

Name of Product: HIGH POTENCY FACTORATE

Licence Number: PL 0231/0044

2

Address for reply:

AI000116

J.H.S. file

Mr. C.J. Collins,
Armour Pharmaceutical Company Limited,
St. Leonard's House,
St. Leonard's Road,
Eastbourne, E. Sussex.

20 JUN 1985

Give the present product particulars and proposed change. If the change refers to particulars on the Schedule of the product licence you should give them exactly as they currently appear on the licence and how you propose they should be stated (continue on a separate sheet if necessary). Please attach supporting evidence to the application and indicate the number of volumes and copies.

Present

Proposed

Method of Manufacture

As currently detailed in the
particulars submitted under PL 0231/0044
(see also for reference
PL 0231/0072 - H.P. Factorate Heat
Treated)

The method of manufacture will be
as currently undertaken but with
an additional step involving heat
treatment. The finished lyophilised
vials from the current process will
be subjected to a heat treatment in
a water bath at an attained temperature
of $60^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for a period of 30 hours.

I hereby make application for the above licence to be changed in accordance with the proposals given above and certify that the changes will not adversely affect the quality of the product.

Signed

GRO-C

Date

4th January 1985

Status Regulatory Affairs Manager

The licensing authority *consents to/acknowledges your request to change the product licence as outlined at 8 above.

Please retain this form with the formal documents relating to the product licence as evidence of *approval/notification of the change.

Signed:

GRO-C

Date:

7 JUN 1985

A person authorised to sign
on behalf of the Secretary of
State for Social Services

*Delete as appropriate

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