DEVELOPMENT, STABILITY AND FLAVOUR ACCEPTABILITY OF TWO ORAL LIQUID FORMULATIONS OF PHENOBARBITAL FOR USE IN PAEDIATRICS

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Background and Objectives
Phenobarbital has been a part of the antiepileptic therapeutic arsenal since 1912 and remains the mainstay treatment for neonatal seizures. The pharmaceutical industry supplies oral solid dosage forms that are generally inadequate for paediatric needs. This obliges pharmacies to prepare capsules with doses corresponding to the age and weight of the children. To reduce individualised preparations, oral liquids have been developed. In the case of phenobarbital no such preparations are available on the Swiss market except an elixir containing alcohol which is not recommended for children. The objective of this study was to formulate oral liquid solutions of phenobarbital covering the usual paediatric and neonatal doses (5 - 45mg), to carry out a flavour acceptability evaluation in adults using a standard questionnaire and to determine the chemical stability of the solutions.

Methods
Two alcohol-free solutions, containing 5mg ml of phenobarbital as the sodium salt, were prepared with (WS) and without sorbitol (NS), saccharin sodium as artificial sweetener, parabens as preservatives, glycerol and the chosen flavour (cf. Table 1). Twenty five adult volunteers were enrolled to determine flavour acceptability of 6 flavours in 4 combinations, using a standardised questionnaire that included parameters such as bitterness, sweetness, acidity, odour etc...

Conclusions
The two oral formulations of phenobarbital were found to be flavour acceptable for adults and chemically stable for 150 days at 25°C. It will be necessary to determine which of them will be used and to test it for paediatric approval. This kind of preparation, as well as reducing the number of individual preparations contributes to security improvement in drug use by avoiding errors due to the large number of dosages, the extemporaneous manufacture and the absence of analytical controls.

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Possible conflict of interest : nothing to disclose