File No: 12-28/00-DC

1984/884
4.11.03

Form - 46

(See rules 122 B and 122-D and 122 DA)

Permission/approval for manufacture of new drug formulation

Number of the permission and date of issue M.F. (1036)

M/S Cipla Limited

Mumbai Central, Mumbai-8 (address)

Your Letter No. Nil dated 31/10/03

is hereby granted permission/approval to manufacture the following new drug formulation under rule 122-B/122-D/122-DA of the Drugs and Cosmetics Rules -1945, - namely

(1)	Name of the formulation	Bicalutamide Tablets
(2)	Dosage form	Tablets
(3)	Composition	Each film-coated tablet contains:- Bicalutamide -------- 150mg
(4)	Indication	for the management of patients with locally advanced, non-metastatic prostatic cancer for whom surgical castration or other medical intervention is not considered appropriate or acceptable.

Dated 04 DEC 2003

Signature:

Ashwini Kumar
Drugs Controller General (India)
(Name and Designation of Licensing Authority)

Conditions for Grant of Approval/Permission

1. The formulation shall conform to the specifications approved by the Licensing Authority.

Contd...2/-

cl: A/l 5/12

REPUBLICA MOLDOVA, ANEXII NOI, RUSENI, SOCIETATEA CU R.L. IDNO 1002600053289 «MEDEFERENT GRUP» S.R.L.

2. The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any which shall be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.

3. The label of the innermost container of the drug and every other covering in which the container is packed shall bear a conspicious red vertical line of the left side running throughout the body of the label which shall not be less than 1 mm in width and without disturbing the other conditions printed on the label to depict it is prescription drug.

4. The label of the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

"WARNING: To be sold by retail on the prescription of a Oncologist only"

5. Post marketing surveillance study shall be conducting during initial period of two years of marketing of the new drug formulation, after getting the protocol and the names of the investigators duly approved by the Licensing Authority.

6. All reported adverse reactions related to the drug shall be intimated to the Drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be compiled with.

7. No claims, except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.

8. Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drug is marketed.

Copy to:

The Commissioner,
FDA, Griha Nirman Bhawan,
Bandra East, Mumbai-51

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

Ph: (0832)-2220245, 2430948, 2224639
FAX: (0832)-2224639
Website: www.dfda.goa.gov.in

No: 789/(39)/MFG/DFDA/2011/ 1820
Government of Goa,
Dte Of Food & Drugs Admn.,
Old IPHB Complex, Altinho
Panaji, Goa-403001

Date : 15/7 */2011*

To,
M/s Cipla Ltd.
S-103 to S-105
S-107 to S-112 &
L-147 to L-147-1
Verna Industrial Estate,
Verna-Goa.

Sub: - Permission to manufacture additional product under Mfg. Lic.No.616.
For Export under Neutral Code.

Sir,

With reference to your application Dated: 05.07.2011 on the above subject, I am to inform you that permission is hereby granted to manufacture the below mentioned product, (As per the formula mentioned in attached list) under Mfg. Lic.No.616.for Export Under Neutral Code bearing No. GO/DRUGS/616.

Name of the product:

1. **Bicalutamide Tablets USP 150 mg.** **[For Export Only]**

Shelf Life: 24 Months.
Pack Size: 10 Tablets in Blister pack.

However permission granted Earlier to your Vide Letter no.789/(39)/MFG/DFDA/2009/10630 Date: 21.01.2009 Stands cancelled forth With.

Further you are directed to comply interalia as under:

1. That the product will be labelled in the manner so as to meet specific requirement of importing country subject to compliance of the provision of Rule 94 of Drug & Cosmetics Rules and instructions issued by the Drugs Controller General (India) from time to time.

2. To submit the test report of the first two batches and specimen carton / label / strip of first two batches of the products within 15 days from the release for sale/ export.

DIRECTORATE OF FOOD & DRUGS ADMINISTRATION GOA

Contd..... 2

MOLDOVA, ANENII NOI, REPUBLICA MEDEFERENT GRUP IDNO 1002600053289 «MEDEFERENT GRUP» S.R.L.

3. In case, of patent and proprietary items or Pharmacopoeial preparations were alternate methods of analysis is used or own method of analysis is adopted. The first five batches of the products manufactured shall be analysed at the approved laboratory according to your protocol of test and method of analysis submitted to this Directorate to ensure accuracy and reproducibility of the method.

4. That the technical specification should also comply to all the requirements of the Government Drug Regulatory agencies of the importing country.

DIRECTORATE OF FOOD AND DRUGS ADMINISTRATION

Yours faithfully,

SALIMA VELJEE
Director, Food & Drugs Admn.

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

Cipla

Cipla Ltd.
S-103 to S-105,
S-107 to S-112&
L-147to L-147-1
Verna Industrial Estate,
Verna, Salcette,
Goa - 403 722

LIST OF PRODUCTS INTENDED TO BE MANUFACTURED FOR SALE OR FOR DISTRIBUTION OF DRUGS, SPECIFIED IN OTHER THAN THOSE SCHEDULE C, C1 EXCLUDING SCHEDULE X, UNDER LICENCE NO 616, AT M/S. CIPLA LTD., PLOT NOS S-103 TO S-105 & S-107 TO S-112, VERNA IND. ESTATE, VERNA-GOA. FOR EXPORT UNDER NEUTRAL CODE.

