THE EFFECT OF LONG TERM STORAGE ON THE BLEEDING NUMBER AND MICROSCOPICAL APPEARANCE OF PROCESSED WHITE SOFT PARAFFIN

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White soft paraffin (WSP) is a major component of many pharmaceutical topical products. It has many useful properties, but at least one major drawback, this being its susceptibility to syneresis, i.e. the tendency for it to separate into solid and liquid phases during storage. Earlier work performed on WSP has shown that the extent of syneresis exhibited by a sample may be influenced by its processing history. Dash (1988) reported that the bleeding number and microscopical structure of WSP samples alters as a function of the minimum temperature to which a melted sample was stirred during solidification.

In the current work, 100g samples of WSP (ex-Wellcome) were placed in 200 ml glass jars and heated to 80 °C to ensure full liquification. The samples were subjected to a fixed rate of shear (Citenco FHP-1 motor at 60 rpm, fitted with a 40 mm paddle), as they cooled under ambient conditions to room temperature. Shearing was stopped at certain predetermined temperatures for different samples, after which they were left to cool to room temperature unaided. The products were stored at constant temperature (25 ± 0.5 °C) and aliquots were removed at various times over a 365 day period for structural examination.

Optical Microscopy (Olympus, BHS) of the freshly prepared products demonstrated that when stirring was terminated at temperatures higher than 35 °C a cohesive structure composing of many large (ca 100 um) acicular needle crystals on a continuous background was present. When stirring was continued below 35 °C there was a gradual change from needle crystals to a structure composed of globular crystal deposits of varying sizes, apparently not connected to each other and separated by areas of free oil. Free oil was assessed by means of a bleeding study (Fig. 1) (Whatman Chr-1 paper, 24 hours at 32 °C), a value of between 29-30 units was obtained for products in which stirring was terminated above 35 °C, however, those stirred to lower temperatures had a significantly higher free oil content (bleed number ca 39 units).

The aged samples (Fig. 2) showed no evidence of structural recovery for products that were stirred down to 25 or 30 °C over the 1 year period. Samples stirred to temperatures that approached 30 °C deteriorated during storage. The rate of deterioration of the structure was directly related to the temperature at which stirring was terminated, the higher the termination point, the less significant was the deterioration. Microscopical examination of the products could not detect any significant changes over the storage period.

Figure 1. Bleeding number of 1 day aged products, as a function of the temperature at which stirring was terminated.

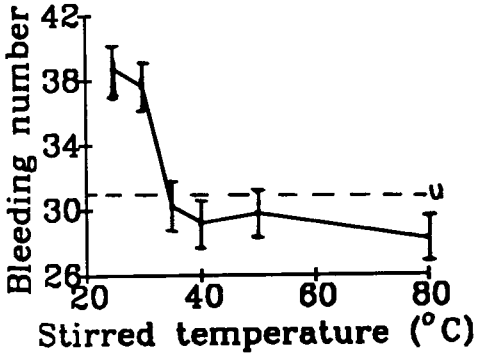
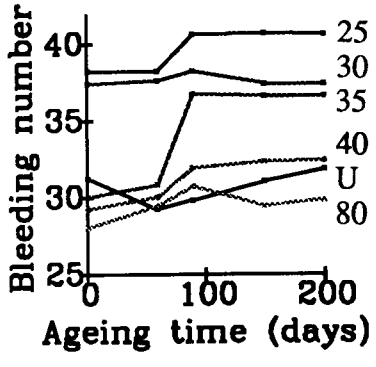


Figure 2. Ageing profile of products
(Key - U = untreated, numbers = temperature at which stirring was terminated)



Dash,M. (1988), R P Scherer Award Lecture, Unpublished.