



CERTIFICATE

Quality Austria Trainings-, Zertifizierungs- und Begutachtungs GmbH awards this **qualityaustria** certificate to the following organisation:

This **qualityaustria** certificate confirms the application and further development of an effective

Apex Pharmaceuticals Pvt Ltd
HO-13/45 Adarshnagar Birgunj Nepal
Site-Agriculture Farm Road Parwanipur Bara Nepal

ENVIRONMENTAL MANAGEMENT SYSTEMS
complying with the requirements of standard
ISO 14001:2004

Quality Austria Trainings-,
Zertifizierungs- und
Begutachtungs GmbH is
accredited according to
the Austrian Accreditation
Act by the BMWi
(Federal Ministry of
Science, Research and
Economy).

Quality Austria is recognised
as an organisation for
environmental verification
by the BM/LUW (Federal
Ministry of Agriculture,
Forestry, Environment
and Water Management).

Quality Austria is authorised
by the VDA
(Association of the
Automotive Industry).

For accreditation
registration details please
refer to the applicable
decisions or recognition
documents.

Quality Austria is the
Austrian member of ICQI
(International Certification
Network)
DIN EN ISO 9001

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8153-024-000000



Manufacturer and Marketing of Pharmaceuticals products

The validity of the **qualityaustria** certificate will be
maintained via annual surveillance audits and one
renewal audit after three years.

Registration No.: 02605/0

Date of initial issue: 15 October 2014

Valid until: 14 October 2017

Vienna, 15 October 2014

Quality Austria Trainings-, Zertifizierungs- und Begutachtung
A-1010 Vienna, Zelinkagasse 10/3

Scheiber
Konrad Scheiber
General Manager

Hackensauer
Ing. Wolfgang Hackensauer,
Specialist representative

The current validity of the certificate is documented exclusively on the Internet under
<http://www.qualityaustria.com/en/cert> EAC: 13



qualityaustria
Succeed with Quality

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Apex Pharmaceuticals Pvt Ltd
HO-13/45 Adarshnagar Birgunj Nepal
Site-Agriculture Farm Road Parwanipur Bara Nepal

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2008



Quality Austria Trainings-, Zertifizierungs- und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMJV (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental verification by the BMFLW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VDA (Association of the Automotive Industry).

For accreditation registration details please refer to the applicable decisions or recognition documents.

Quality Austria is the Austrian member of IQNet (International Certification Network).



Manufacturer and Marketing of Pharmaceuticals products

The validity of the **qualityaustria** certificate will be maintained via annual surveillance audits and one renewal audit after three years.

Registration No.: 15520/0

Date of initial issue: 15 October 2014

Valid until: 14 October 2017

Vienna, 15 October 2014

Quality Austria Trainings-, Zertifizierungs- und Begutachtungs GmbH
A-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
Konrad Scheiber
General Manager

Eckehard Bauer
Eckehard Bauer, MSc
Specialist representative

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The current validity of the certificate is documented exclusively on the Internet under <http://www.qualityaustria.com/en/cert> EAC: 13

Ministry of Health
Department of Drug Registration
Certificate of Good Manufacturing Practices

This one-page certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).

Certificate No. Apex/14134 Date: 27 January, 2015

On the basis of the inspection carried out on June 18/19, 2015, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name and address of site: **M/S Apex Pharmaceuticals Pvt. Ltd.**
Parwanipur, Bara, Nepal

2. Manufacturer's license number:

3. Table 1:

Dosage Form(s)	Category	Activities
Tablets	Non-Parenteral	Production, Packaging, Quality Control
Capsules	Non-Parenteral	Production, Packaging, Quality Control
Oral Liquid	Non-Parenteral	Production, Packaging, Quality Control
Powder (Powder for oral suspension, granules)	Non-Parenteral	Production, Packaging, Quality Control
Oralmin Cream, Gel	Non-Parenteral	Production, Packaging, Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured during this process lies with the manufacturer.

This certificate remains valid until 27 January, 2018. It becomes invalid if the activities and/or categories certified herein are changed or if the site is no longer considered to be in compliance with GMP.

Address of issuing authority: **17th, Madan Bhawan Park, Bhatbhateni, Kathmandu, Nepal**

Name and function of responsible person: **Narayan Prasad Dhakal, Director General**

Telephone no.: **977-1-4266 227** Fax no.: **977-1-4266 275** Website: **www.dhaka.gov.np**

Signature: *[Signature]* Director General Date: 27 January, 2015

