OGYÉI
National Institute of
Pharmacy and Nutrition

H-1051 Budapest, Zrínyi u. 3.
1372 P.O. Box:450.
Tel: +36 1 88 69-300, Fax: +36 1 88 69 460
E-mail: ogyei@ogyei.gov.hu, Web: www.ogyei.gov.hu

Dr. Venkataramana Madireddy
Associate Vice President - CQA

Hetero Labs Limited, Unit I.
Survey No. 10, IDA, Gaddapotharam village
Jinnaram Mandal, Sanga Reddy District
502319, Telangana, India

Ref: OGYÉI/64262-6/2018
Subject: GMP Certificate
Date: 24 May 2019

Dear Dr. Venkataramana Madireddy,

Please find attached the GMP certificate of your facility registered in EudraGMDP database.

Hetero Labs Limited, Unit I.
Survey No. 10, IDA, Gaddapotharam village
Jinnaram Mandal, Sanga Reddy District
502319, Telangana, India

Please consider that any event which affects the GMP compliance shall be reported in a timely manner, major changes related to the GMP system on a yearly basis.

Yours sincerely,

Dr András Mittner
Inspectorate Head

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet 20.

OGYÉI
National Institute of
Pharmacy and Nutrition

H-1051 Budapest, Zrínyi utca 3.
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E-mail: ogyei@ogyei.gov.hu
Web: www.ogyei.gov.hu

National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: ***OGYÉI/64262-6/2018***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

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

The competent authority of Hungary confirms the following:
The manufacturer: ***Hetero Labs Limited, Unit I.***
Site address: ***Survey No. 10, IDA,, Gaddapotharam village, Jinnaram Mandal, Sanga Reddy District, Telangana, 502319, India***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-03-22*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/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 valid only 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.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection :
ANASTROZOLE(en)
BICALUTAMIDE(en)
CAPECITABINE(en)
ESCITALOPRAM OXALATE(en)
ETORICOXIB(en)
LETROZOLE(en)
LEVETIRACETAM(en)
QUETIAPINE FUMARATE(en)
RAMIPRIL(en)
TERBINAFINE HYDROCHLORIDE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : ANASTROZOLE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : BICALUTAMIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : CAPECITABINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : ESCITALOPRAM OXALATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : ETORICOXIB

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : LETROZOLE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : LEVETIRACETAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : .

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : QUETIAPINE FUMARATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : RAMIPRIL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : TERBINAFINE HYDROCHLORIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

2019-05-24

Name and signature of the authorised person of the Competent Authority of Hungary

Dr. Mittner András

Dr. Andras Mittner
National Institute of Pharmacy and Nutrition
Tel:
Fax:

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Surveillance
Division of Quality Surveillance Assessment
10903 New Hampshire Avenue
Building 51, Room 4316
Silver Spring, MD 20993
TELEPHONE: (301) 796-3254
FAX: (301) 847-8742

04/28/2017

Hetero Labs Limited
Survey No. 10, IDA, Kazipally
Gaddapotharam, Jinnaram Mandal
Medak District, Andhra Pradesh , IN

UNCONTROLLED & CONFIDENTIAL
Not for public distribution use
Sign
Date 16/10/17

Reference: Inspection Date(s): 03/06/2017 - 03/14/2017

Location: Hetero Labs Limited
Survey No. 10, IDA, Kazipally
Gaddapotharam, Jinnaram Mandal
Medak District, 502319 , IN

Dear Dr. C. Mohan Reddy,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at 301-796-3254.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

M. SADA SIVA KUMAR REDDY, ADVOCATE ★ NOTARY Regn.No.198 ★ F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY ★ KUKATPALLY, HYDERABAD ★ NOTARY

Sincerely,

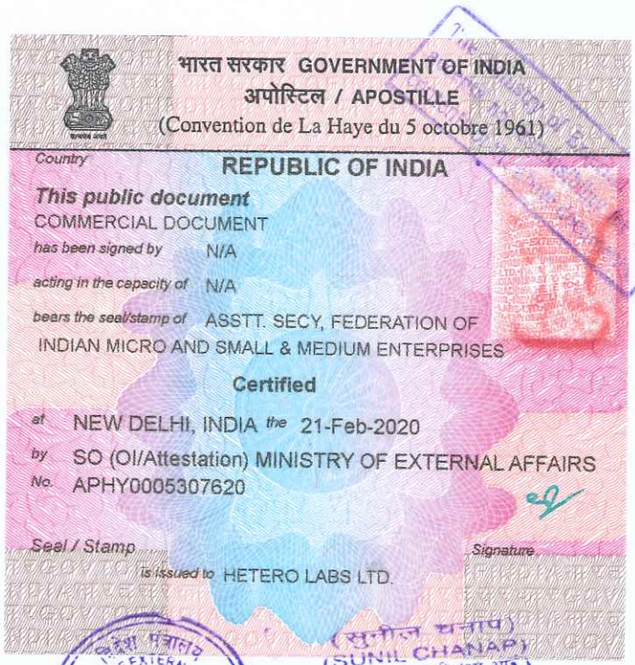
ATTESTED
Ramadevi.C
CH. RAMA DEVI
Assistant Secretary

