



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Katrina Lea
Aspen Pharma Pty Ltd
34-36 Chandos Street
ST LEONARDS NSW 2065

Sponsor Client ID: 482

GMP Clearance Application MI-2011-CL-06086-3 Notification.

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

Centaur Pharmaceuticals Pvt. Ltd
Plot No 75/76 Chikhloli MIDC, Ambarnath West District Thane
Maharashtra 421 501
India

Manufacturer Client ID: 53041

API Name	Manufacturing Step
alprazolam	Active material manufacture
diazepam	Active material manufacture
oxazepam	Active material manufacture
temazepam	Active material manufacture
zolpidem tartrate	Active material manufacture

This Clearance remains current until 24/09/2014 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



Michael Carland
GMP Clearance Unit
Office of Manufacturing Quality
Monitoring and Compliance Group
Therapeutic Goods Administration
14/09/2011