नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
(अनुगमन, मुल्यांकन तथा कानुन कार्यन्वयन महाशाखा)

फोन नं.: ४७९०४३२
पोष्ट बक्स नं. १००३८
ई-मेल: info@dda.gov.np
inspection@dda.gov.np
मदन भण्डारी पथ, बिजुलीबजार
काठमाडौं, नेपाल

पत्र संख्या: ०८१/०८२
चलानी नं: ०४६८

मिति: २०८१/०८/१४

श्री Apex Pharmaceuticals Pvt. Ltd.
Birgunj-21, Parwanipur, Parsa, Nepal.

विषय: WHO GMP तथा औषधि उत्पादन कुशल अभ्यास प्रमाणीकरण सम्वन्धमा

उपरोक्त सम्वन्धमा मिति २०८१/०८/१४ को विभागीय निर्णयानुसार त्यस उद्योगलाई WHO GMP Guideline वमोजिमको प्रमाणीकरण निर्णय मितिले २ (दुई) वर्ष तथा औषधि उत्पादन कुशल अभ्यास संहिता (पहिलो संशोधन) २०७२ वमोजिमको प्रमाणीकरण निर्णय मितिले ३ (तिन) वर्षका लागि गरिएको व्यहोरा जानकारी गराईन्छ ।

साथै Audit Report मा औंल्याईएका कमि कमजोरीहरुको सम्वन्धमा उद्योगबाट प्रेषित CAPA अनुरुप सुधार कार्य गर्नहुन, निरन्तर Self-Audit गरि सोको प्रतिवेदन विभागमा पेश गर्नहुन र कुशल अभ्यास कायम गरि औषधि उत्पादन गर्नहुन समेत जानकारी गराईन्छ ।

राजेश श्रेष्ठ
फार्मेसी अधिकृत
फार्मेसी अधिकृत

संलग्न
१. WHO GMP Guideline वमोजिमको प्रमाणपत्र
२. औषधि उत्पादन कुशल अभ्यास प्रमाणपत्र

बोधार्थ
श्री औषधि मुल्यांकन तथा दर्ता महाशाखा, औषधी व्यवस्था विभाग
श्री योजना, समन्यव तथा व्यवस्थापन महाशाखा, औषधी व्यवस्था विभाग

संहिताको ७७(४) सँग सम्बन्धित
(औषधि उत्पादन कुशल अभ्यास प्रमाणपत्रको ढांचा)
नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था विभाग
औषधि उत्पादन कुशल अभ्यास प्रमाणपत्र

प्रमाणपत्र नम्बर: Apex/०३/२०८१/१०५

मिति: २०८१/०८/१४

उत्पादकको इज्जातपत्र नम्बर र प्राप्त मिति:
श्री Apex Pharmaceuticals Pvt. Ltd.
Birgunj-21, Parwanipur, Parsa, Nepal,

तपाई/त्यस उद्योगले औषधि उत्पादन कुशल अभ्यासको प्रमाणपत्र पाउँ भनि मिति २०८१/०१/३१ मा 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 ।

Dosage Form(s)	Category(ies)	Activity(ies)
Tablets	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control
	Cephalosporin	
Capsules	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control
	Cephalosporin	
Powder for Oral Suspension	Cephalosporin	Production, Packaging, Quality Control
Semisolid (ointment/ Cream /Gel/ Lotion)	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control
Liquid (Oral)	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control

नविकरण गराएको अवस्था बाहेक प्रमाणपत्रको मान्य अवधि : २०८४/०८/१३
प्रमाणपत्र जारी गर्ने अधिकारीको,-
दस्तखत:
कार्यालयको छाप :
नाम, थर : नारायण प्रसाद ढकाल
पद : महानिर्देशक
मिति: २०८१/०८/१४

महानिर्देशक

द्रष्टव्य:
१. यस प्रकिया बमोजिम उत्पादन गरिएका औषधिको प्रत्येक ब्याचको गुणस्तर कायम गर्ने सम्बन्धि जिम्मेवारी उत्पादन जिम्मेवारी उत्पादकमा निहित रहेनछ।
२. औषधि उत्पादन सम्बन्धमा यस संहिता बमोजिमको कुशल अभ्यास कायम गर्न नसकेमा वा प्रमाणपत्रमा उल्लेख गरिएको कियाकलाप वा प्रकारमा परिवर्तन गरेमा यो प्रमाणपत्र स्वत: अमान्य हुनेछ।
३. यो प्रमाणपत्र तीन वर्षको लागि मान्य हुनेछ र प्रमाणपत्रको नवीकरण गराउनको लागि अवधि समाप्त हुनुभन्दा ६० दिन अगावै विभाग समक्ष निवेदन दिई सक्नुपर्नेछ ।

Government of Nepal
Ministry of Health and Population
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).

Certificate No: Apex/06/24/235 **Date: 29 November, 2024**

On the basis of the inspection carried out on 3-4, July, 2024 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.
Birgunj-21, Parwanipur, Parsa, Nepal.

2. Manufacturer's licence number:

3. Table 1:

Dosage Form(s)	Category(ies)	Activity(ies)
Tablets	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control
	Cephalosporin	
Capsules	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control
	Cephalosporin	
Powder for Oral Suspension	Cephalosporin	Production, Packaging, Quality Control
Semisolid (ointment/ Cream /Gel/ Lotion)	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control
Liquid (Oral)	Non-Penicillin & Non-Cephalosporin	Production, Packaging, Quality Control

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 28 th November, 2026. 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.: +977-1-4791 027 Fax no.: +977-1-4780572 Website: www.dda.gov.np Email: info@dda.gov.np

Signature: ..... Director General **Date: 29 November, 2024**

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Explanatory notes

(1) This certificate, which is in the format recommended by WHO, certifies the status of the Site listed in point 1 of the certificate.
(2) The certification number should be traceable within the regulatory authority issuing the certificate.
(3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in case where there is no legal framework for the issuing of a licence.

(4) Table 1

List the dosage forms, starting materials, categories and activities. Examples give below.

Example 1

Pharmaceutical Product(s)[1]	*Category(ies)*	*Activity(ies)*
Dosage form(s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
Capsules	Penicillin	Repackaging and labelling
Injectables	Cephalosporin	Aseptic preparation, packaging, labelling

Example 2

Pharmaceutical Product(s)[1]	*Category(ies)*	*Activity(ies)*
Starting material(s):[2]		
Paracetamol	Analgesic	Synthesis, purification, packing, labelling

Use, whenever available, International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

(5) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
(6) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in *Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2*, 1999. World Health Organization, Geneva and subsequent updates.

[1] Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.
[2] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

Director General

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