CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of certificate : **789/MFG/WHO-GMP/DFDA/2020/129 (13)** **VALID UPTO: 19/05/2022**

Exporting (certifying country) : India

Importing (requesting country) : As stated at Page 3.

1. Name and dosage form of the product : **Dolutegravir (as Sodium), Lamivudine and Tenofovir Disoproxil Fumarate Tablets**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : As stated at Page 3.

For complete composition including excipients, see attached[4]:

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country? Yes ☒ No ☐ Unknown ☐

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.
If the answer to 1.2 is no, omit section 2A and continue section 2B[6]:

2 A

A.1 Number of product licence[7] and date of issue:
616, dated 20.05.2003, Letter No. 789/(395)/MFG/DFDA/2019/2565, Dated: 07/10/2019

A.2 Product licence holder: (name and address)
M/s Cipla Ltd.,
Plot No. S-103 to S-105,
S-107 to S-112, L-138,
L-147, L-147/1 to L-147/3 & L-147/A
Verna Industrial Estate,
Verna, Goa.

A.3 Status of product licence holder[8]:
a ☒ b ☐ c ☐

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]: Not applicable

A.4 Is a summary basis of approval appended?[10]
Yes ☐ No ☒

A.5 Is the attached, officially approved product information complete and consonant with the licence?[11]
Yes ☐ No ☐ Not provided ☒

A.6 Applicant for certificate, if different from licence holder (name and address)[12]: Not applicable

NOT APPLICABLE

2 B

B.1 Applicant for certificate (name and address):

B.2 Status of applicant:
a ☐ b ☐ c ☐

B.2.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]

B.3 Why is marketing authorization lacking?
not required ☐ not requested ☐ under consideration ☐ refused ☐

B.4 Remarks[13]:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes ☒ No ☐ Not applicable[14] ☐
If not or not applicable, proceed to question 4.

3.1 Periodicity of routine inspections (years): **Minimum Once in a year**

3.2 Has the manufacture of this type of dosage form been inspected? Yes ☒ No ☐

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]
Yes ☒ No ☐ Not applicable[14] ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
Yes ☒ No ☐

If no, explain:

Address of certifying authority:

Director, Directorate of Food & Drugs Administration,
Government of Goa,
DHANWANTARI,
Opp. The Shrine of Holy Cross,
Bambolim, Goa – 403 202, INDIA.
Phone nos.: 0832-2459226 / 2459230
Tele-Fax : 0832-2459223
Website: www.dfda.goa.gov.in

DIRECTORATE OF FOOD & DRUGS ADMINISTRATION GOA

Name of authorized person: JYOTI J. SARDESAI
Director

Signature:

Stamp and date: 07 OCT 2020

«MEDEFERENT GRUP» S.R.L.

General Instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand written.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1] This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[2] Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

[3] The formula (complete composition) of the dosage form should be given on the certificate or be appended.

[4] Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.

[6] When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

[6] Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.

[9] This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.
It should be noted that information concerning the site of production is part of the product licence. If the production site is changed the licence has to be updated or it is no longer valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)

[12] In this circumstance, permission for issuing the certificate is required from the product licence holder. This permission has to be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration:

(a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
(b) the product has been reformulated with a view to improving its stability under tropical conditions;
(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
(e) any other reason, please specify.

[14] Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE TO CERTIFICATE NO. : **789/MFG/WHO-GMP/DFDA/2020/129 (3)**

Name of product : **Dolutegravir (as Sodium), Lamivudine and Tenofovir Disoproxil Fumarate Tablets**

Composition : Each film coated tablet contains:
Dolutegravir Sodium equivalent to Dolutegravir.....50 mg
Lamivudine USP.....300 mg
Tenofovir Disoproxil Fumarate.....300 mg
equivalent to Tenofovir Disoproxil.....245 mg
Colours: FD&C Blue#1, FD & C Blue#2 and Titanium Dioxide.

