

MEDICINES ACTS 1968 AND 1971

APPLICATION FOR A PRODUCT LICENCE

1. Name of Product:	PROFILATE HEAT TREATED	PL/4447/0007
2. Full name and address of proposed licence holder:	ALPHA Therapeutic U.K. Ltd. Unit 10, Lodge Way Fison Way Industrial Estate Thetford, Norfolk IP24 1HE	
3. Trading style to be shown on licence if different from above:	not applicable	
4. Role of proposed licence holder: (please tick in appropriate box(es))	<input type="checkbox"/> (i) as person responsible for composition of product manufactured in UK, <input checked="" type="checkbox"/> (ii) in the case of a proprietary medicinal product, as person responsible for placing it on the UK market, <input checked="" type="checkbox"/> (iii) as person who imports or procures its importation, <input checked="" type="checkbox"/> (iv) as person who first sells or supplies it as a medicinal product.	
5. Activities for which licence is required: (please tick in appropriate box(es))	<input type="checkbox"/> (i) selling or supplying product in the UK <input checked="" type="checkbox"/> (ii) procuring the manufacture or assembly of the product for sale or supply in the UK. <input checked="" type="checkbox"/> (iii) importing or procuring the importation of the product. <input type="checkbox"/> (iv) Other (specify)	
6. Applicants own reference no:	Wholesalers licence No. WL/4447/001 (Ref.No. 4029)	
7. Details of earlier applications:	not applicable	

8. To cover sale and supply of the product manufactured before the grant of the licence:

~~YES~~/NO

9. Scientific Evidence:

(i) Chemistry and Pharmacy 350 Pages

(ii) Experimental and Biological Studies 79 Pages

(iii) Clinical Trials 40 Pages

10. Do you give your consent to the disclosure to the British Pharmacopoeia Commission of information given in or in connection with this application or to the pharmaceutical standards applicable to the product or its active ingredient on the understanding that such information will not be used in the compilation of a pharmacopoeia monograph without prior reference to you?

YES/~~NO~~

11. ~~11~~ We apply for the grant of a product licence to the proposed holder named above in respect of the product(s) to which the Product Particulars in Part 1A refer and in accordance with the other particulars annexed; the said licence to be for a period of five years and subject to the following provisions -

11.1 All the Standard Provisions applicable to product licences under regulations for the time being in force under Section 47 of The Medicines Act 1968.

11.2 The product shall not be recommended to be used for any purpose other than those specified in the Product Particulars as Uses, and shall be sold or supplied in accordance with the said Product Particulars except in so far as may from time to time be approved by the licensing authority.

11.3 The specification of the constituents and of the finished product shall be in accordance with the information contained in or furnished in connection with the application.

11.4 The product is to be manufactured only in accordance with the methods set out in this application or furnished in connection with it.

11.5 No material information has been omitted (within the knowledge of the signatory).

Date 3/1/85

Signature

GRO-C

State capacity in which signed

MARKETING DIRECTOR