

THE EFFECT OF IONISING RADIATION ON BECLOMETHAZONE DIPROPIONATE

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Generally, pharmaceuticals are considerably less stable in aqueous solution to ionising radiations than in the dry solid state or in ointment bases (Phillips, 1973). We have found that micellar surfactants, such as CTAB and sodium lauryl sulphate, modified the sensitivity of benzocaine to such radiolytic products of water as the hydroxyl radical, the hydrogen atom and the hydrated electron (Chingpaisal et al 1977; Chingpaisal 1979). This communication is a report on the sensitivity of beclomethazone dipropionate to gamma-irradiation in the dry state and in the presence of methanol and propylene glycol which is used to incorporate the steroid in the official Beclomethazone Ointment, B.P.

Beclomethazone dipropionate powder and 0.04% w/v solutions of the powder in methanol and propylene glycol were irradiated in a cobalt 60 source and samples taken at time intervals for assaying the residual content of the steroid. 20 μ l aliquots of suitable dilutions of the samples were injected on to a 10cm Spherisorb S5 ODS column, using a mobile phase consisting of methanol-water mixture (64:36). Deoxycorticosterone was used as an internal standard and detection was at 239nm. Quantification of the beclomethazone dipropionate was by peak height ratio and the calculated percentage residual concentrations of the steroid are plotted against dose of irradiation in Fig.1.

It is apparent that beclomethazone dipropionate in the dry solid state is not affected by gamma radiation whereas it is sensitive in the presence of methanol and propylene glycol. As propylene glycol apparently increases the drug's sensitivity to ionising radiation, this could explain some of the observed differences in the effect of gamma radiation on beclomethazone cream and beclomethazone ointment which we have also investigated.

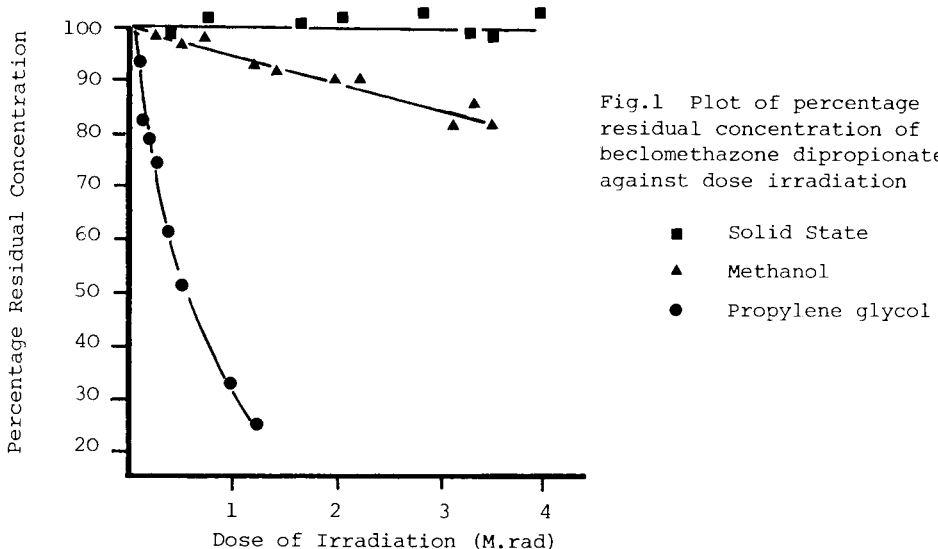


Fig.1 Plot of percentage residual concentration of beclomethazone dipropionate against dose irradiation

- Solid State
- ▲ Methanol
- Propylene glycol

Phillips, G.O. (1973) Technical Report Series No.149 "Manual on Radiation Sterilization of Medical and Biological Materials", International Atomic Energy Agency, Vienna

Chingpaisal, P. et al (1977) J. Pharm. Pharmac. 29, 47P

Chingpaisal, P. (1979) M.Sc. Thesis. "The Sensitivity of Benzocaine Solutions and Creams to Gamma-Radiation", University of Bath