Product Presentation : **Tablets**

Excipients Used :

Sr. No.	Ingredients	Standard
1.	Microcrystalline Cellulose (Avicel PH 101)	NF
2.	Mannitol (Pearlitol 50 C)	USP
3.	Sodium Starch Glycolate (Primojel) (Type A)	NF
4.	Povidone (PVPK 30)	USP
5.	Purified Water	USP
6.	Croscarmellose Sodium (Ac-Di-Sol)	NF
7.	Magnesium Stearate (Vegetable Grade)	NF
8.	Microcrystalline Cellulose (Avicel PH 112)	NF
9.	Hydroxy Propyl Methyl Cellulose (HPMC-6cps)	USP
10.	Isopropyl Alcohol	USP
11.	Opadry AMB II 88A505017 Blue	INH

Expiry Date : **24 Months**

Pack Size : **30 Tablets in a container pack.**

Importing (requesting country):
Afghanistan, Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Bosnia, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, Chile, China, Colombia, Comoros, Congo, Cook Islands, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Herzegovina, Honduras, Hungary, Iceland, Indonesia, Iran, Iraq, Ireland, Italy, Ivory Coast, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Kuwait, Kyrgyzstan, Laos, Latvia, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriyan, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia, Moldova, Monaco, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Niue, North Korea, Norway, Oman, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russia, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, South Korea, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syria, Tajikistan, Tanzania, Tchad, Thailand, The former Yugoslav Republic of Macedonia, Timor-Leste, Tobago, Togo, Tonga, Trinidad, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Yemen, Zambia, Zimbabwe, Aruba, Brunei, Curacao, Guinee, Hong Kong, Jamahiriya, Kosovo, Kurdistan, Libya, Liechtenstein, Macau, Netherlands Antilles, Palestine, Puerto Rico, Republic de Guinee, Republic of Maldives, Somaliland, Tadzhikistan, Taiwan, Vatican City, West Indies, Western Sahara, Yugoslavia.

DIRECTORATE OF FOOD & DRUGS ... PANAJI-GOA

JYOTI J. SARDESAI
Director, Food & Drugs Admn.,
Bambolim, Goa.

SOCIETATEA CU RASPUNDERE LIMITATA A REPUBLICA MOLDOVA, ANENII NOI, RUSENI
IDNO 1002600053289
«MEDEFERENT GRUP» S.R.L.

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: HA702-0/MS/EG

Your reference:

Ms Vaishali Shridhankar
Regulatory Affairs
Cipla Ltd
Building No.5, 7th Floor, North Block Cipla
R&D Centre
L.B.S. Marg Vikhroli (West)
Mumbai 400 083
Maharashtra
Inde

5 April 2019

Dear Ms Shridhankar,

WHO Prequalification Team – Medicines Assessment
FPP Prequalification – Letter of Prequalification

Application number: HA702-0

I refer to your letter expressing Cipla Ltd's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and published in the WHO Technical Report Series No. 908, and amended subsequently in the Forty-fifth report, as published in the WHO Technical Report Series No. 961 in 2011.

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- **HA702 - Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg**

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

ENCLS: (2)

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and
- submit the respective information about the intended variations and the required additional data in electronic format (CD or DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

CONFIDENTIAL
Attention: Dr Matthias Stahl
WHO Prequalification Team – Medicines
Product Ref Number: HA702

UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn Copenhagen
Denmark

Please send the link to **FPPassessment@who.int**, if you prefer to submit the response via a file transfer link.

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Cipla Ltd and the WHO Prequalification Team – Medicines, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Cipla Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
MVP/EMP/RHT/PQT Room 615
20 Avenue Appia
1211 Geneva 27
Switzerland

I look forward to receiving this information from within two weeks of the date of this letter at the latest. For further information please use the email address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

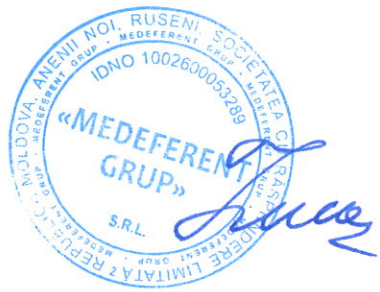
Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