---

1. **Bicalutamide Tablets USP 150 mg** **[For Export Only]**

   Each film-coated tablet contains:
   Bicalutamide USP ..... 150 mg
   Colour: Titanium Dioxide

   Shelf Life: 24 months
   Pack Size: 10 Tablets in a Blister Pack

UNDERTAKING

1. This is the only product to be manufactured at present. We undertake that any further addition/ommission therefrom will not be carried out without prior permission of Director, F.D.A., Goa.

2. We undertake to comply with all the provisions of the acts in force and directions issued from time to time and not to undertake manufacturing of a product under the name belonging to another manufacturer.

3. We herewith undertake that the thermolabile products which will be manufactured by us under the provisions of Drugs & Cosmetics Act will be subjected to the stability studies for the period of atleast one year with periodic testing atleast for three months of every product and the reports thereof will be submitted to Director, Food & Drugs Administration, Panaji, Goa.

Authorized to manufacture the above Mentioned Additional product for Export Only, Under Neutral Code bearing No.: GC/DRUGS/616, Under Mfg.Lic. No: 616

For Cipla Ltd.,

Dinesh Sharma.
(Authorized Signatory) **Date:** 12/7/2011

Salim A. Veljee
Director, Food & Drugs Admn.,
Licensing Authority.

Phone: (0832) 2889543, 2889535, 2889555 Fax: (0832) 2782799, 2782804
Reg. Office: Cipla Ltd., Mumbai Central, Mumbai-400 008

690.	Anastrozole tablets IP 1 mg Permission No: 789/(170)/Vol-II/MFG/DFDA/2014/4991 Dated: 22.01.2014	For Local Sale
691.	Anastrozole Tablets 1 mg Armotraz Permission No: 789/(170)/Vol-II/MFG/DFDA/2014/2058 Dated: 04.08.2014	For Export Only
692.	Bicalutamide Tablet 50 mg Permission No: 789/(39)/Vol-II/MFG/DFDA/2013/4204 Dated: 06.12.2013	For Export Only
693.	Bicalutamide Tablets 150 mg Bicalutamida 150 mg Tablets Permission No: 789/(39)/Vol-II/MFG/DFDA/2013/1010 Dated: 17.06.2013	For Export Only
694.	Bicalutamide Tablets 150 mg Calutide - 150 Permission No: 789/(39)/Vol-II/MFG/DFDA/2011/4157 Dated: 18.10.2011	For Export Only
695.	Bicalutamide Tablets USP 50 mg Cassotide - 50 Permission No: 789/(39)/Vol-II/MFG/DFDA/2011/4627 Dated: 18.11.2011	For Local Sale
696.	Bicalutamide Tablet 50 mg Calutide - 50 Permission No: 789/(39)/Vol-II/MFG/DFDA/2011/4158 Dated: 18.10.2011	For Export Only
697.	Bicalutamide Tablets 50 mg Bicalutamida Atb 50 mg Permission no: 789/(39)/Vol-II/MFG/DFDA/2011/3440 Dated: 15.09.2011	For Export Only
698.	Bicalutamide Tablets USP 50 mg Calutide - 50 Permission No: 789/(39)/Vol-II/MFG/DFDA/2011/3109 Dated: 29.08.2011	For Local Sale
699.	Bicalutamide Tablet USP 150 mg Calutide - 150 Permission No: 789/(39)/Vol-II/MFG/DFDA/2011/3108 Dated: 29.08.2011	For Local Sale
700.	Bicalutamide Tablets USP 50 mg Permission No: 789/(39)/MFG/DFDA/2011/1967 Dated: 22.07.2011	For Export Only
701.	Bicalutamide Tablet USP 150 mg Calutide - 150 Permission no: 789/(39)/MFG/DFDA/2011/1966 Dated: 22.07.2011	For Export Only
702.	Bicalutamide Tablet USP 150 mg Permission no: 789/(39)/MFG/DFDA/2011/1820 Dated: 15.07.2011	For Export Only

DIRECTORATE OF FOOD & DRUGS ADMN.

For CIPLA LIMITED

VIRAJ SINARI
Authorised Signatory

List of product retained for the period from 20/05/2018 to 19/05/2023 under MFG. LIC No. 614 in form 25

MEDEFERENT GRUP S.R.L.

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

«MEDEFERENT GRUP» S.R.L. IDNO 1002600053289

[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

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.

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

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

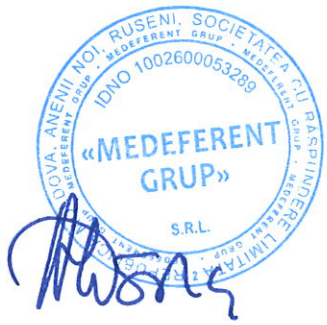
Not Authorised

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