

BRIEF COMMUNICATIONS

Isaac O. Kibwage, PhD, MPS, CChem MRSC

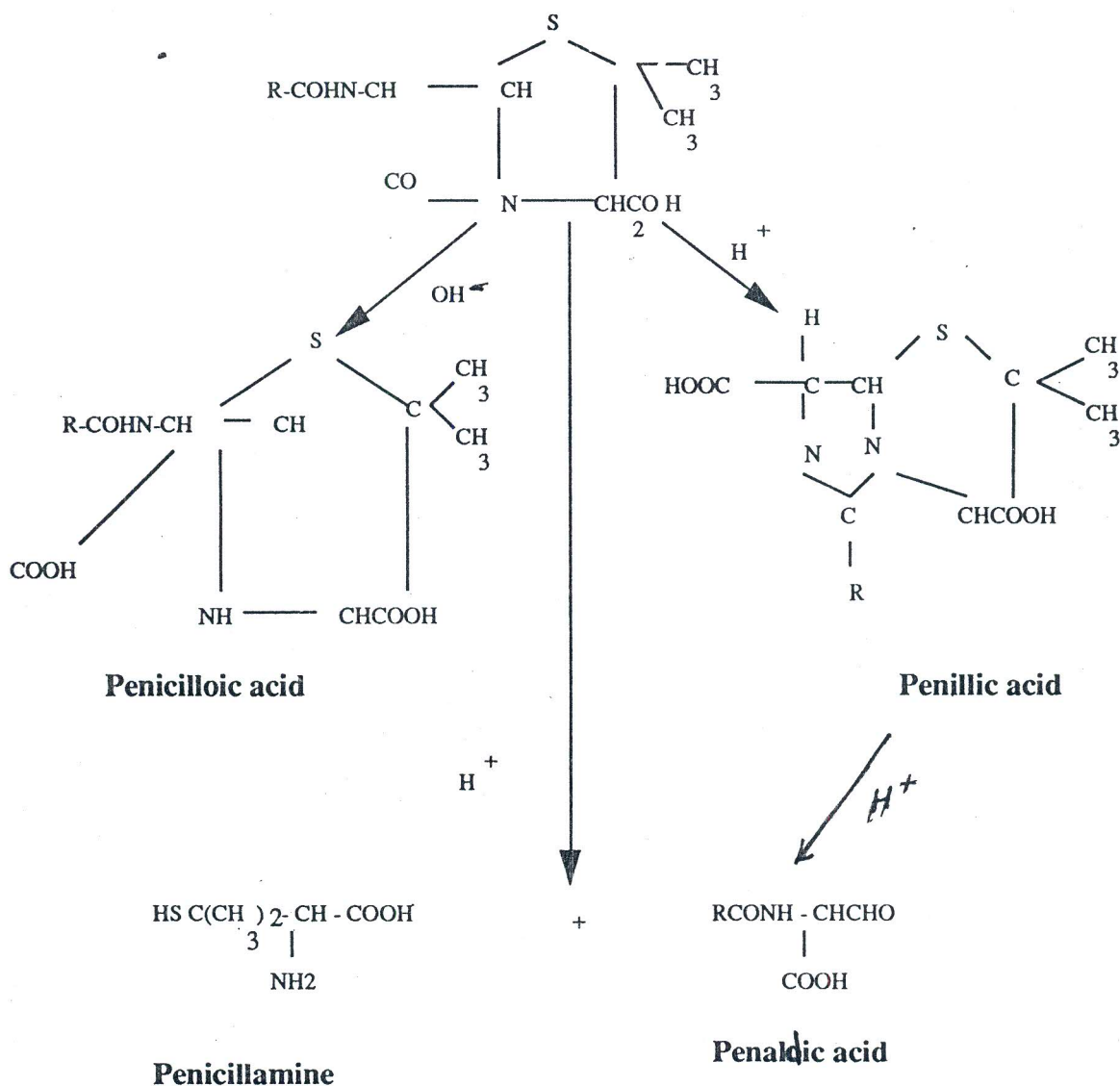
Sarah Vugigi, BPharm, MPS

Drug Analysis and Research Unit, University of Nairobi

QUALITY OF PHENOXYMETHYLPENICILLIN DRY SUSPENSIONS

The antibiotic phenoxymethylpenicillin (penicillin V) is still a drug of choice as a prophylactic agent in rheumatic fever and in the treatment of otitis media, erysipelas and tonsillitis. Penicillin V is composed of the biologically important fused thiazolidine and beta-lactam rings. These rings are unstable in aqueous media both at low and high pH values wherein they undergo hydrolysis as shown in Figure 1. The hydrolytic products have no antibacterial activity.

Fig. 1. Acid and base catalysed decomposition of penicillin in aqueous media



Penicillin V is formulated as a dry suspension which is the suitable preparation for use by children. The dry suspension is reconstituted with water just before use. Such a suspension or elixir is normally assigned a maximum shelf-life of seven days. It is, therefore, important that the concentration of penicillin V be within specified limits for the duration of the shelf-life.

Method

Samples of penicillin V dry syrup from the manufacturers, Dawa Pharmaceuticals, Laboratory and Allied, Elys Chemical industries, Mac's Pharmaceuticals, Regal Pharmaceuticals and Servipharm were evaluated using the pharmacopoeial methods. The products were sampled from those on the Kenyan Market, as were the dry syrups. The same procedure was maintained throughout the assay. The pH of reconstituted suspensions from Regal and Servipharm was investigated during the shelf-life period.

Results and discussion.

The products were of loose powder except those from Regal which had formed cakes. Further examination showed the containers of the two had caps that were not tight. This allowed entry of moisture into the bottles, resulting in the caking of the diluent which is sugar. All the syrups had label claims of 125 mg penicillin V per five millilitres when reconstituted. The penicillin V content over the seven days period is shown in Table 1.

Except for products from manufacturer E, all the other products had penicillin V contents within the B.P. specifications. Product A had a penicillin content below the BP's lowest Unit.

Table 1. Penicillin V content of syrups (Mg/5ml)

Manufacturer	Day			
	0	2	5	7
A	130.8	127.7	123.3	126.6
B	108.5	101.8	93.8	91.9
C	1224.4	118.9	118.9	114.4
D	125.0	125.2	121.7	114.4
E	41.9	43.3	33.2	38.3
F	131.1	126.6	109.6	105.3

*Manufacturers names have been withheld for ethical reasons.

Table 2. pH value for penicillin V syrups

Manufacturer	Day			
	0	2	5	7
Regal	5.6	5.4	5.4	5.3
Servipharm	5.7	5.4	5.45	5.4

Product E had a penicillin content of about 35% of the expected.

Further investigation revealed absence of extensive degradation in these products. It was therefore concluded that the low penicillin content in products B and E was due to deliberate use of low amounts. The degradation of penicillin V in each product was minimal and gradual, indicating good stability of the syrups.

Since stability of penicillin is a function of pH, two products were chosen to investigate change in pH of the syrups during the shelf-life. The results are presented in Table 2 and show that pH changes are insignificant. This indicates use of buffer systems in the formulae.

In conclusion, it was observed that the penicillin V dry syrups are properly formulated with an incorporation of buffers to ensure maximum stability during the shelf-life of the reconstituted syrup. Nevertheless, pharmacists, doctors or nurses who dispense medicines should check the products to check for caking. Caking of the dry syrup implies presence of excessive moisture and probability of extensive degradation in spite of the presence of a buffer. It is advisable that in such situations, the samples are discarded, but if the stock is much, advice should be sought from the Drug Analysis and Research Unit, Department of Pharmacy, University of Nairobi or from any other dependable drug analysis unit in your region.