



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Anne O'Shea
Ballia Holdings Pty Ltd
Level 2 / 61 Station Street
MALVERN VIC 3144

Sponsor Client ID: 15775

GMP Clearance Application MI-2010-CL-07123-3 Notification.

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

Promed Exports Pvt Ltd
Kheran Nihla Tehsil Nalagarh Solan
Himachal Pradesh
India

Manufacturer Client ID: 54727

Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	Not Applicable	Eye Drops	Registered Therapeutic Good	Sterile Finished Product Manufacture

This Clearance remains current until 23/10/2012 unless otherwise revoked.

You are advised to submit a new electronic GMP Clearance application with updated GMP evidence 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 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/manuf/gmpsom.htm> alternatively you may contact the undersigned.

Yours sincerely

Michael Carland
GMP Clearance Unit
Office of Manufacturing Quality
Therapeutic Goods Administration
13/07/2011