



Australian Government

**Department of Health and Ageing
Therapeutic Goods Administration**

John Timmins
Nova Pharmaceuticals Australasia Pty Ltd
PO Box 8172
BAULKHAM HILLS NSW 2153

Sponsor Client ID: 41266

GMP Clearance Application MI-2012-CL-05856-3 Notification.

Please be advised that GMP Clearance is approved for the following manufacturer:

Encube Ethicals Private Limited
Plot No. C1-C4 and C17-C20 Madkaim Industrial Estate Madkaim Post Mardol
Ponda Goa 403 404
India

Manufacturer Client ID: 43321

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Semi Solids - Creams, Gels and Ointments	Registered Therapeutic Good	Finished Product Manufacture

This Clearance remains current until 28/12/2015 unless otherwise revoked.

This clearance has been issued with an additional six months to allow re-certification and application activities to be completed before expiry. You are advised to submit a new electronic GMP Clearance application with updated GMP evidence not less than three months prior to the expiry date to avoid delays in the registration/listing of new products and maintain products on the Australian Register of Therapeutic Goods (ARTG). Expired GMP Clearance could result in affected product(s) being removed from the ARTG.

This Clearance letter should be used only for future listing/registration of the product types specified above.

For further information please refer to the Therapeutic Goods Administration website:
<http://www.tga.gov.au/industry/manuf.htm> Alternatively you may contact the undersigned.

Yours sincerely

Cheryl Regan
GMP Clearance Unit
Office of Manufacturing Quality
Therapeutic Goods Administration
21/01/2013