RESTRICTED – COMMERCIAL
Mr Ashwin Upasane
CIPLA LIMITED (UNIT VII)
UNIT VII
PLOT NO L-139
S-103 & M-62
VERNA INDUSTRIAL ESTATE
VERNA
GOA
IN-403 722
INDIA



Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 14694 Insp GMP 14694/4630235-0004

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	CIPLA LIMITED (UNIT VII)
Site address	UNIT VII PLOT NO L-139 S-103 & M-62 VERNA INDUSTRIAL ESTATE VERNA GOA IN-403 722 INDIA

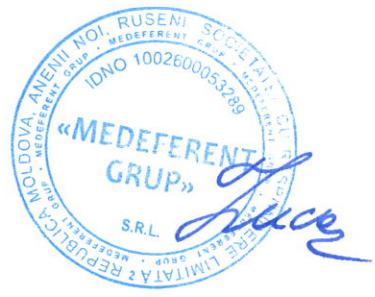
Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art.111(4) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/08/2019, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.



Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 14694 Insp GMP 14694/4630235-0004

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.1 Capsules, hard shell
1.2.1.13 Tablets

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 14694 Insp GMP 14694/4630235-0004

Any restrictions or clarifying remarks related to the scope of this certificate:

The company committed to the MHRA to improvements following this inspection and other regulatory agency findings, in particular for controls with respect to cross contamination.

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 02/07/2020

Ph.No.:0832-2459230 / 2459226
Tele.Fax: 0832-2459223
Website : www.dfda.goa.gov.in

No. 789/MFG/WHO-GMP/DFDA/2019/ 737
Dte. of Food & Drugs Admn.,
Government of Goa,
"DHANWANTARI",
Opposite Shrine of the Holy Cross,
Bambolim, Goa – 403 202
Dated: 28/5/19

CERTIFICATE

On the basis of the inspection carried out on 12/12/2018 to 14/12/2018 and 18/12/2018, 20/12/2018 & 21/12/2018 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 Cipla Ltd. Plot No.S-103 to S- 105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna-Goa

2. Manufacturer's license number:
   611 in Form 28
   616 in Form 25
   749 in Form 28-D

3. Table 1.

Dosage form(s)	Category(ies)	Activity(ies)
Liquid Injections	Cytotoxic *	Production, packaging, quality control
	Hormone *	
Lyophilized Injection	Cytotoxic *	
Liposome Injection	Cytotoxic *	
Nano particle Injection	Cytotoxic *	
Tablets	Cytotoxic *	
	General	
	Hormone *	
Hard gelatin Capsules/Dry powder Inhalation	Cytotoxic *	
	General	
	Hormone *	
Soft gelatin capsules	Cytotoxic *	
Topical Preparations	Hormone *	

*** Manufactured in Dedicated facilities.**

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 **19.05.2022** 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:
Director, Directorate of Food & Drugs Administration, Govt. of Goa, "DHANWANTARI", Opposite Shrine of The Holy Cross, Bambolim, Goa – 403 202, INDIA

Name and function of responsible person:
Mr. Jyoti J. Sardesai, Director
Email:Website: www.dfda.goa.gov.in Telephone No.:**0832 – 2459230, 2459226** Fax no.:**0832-2459223**

Signature:

Stamp and date: 28 MAY 2019

DIRECTORATE OF FOOD & DRUGS ADMN. BAMBOLIM-GOA

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[1]This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

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 Products (s)[2]	Category(ies)	Activity(ies)
Dosage form(s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labeling
Injectables	Cefalosporin	Aseptic preparation, packaging, labeling

Example 2

Pharmaceutical Products(s)[2]	Category(ies)	Activity(ies)
Starting materials(s).3		
Paracetamol	Analgesic	Synthesis, purification, packing, labeling

[2] 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.
[3] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

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

(5) The Certificate remains valid until the specifies date: The certificate becomes invalid if the activities and/or categories certifies 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.

Jyoti J. Sardesai
Director, Food & Drugs Administration