

THE IN VITRO NEUTRALISATION CHARACTERISTICS OF OLEAGINOUS ANTACID SUSPENSIONS

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The preparation of oily antacid suspensions has been investigated in our laboratories with particular reference to any effects the oil may exert on the neutralisation characteristics of the formulation. It has been previously reported that oil coating had no retardation effect on the release of the antacid agent in gastric juice. (William H Rorer Inc 1973).

The in vitro test method adopted for this work is based on the original method of Fuchs (1949). In our method the pH of a reaction mixture originally containing 100 mls of 0.05 M hydrochloric acid and the antacid under test, is continuously recorded while 0.1 M hydrochloric acid is continually added to the system at the rate of 2 mls/minute. A constant level device maintains the total volume of the system at 100 mls.

We have concluded that the major influence on in vitro neutralisation characteristics is the degree of emulsification of the oil formulation in the aqueous test medium. Figure 1 shows the effect of adding Polysorbate 80 and sorbitan monooleate to oil suspensions containing calcium carbonate and magnesium hydroxide.

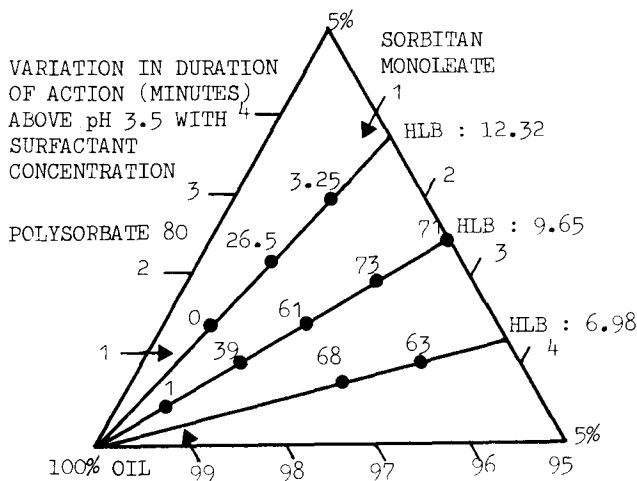


Figure 1

Variation of the HLB value of the surfactant system results in marked changes in the duration of the action recorded. Careful selection of the HLB value of the system may therefore offer a means of designing a formulation with the desired characteristics. Other factors found to exert influence on the in vitro neutralisation characteristic are :

- i) the size and nature of the suspended particles
- ii) the viscosity of the suspension.

Variation of these parameters, particularly the particle size, provides a further means of controlling the neutralisation profile of the formulation.

Burton, J.S. (1975) Foams Proc. Symp. : 127-45

Fuchs, C. (1949) Drug and Cosmetic Industry 64 : 692

William H. Rorer Inc. (1973) UK Patent No. 1380206