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EXTEMPORANEOUS ORAL LIQUID MEDICATIONS – A REVIEW OF STABILITY ISSUES

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The pharmacist, both in community and hospital pharmacy practice, is often challenged with the preparation of a liquid dosage form not available commercially. A number of parameters need to be considered in the formulation of both a stable and bioavailable liquid dosage form, however limited formulation and stability data is available to the pharmacist. This study reviews the stability considerations of 83 liquid dosage forms, extemporaneously prepared from commercially available products as opposed to raw material, as this is the situation most commonly encountered in practice. Results indicate that only 7.2 % of the formulations (i.e. captopril, hydralazine hydrochloride, isoniazid, levothyroxine sodium, phenoxybenzamine hydrochloride, and tetracycline hydrochloride) present stability considerations. Inclusion of the antioxidant, sodium ascorbate in the captopril liquid dosage form resulted in improved stability at 4°C. Hydralazine hydrochloride, isoniazid and phenoxybenzamine hydrochloride were adversely affected due to interactions with excipients in the formulation, while the effect of the preservative in lowering the pH in a levothyroxine sodium mixture resulted in decreased stability. Interestingly the instability of these formulations was primarily due to interactions between the active pharmaceutical ingredient (API) and the formulation excipients, rather than degradation of the API by standard routes such as oxidation, hydrolysis, photolysis or thermolysis. This low percentage of instability illustrates the low risk associated with these dosage forms. Further, pharmacists taking cognisance of factors such as drug stability, mechanisms and routes of degradation, and potential interactions with excipients in the tablets and/or capsules utilised in the preparation of the formulation, are further able to minimise the risk involved. When considering the safety and efficacy of liquid dosage forms prepared extemporaneously, it is therefore important to consider not only the stability of the drug substance but also the entire formulation. A management flow chart to address the issues of liquid preparations in practice is presented to further assist the pharmacist in minimising the risk involved, thus ensuring that safe, effective and high quality products are delivered to patients.