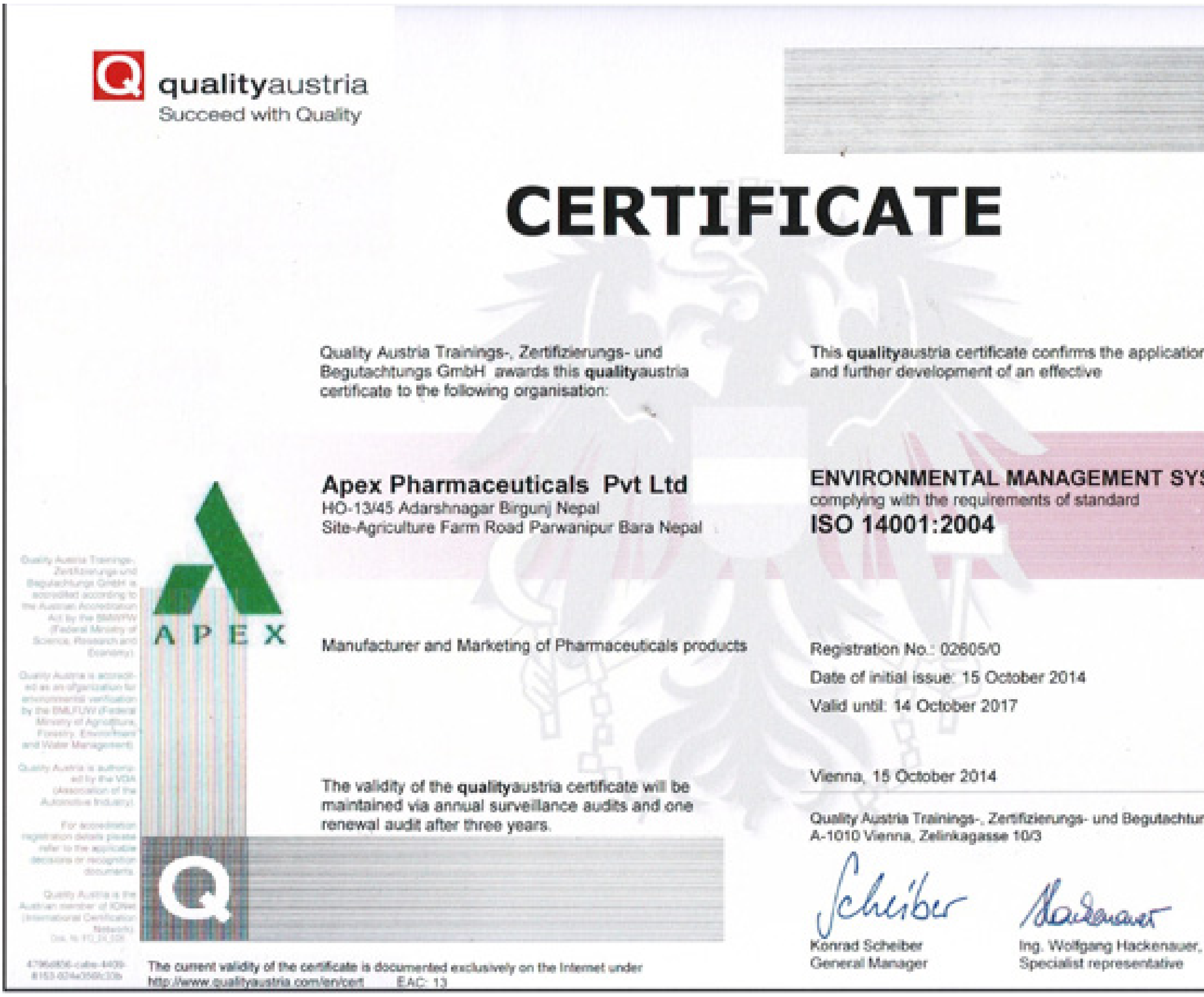


qualityaustria
Succeed with Quality

CERTIFICATE

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

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

A P E X

Manufacturer and Marketing of Pharmaceuticals products

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

This **quality**austria certificate confirms the applicatio
and further development of an effective

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

Registration No.: 02605/0
Date of initial issue: 15 October 2014
Valid until: 14 October 2017

