (≤ 25°C) is acceptable if exposure to excessive heat and light are avoided.

6. **Shelf life (expiry date)**

   If literature has indicated a shelf life of less than 30 days, this is stated in the 'shelf life' section of the batch sheet and should be applied. An arbitrary maximum shelf life of 30 days has been applied so even if literature has indicated stability for more than 30 days, the batch sheet states '30 days'. This is because many stability studies do not assess the effect of in-use conditions on physical, chemical and microbiological stability. Stability studies are carried out in controlled conditions that do not replicate patient use and storage. This conservative approach has been applied to limit potential microbial contamination, evaporation of vehicle and other adverse effects due to in-use conditions.

7. **Further information / CPD opportunities**

   Further information on extemporaneous compounding can be found through these links:

   a. Extemporaneously compounded medicines
      Falconer JR, Steadman KJ. Extemporaneously compounded medicines. Australian Prescriber. 2017; 40(1): 5-8.
   b. Guidance for pharmacists on extemporaneous dispensing
      Pharmaceutical Society of Ireland. Guidance for pharmacists on extemporaneous dispensing. Version 1 June 2015.

On behalf of the Compounding Working Group

David Woods
Chair, Compounding Working Group
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