

BRITISH PHARMACOPŒIA COMMISSION
8 BULSTRODE STREET LONDON W1M 5FT

497 **GRO-C**

TELEPHONE 01-933-7204

REFERENCE

23rd November, 1977.

Dear Dr Thomas,

I enclose a copy of my notes of your decisions conveyed during our telephone conversation of Monday morning, and the comments from members and makers. We shall amend the monographs as indicated before we send them to the printer, subject to your confirmation, and I should be glad if you would let me know if I have misconstrued anything.

With best wishes,

Yours sincerely,

GRO-C

Dr Duncan
18/11/78

APPENDUM 1978
Committee IV: Biological Products
Blood Products Panel.

2p Dr Duncan Thomas re. comments from members etc.

Anticoagulant and Preservative Solutions for Blood ~~X~~

Travelled comment re p. 1, l. 4. D.P.T. agrees 'was a minimum of delay'

Dried Human Antihaemophilic Fraction (Revised monograph)

1. Dr Bidwell's comment; p. 1, line 22. keep 12 hr (WHO. require 6 hr) - only say 'should be ...'. Add 'preferably'.
2. Mr Valler's comment, p 2, l. 15. Change to 'clotting factor VIII'.
3. EB's comment re pH. p. 2, l. 16-17. Change to '6.8 to 7.4'.
4. EB's comment re p. 3, l. 23. change to '... protein in g per litre'.
5. W. d'A. M's comment re p. 3, l. 29-30. Dr Thomas feels that most haemophiliacs are v. well aware of hepatitis risk - and indeed a lot given have had hepatitis. Therefore he does not agree with the argument (feels older generation would be more inclined to keep patient in the dark whereas younger practitioners would hold view that patient should be made fully aware of risk). He also said that (subject ^{does} to confirmation) all splees. from USA. have warning on label - FDA. requirement - if we hear nothing leave in for factor VIII ^{and} (but don't put in for Factor IX).

Dried Human Factor IX Fraction

1. Dr Bidwell's comment re p. 1, l. 10. Change to: - 'may have been stored for longer periods at a temperature ...'.
2. E.B.'s comments re p. 2, l. 2 and 22. Change 'tris-buffered saline' to water. ^{D.P.T.} [Also accepts change from 'tris-buffered saline' to 'tris-chloride buffer solution, pH 7.5'.
3. E.B.'s comment re p. 3, l. 33 to read '1 ml of a 5 per cent w/v solution of trichloroacetic acid treated ...'.
4. E.B.'s comment re p. 4, l. 34. Change to '...protein is g per litre ...'.
5. Mr Valler's comments on p. 4, l. 34 - 37. Change to and:
'phosphate ions in millimoles per litre and for preparations containing heparin, the number of units of heparin per container; (4) the name and amount of any other ^{added} substance contained in it; (5) the volume ...' [and change subsequent numbers accordingly]
6. E.B.'s comments re p. 6, l. 11. '49.7' to read '4.97' (already notified by Mr Snape).

Heparin Calcium
Heparin Sodium

Evans' comments re sterility requirement. Keep in monographs for Add. and reconsider for B.P. 1980 replaced with test for microbial contamination. [Spoke to Mr Newbery re this and he accepts - he will also provide proposals for more specific clarity and colour of solution tests in terms of Ph. Eur. by beginning of March 1978.]

board no longer
needed