Vienna, 15 October 2014

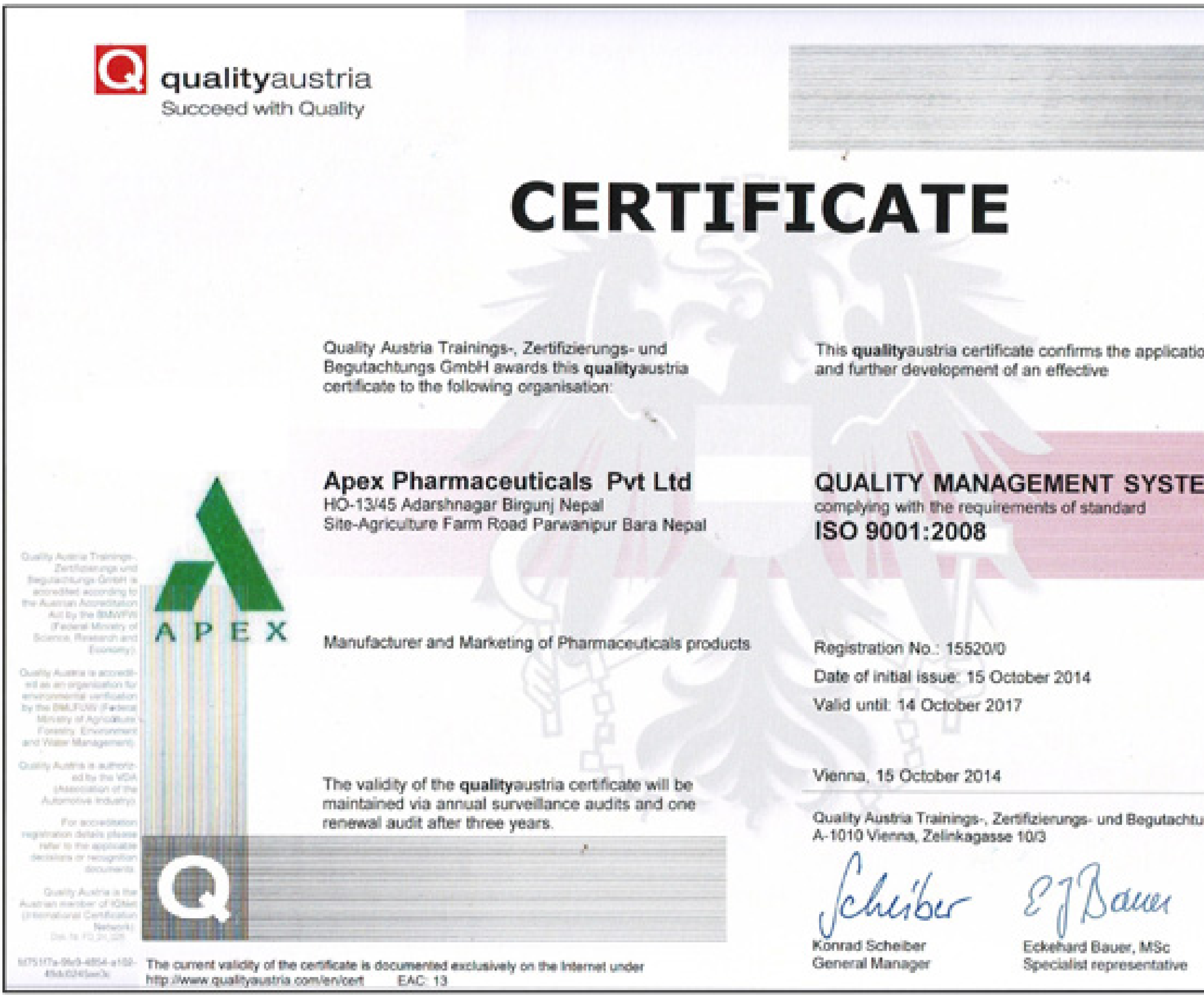
Quality Austria Trainings-, Zertifizierungs- und Begutachtu
A-1010 Vienna, Zelinkagasse 10/3

