



Armour Pharmaceutical Company Limited

Hampden Park, Eastbourne, Sussex BN22 9AG Registered Office Registered No 625229 England

Office: tel. Eastbourne 21422 (STD 0323) telex 87141 Armiab Eastbourne

Plant: tel. Eastbourne 51111 telex 877411 Labarm. telegrams and cables. Armolab Eastbourne

Dr. D.P. Thomas,
Head of Division of Blood Products,
National Institute for Biological Standards & Control,
Holly Hill,
LONDON, NW3 6RB.

7th September, 1978

Dear Dr. Thomas,

Dried Human Antihaemophilic Fraction (Sterile) B.P. - Factorate

Recently, I have discussed informally with Dr. Barraclough, the possibility of using our parent company's potency determination as the only assay in the protocol submission to you for release of batches of our Factorate.

This follows assays of the International Standard against the American standard by Armour Pharmaceutical Company in Kankakee, and a statement they have received from the Bureau of Biologies which states unequivocally that, in their opinion, the two units are identical. In addition we have analysed the results from the comparison of assays on 45 batches of our Factorate assayed in AHF units and by Oxford Haemophilia Centre against the International Standard; as you will see this supports the BOB statement. We therefore wish to discontinue the second assay and would appreciate your early approval of our request.

Also enclosed is a copy of our parent company's assay procedure which Dr. Barraclough requested me to submit with our data.

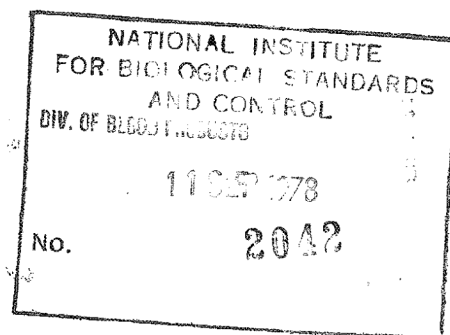
Yours sincerely,
ARMOUR PHARMACEUTICAL CO. LTD.,

GRO-C

E.R. JAMES, C. Chem. MRIC,
Quality Control Manager.

cc. Mr. P.B. Lloyd
file.

enc.



ARMOUR PHARMACEUTICAL CO. LTD.

FACTORATE - COMPARISON OF KANKAKEE AND OXFORD HC ASSAYS

BATCH NO.	AHF	IU
P75402	272	235
P75702	222	209
P79805	282	294
P80006	292	283
P80106	305	312
P82007	310	318
P82107	295	335
P81807	285	310
P81907	312	328
P81506	330	374
P81406	318	320
P84108	295	264
P84308	312	276
P88812	252	301
P88912	280	278
P89012	285	309
P87811	290	304
R98806	290	309
R99407	268	248
R2709	565	550
R98906	302	302
R97906	615	617
R1208	300	284
R7011	290	276
R6911	262	250
R7311	250	248
R7411	260	288
R8112	282	265
R8312	272	272
R5610	675	656
R7111	268	273
R8212	280	275
R8412	278	226
R6511	520	544
S10001	290	278
S10101	292	276
R5810	680	677
R5910	685	657
S9801	275	264
S10201	250	251
S9901	342	298
S12803	300	282
S13103	285	278
S12303	740	635
R8612	723	632

Regression Analysis

Slope 0.908

Ideal 1.00

Intercept 25.2

Ideal 0.00

Std. Deviation % 7.93 (Between both methods of analysis)

Mean % 101.9

There is a good correlation between the two sets of data.

