DHSS FILE

Armour Pharmaceutical Company Limited

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WJT/JJ

10th February, 1982

Variations Section,
Department of Health and Social Security,
Medicines Division,
Market Towers,
1 Nine Elms Lane,
Vauxhall,
LONDON,
SW8 5NQ

Dear Sirs,

PRODUCT LICENCE VARIATION
HIGH POTENCY FACTORATE - PL 0231/0044

We enclose two copies of Form MLA 221 completed in respect of our application to vary our Product Licence PL 0231/0044 for High Potency Factorate to include a new presentation containing 2000 iu/vial.

The manufacture and testing of this presentation is identical to the procedures already supplied in connection with the other presentations covered by this licence and a finished product specification for this product is included in our application.

We trust that the data supplied will be adequate for your purposes but in the event of further queries the undersigned would be pleased to assist. We would appreciate your early attention to this matter and look forward to hearing from you in due course.

Yours faithfully,
ARMOUR PHARMACEUTICAL COMPANY LTD.

GRO-C

W. J. TARBIT
Registration Department

Encs.

ARMOUR PHARMACEUTICAL COMPANY LIMITED

Eastbourne **England**

QUALITY CONTROL DEPARTMENT

SPECIFICATION

	No. S90/1
Title	Date Feb 1982
HIGH POTENCY FACTORATE (NOMINAL 2000 IU/VIAL) (DRIED HUMAN ANTIHAEMOPHILIC FRACTION (STERILE) B.P.)	By E. R. James
	Page 1 of 2

DESCRIPTION

A white to pale yellow lyophilised cake in a 100 ml vial closed with a brown non-traumatic flip-cap.

SAMPLING

Ten pre bulk-shipment vials supplied by Q.C. Department, A.P.C., Kankakee. No samples taken of bulk delivery.

TEST	SPECIFICATION	METHOD
Mammalian Protein	Human positive Bovine, ovine and porcine negative	351/K
Potency	Not less than 1600 iu/vial (not less than 26.5 iu/ml when reconstituted with 60 ml Water for Injections B.P.)	B.P.
Heparin	Not more than 50 iu per vial	1073/K
Total Protein	Not more than 1200 mg per vial (not more than 20 g/litre reconstituted)	993/K
Fibrinogen	Not more than 960 mg per vial (not more than 16 g/litre reconstituted)	1344/K
Aluminium	Not more than 300 µg per vial	995/K
Moisture	Not more than 2% w/w	43-D(K)
Freedom from abnormal toxicity		
Mouse	Passes Test	963/K
Guinea Pig	Passes Test	(Inject >538 iu/kg)
Pyrogens	Passes Test	208/K (10 iu/kg)

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TEST	SPECIFICATION	METHOD
Sterility	Passes Test	303/K
Solution Time	Not more than 30 minutes, typically less than 10 minutes	1343/K
pH	6.8 - 7.4 (when reconstituted with 60 ml of Water for Injections B.P.)	53/K
Isoagglutinins	Not more than 1:256 without pre-dilution and typically less than 1:64 when tested against Anti-A and Anti-B.	386/K
Sodium	Not more than 200 mM per litre (when reconstituted with 60 ml of Water for Injections B.P.)	1301/K
Citrate	Not more than 55 mM per litre (when reconstituted with 60 ml of Water for Injections B.P.)	1402/K
Hepatitis Bs Antigen	Negative	379/K or 1410/K

1767-10

APPLICATION FOR VARIATION OF PRODUCT LICENCE
NOTIFICATION OF CHANGE IN PRODUCT LICENCE

1. Licence Number: 0231/0044 Your reference: R81/84

	At present	Any proposed change
2. Name and Address of Licence Holder:	Armour Pharmaceutical Company Ltd., Hampden Park, Eastbourne, East Sussex.	

Name of Product: HIGH POTENCY FACTORATE

3. Please indicate if you have changed or propose to change any of the following:

- ☐ Pharmaceutical Form
- ☐ Active Ingredients
- ☐ Indications
- ☐ Dosage
- ☐ Contra-Indications and Warnings
- ☐ Method of Retail Sale and Supply
- ☐ Manufacturer
- ☐ Date of Expiry of Licence
- ☐ Activities covered by Licence
- ☐ Assembler
- ☐ Arrangements for Storage
- ☐ Container
- ☐ Shelf Life or Storage Precautions
- ☐ Method of Manufacture
- ☐ Quality Control Procedures
- ☐ Finished Product Specifications
- ☐ Excipients
- ☐ Supplier of Active Ingredients
- ☒ Other (specify) Additional presentatior

4. On the attached sheet, give the present particulars, the change or proposed change and the reason. Supporting evidence should be attached to the application. Please indicate the number of volumes and number of copies sent:-
1 volume, 2 copies

5. If you need approval urgently, please give the date by which an answer is required: Would appreciate approval by 28.2.82

For Licensing Authority use only

F	N	M	P	C	A	NF	U

Pharm:
Med:

Received .....
Acknowledged .....

Approved:
Date:

ARMOUR001004

Licence Number: 0231/0044 Your reference: R81/84

Name of Product: HIGH POTENCY FACTORATE

Give the present particulars and the change or proposed change. If the particulars appear on the licence document itself, you should give them exactly as they are given on the licence, or as you propose they should be given. (The items in the lefthand column of (3) are usually specified on product licences.)

Present	Proposed
Vials containing the following dose strengths: 250 iu/vial nominal 500 iu/vial nominal 1000 iu/vial nominal	Additional dose strength of 2000 iu/vial nominal

(continue on a separate sheet if necessary)

Reason for the change

Certain situations in treatment of patients with haemophilia A, require use of large doses of Factor VIII. This larger dose-strength presentation provides a more convenient way of achieving such treatment levels.

I hereby make application for the above licence to be varied in accordance with the proposals given above.

Signed: GRO-C

W. J. TARBIT

Date: 10th February, 1982

ARMOUR001005

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