

APPLICATIONS FOR CHANGE OF PRODUCT LICENCE

1. PRODUCT NAME: KOATE LICENCE NUMBER: 0055/0065

2. Name and Address of Licence Holder Miles Laboratories Ltd.,
Stoke Court,
Stoke Poges.
Slough SL2 4LY.

Telephone Number: GRO-C

Name of Contact: Mrs. M.W. Tatt

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

- | | |
|---|--|
| <input type="checkbox"/> Name of Product | <input type="checkbox"/> Manufacturing process where changes does not affect quality |
| <input type="checkbox"/> Pharmaceutical Form | <input type="checkbox"/> Manufacturer or assembler |
| <input type="checkbox"/> Specification of container, shelf life and storage precautions | <input type="checkbox"/> Supplier of active ingredients |
| <input checked="" type="checkbox"/> Manufacturing process where change affects the quality of the product | <input type="checkbox"/> Quality control procedure |
| <input type="checkbox"/> Site of Manufacture | <input type="checkbox"/> Method of retail sale or supply |
| <input type="checkbox"/> Finished product specification | <input type="checkbox"/> Activities covered by the licence |
| <input type="checkbox"/> Ingredients | <input type="checkbox"/> Labels, leaflets, data sheets |
| <input type="checkbox"/> Uses, directions for use, route of administration | <input type="checkbox"/> Cancellation of licence |
| <input type="checkbox"/> Dosage and dosage schedule | <input type="checkbox"/> Other |
| <input type="checkbox"/> Contraindications, precautions and warnings | |

4. Reasons for change

The process changes were made in order to produce a product suitable for heat-treatment. The adoption of a single process for both heated and non-heated product affords stream-lining of production.

For Licensing Authority use only:

5. Application dated	Route
Received	Pharm:
Stats ref	Med:
Code	
ADP	Application Approved*/Refused (See M.)
<input type="checkbox"/> no copies required	<input type="checkbox"/> MLA 221 and flagged pages only
<input type="checkbox"/> MLA 221 only	<input type="checkbox"/> Complete data
	Pharmacist: Date:
	Doctor: Date:

*Delete as appropriate

6. Name of Product KOATE Licence Number: 0055/0065

7. Address for reply:

Mrs. M.W. Tatt,
Miles Laboratories Ltd.,
P.O. Box 37, Stoke Court,
Stoke Poges.
Slough. SL2 4LY.

8. 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

Manufacturing process

Cold ethanol precipitation
of Factor VIII fraction

(Details of process provided
in attached Appendix)

Proposed

Manufacturing process

Glycine precipitation of
Factor VIII fraction

(Details of changes provided
in attached Appendix)

9. 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

Status

Registration Manager

Date 7th December 1984.

10. 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

Date

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

*Delete as appropriate