Scheiber

Konrad Scheiber
General Manager

Ing. Wolfgang Hackenauer,
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

CERTIFICATE

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

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

Manufacturer and Marketing of Pharmaceuticals products

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

This **quality**austria certificate confirms the applicatio
and further development of an effective

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

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 Begutachtu
A-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
General Manager

Eckehard Bauer, MSc
Specialist representative

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

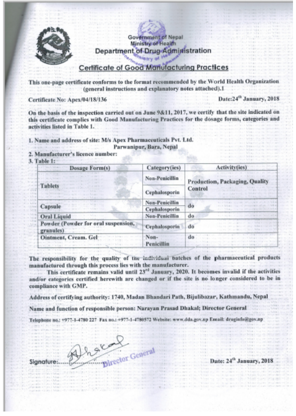
Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

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).

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



Government of Nepal
Ministry of Health
Department of Drug Administration

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).1

Certificate No: Apex/04/18/136

Date:24th January, 2018

On the basis of the inspection carried out on June 9&11, 2017, 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 licence number:
3. Table 1:

Dosage Form(s)	Category(ies)	Activity(ies)
Tablets	Non-Penicillin	Production, Packaging, Quality Control
	Cephalosporin	
Capsule	Non-Penicillin	do
	Cephalosporin	
Oral Liquid	Non-Penicillin	do
Powder (Powder for oral suspension, granules)	Cephalosporin	do
Ointment, Cream. Gel	Non-Penicillin	do

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

This certificate remains valid until 23rd January, 2020. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority: 1740, Madan Bhandari Path, Bijulibazar, Kathmandu, Nepal

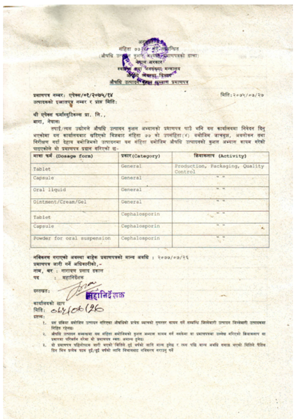
Name and function of responsible person: Narayan Prasad Dhakal; Director General

Telephone no.: +977-1-4780 227 Fax no.: +977-1-4780572 Website: www.dda.gov.np Email: druginfo@gov.np

Signature:.................... Dhakal Director General

Date: 24th January, 2018

Certificates



संहिता ७७ [illegible] सम्बन्धित

(औषधि उत्पादन कुशल अभ्यास प्रमाणपत्रको ढाँचा)

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

औषधि उत्पादन कुशल अभ्यास प्रमाणपत्र

प्रमाणपत्र नम्बर: एपेक्स/०१/२०७५/१४ मिति: २०७५/०७/२७
उत्पादकको इजाजतपत्र नम्बर र प्राप्त मिति:

श्री एपेक्स फर्मास्युटिकल्स प्रा. लि.,
बारा, नेपाल।

तपाईं/त्यस उद्योगले औषधि उत्पादन कुशल अभ्यासको प्रमाणपत्र पाउँ भनि यस कार्यालयमा निवेदन दिनु भएकोमा यस कार्यालयबाट खटिएको विज्ञबाट संहिता ७७ को उपसंहिता (४) बमोजिम जाँचबुझ, अवलोकन तथा निरीक्षण गर्दा देहाय बमोजिमको उत्पादनमा यस संहिता बमोजिम औषधि उत्पादनको कुशल अभ्यास कायम गरेको पाइएकोले यो प्रमाणपत्र प्रदान गरिएको छ-

मात्रा फर्म (Dosage form)	प्रकार (Category)	क्रियाकलाप (Activity)
Tablet	General	Production, Packaging, Quality Control
Capsule	General	" "
Oral liquid	General	" "
Ointment/Cream/Gel	General	" "
Tablet	Cephalosporin	" "
Capsule	Cephalosporin	" "
Powder for oral suspension	Cephalosporin	" "

नविकरण गराएको अवस्था बाहेक प्रमाणपत्रको मान्य अवधि : २०७७/०७/२६
प्रमाणपत्र जारी गर्ने अधिकारीको,-
नाम, थर : नारायण प्रसाद ढकाल
पद : महानिर्देशक

दस्तखत: महानिर्देशक

कार्यालयको छाप
मिति: 075/07/26
द्रष्टव्य: