LETTERS TO THE EDITOR

Preservation of ophthalmic solutions: some observations on the use of chlorbutol in plastic containers

H. D. Blackburn, A. E. Polack*, M. S. Roberts, School of Pharmacy, University of Tasmania, Hobart, GPO Box 252C, Tasmania, Australia 7001

Richardson, Davies & others (1977) in their report of loss of preservatives from contact lens solutions during storage raise the problem of the use of plastic containers with ophthalmic products. We have shown previously that the concentration of some solutes (in aqueous solution) may decrease during autoclaving in polyethylene containers designed for use with ophthalmic solutions (Goss, Gregerson & Polack, 1968; Polack, Roberts & Schumann, 1970). The concentration of chlorbutol in aqueous solution is reduced to about half of that originally present, during autoclaving in polyethylene containers (Polack, 1975).

Results of a recent survey of the chlorbutol content of a selection of commercially available ophthalmic solutions, packaged in plastic containers, obtained at random from the shelves of community pharmacies in Queensland, Victoria and Tasmania are given in Table 1. The chlorbutol content of the solutions was determined by the method of Koshy, Conwell & Duvall (1967) using eucalyptol as the internal standard.

These data support the point made by Richardson & others (1977) that the concentration stated on the label of a plastic container is not always the same as that inside the container. The low concentrations of preservative shown in Table 1 (relative to the label quantity) when considered together with previously published data (Eriksson, 1967; McCarthy, 1970 a,b, 1972; Richardson & others, 1977) may be an indication of a potentially serious problem. The reduced concentrations of chlorbutol shown in Table 1 may be due to the disappearance of the solute during the sterilization process and/or the subsequent storage period (Friesen & Plein, 1971; Richardson & others, 1977).

*Correspondence

Table 1. Chlorbutol content of some commercially available ophthalmic formulations packaged in plastic containers as individual preparations obtained at random from community pharmacies in Queensland, Victoria and Tasmania.

Formulation and batch code		Unelapsed time to expiry date (months)	No. of containers	Chlorbutol	% (w/v)
I	Δ	22	3	Label 0·5	Actual 0.26
	Ŕ	44	6	0.5	0.02
	A B C	59	3 6 3	ŏ.5	0.34
И	A	1	2	0.5	0.29
	В	4	2 2 2	0.5	0.15
	A B C	17	2	0.054‡	0.24
Ш	Α	28	2	0.5	0.24
	В	40	2 2 2	0.5	0.26
	A B C	42	$\overline{2}$	0.5	0.24
IV	A	†	2	0.5	0.29

^{*} Result represents average of the results in all containers.
† No expiry date given.

Richardson & others (1977) do not appear to have considered the effect of the volume in the container. Recent work in this laboratory has shown that the relation which applies during autoclaving (Polack & others, 1970) is also valid for a number of solutes in aqueous solution during storage in polyethylene at lower temperatures. The rate of disappearance of the solute is therefore increased during normal usage.

February 15, 1978

REFERENCES

Eriksson, K. (1967). Acta pharm. suecica, 4, 261-264.

FRIESEN, W. T. & PLEIN, E M. (1971). Am. J. hosp. Pharm., 28, 507-512.

Goss, J., Gregerson, P. & Polack, A. E. (1968). Ibid., 25, 348-353.

Koshy, K. T., Conwell, R. C. & Duvall, R. N. (1967). J. pharm. Sci., 56, 269-271.

McCarthy, T. J. (1970a). Pharm. Weekblad, 105, 557-563.

McCarthy, T. J. (1970b). Ibid., 105, 1139-1145.

McCarthy, T. J. (1972). Ibid., 107, 1-7.

POLACK, A. E. (1975). Proc. R. Aust. Chem. Inst., 42, 79-82.

POLACK, A. E., ROBERTS, M. S. & SCHUMANN, F. (1970). Am. J. hosp. Pharm., 27, 638-645.

RICHARDSON, N. E., DAVIES, D. J. G., MEAKIN, B. J. & NORTON, D. A. (1977). J. Pharm. Pharmac., 29, 717-722.

[‡] Formulation labelled to also contain 0.001 % w/v chlorocresol.