FEI: 3004378446

Enclosure: Establishment Inspection Report (EIR)

ATTESTED
M. SADA SIVA KUMAR REDDY, B.Com. B.
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O.Ms.No.198,Rev (Regn-II),dt. 11.04.2000
102, Sarasathi Enclave,Bhagyanagar Colony,
Kukatpally, Hyderabad.AP, India (Ph: 98480 443[illegible]

Federation of Indian Micro and Small & Medium Enterprises ★ Chamber of Commerce & Industry ★ FISME ★ No.11(RE-2012)/2009-14 ★ Hyderabad ★



भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

has been signed by N/A

acting in the capacity of N/A

bears the seal/stamp of ASSTT. SECY, FEDERATION OF INDIAN MICRO AND SMALL & MEDIUM ENTERPRISES

Certified

at NEW DELHI, INDIA the 21-Feb-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. APHY0005307620

Seal / Stamp Signature

is issued to HETERO LABS LTD.

MINISTRY OF EXTERNAL AFFAIRS

GOVT. OF INDIA, NEW DELHI

(सुनील चनाप)

(SUNIL CHANAP)

अनुभाग अधिकारी (आ. अ.)

Section Officer (OI)

सी. पी. वी. प्रभाग / C.P.V. Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs, New Delhi

ATTESTED

CH. RAMA DEVI

Assistant Secretary

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 753/E1/2019

Dated: 20.06.2019

To
M/s Hetero Labs Limited, Unit-I
Sy.No.10, I.D.A., Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District,
Telangana State, India.

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organization Good Manufacturing Practice Certificate – Regarding.

Ref: 1. Your application dated: 15.02.2019.
2. Joint Inspection Report dated: 02.05.2018 & 03.05.2018.

@@@

I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE CERTIFICATE** for the products recommended by the Joint Inspection Team consisting of officers of CDSCO Zonal Office, Hyderabad and Drugs Control Administration, Telangana State, India for Export purpose.

This Certificate is valid for a period of Three years from the date of issue. This certificate is meant for Export of drugs only.

Yours faithfully,

20/06/19

Dr.B.VENKATESWARLU
Joint Director (FAC)& Licensing Authority

DRUGS CONTROL ADMINISTRATION * HYDERABAD JD(FAC) * GOVERNMENT OF TELANGANA

M. SADA SIVA KUMAR REDDY, ADVOCATE * NOTARY Regn. No. 198. * 102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, KUKATPALLY, HYDERABAD, A.P. INDIA

ATTESTED
10.2.2019
M. SADA SIVA KUMAR REDDY, B.Com., B.L.
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, A.P., India (Ph: 98480 44395)

Federation of Indian Micro and Small & Medium Enterprises * Chamber of Commerce & Industry * FISME * No.111(RE-2012)/2008-14 * Hyderabad

ATTESTED
K.Sujatha
KAMBHAM SUJATHA
Assistant Secretary

H1APO
24Doc

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

The Ministry of External Affairs accepts no responsibility for the contents of the document.

Country **REPUBLIC OF INDIA**

This public document
COMMERCIAL DOCUMENT
has been signed by N/A
acting in the capacity of N/A
bears the seal/stamp of ASSTT. SECRETARY, FEDERATION OF INDIAN MICRO AND SMALL & MEDIUM ENTERPRISES

Certified
at NEW DELHI, INDIA *the* 12-Feb-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. APHY0004178520

Seal / Stamp *Signature*

is issued to HETERO LABS LTD.

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS ०568

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

Apdik
Chinthar

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 753/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.25/MD/AP/97/B/R, dt:31.01.1997.

LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

1.	ATOMOXETINE HYDROCHLORIDE	USP / Ph.Eur / IH
2.	NEVIRAPINE ANHYDROUS	USP
3.	CANDESARTAN CILEXETIL	USP / Ph.Eur / IH
4.	LOPINAVIR	USP / IH / IP / Ph.Eur
5.	LETROZOLE	USP / Ph.Eur
6.	PEMETREXED DISODIUM	IH
7.	CISPLATIN	USP / Ph.Eur
8.	ABIRATERONE ACETATE	IH / USP / IP
9.	ARIPIPRAZOLE	IH / USP / Ph.Eur
10.	ABACAVIR SULFATE	USP / Ph.Eur
11.	ANASTROZOLE	IH / USP / Ph.Eur / IP
12.	ATAZANAVIR SULFATE	IH
13.	BICALUTAMIDE	IH / USP / Ph.Eur / IP
14.	CAPECITABINE	IH / USP / Ph.Eur / IP
15.	CILAZAPRIL	BP
16.	DIDANOSINE	USP / Ph.Eur
17.	EFAVIRENZ	IH / USP / IP
18.	EMTRICITABINE	USP / IH / IP
19.	ESCITALOPRAM OXALATE	IH / USP / Ph.Eur
20.	FINASTERIDE	USP / Ph.Eur / IH / IP
21.	GEMCITABINE HYDROCHLORIDE	USP / Ph.Eur
22.	HYDRALAZINE HYDROCHLORIDE	Ph.Eur
23.	IMATINIB MESYLATE	IP / Ph.Eur / IH
24.	IRBESARTAN	USP / Ph.Eur
25.	LAMIVUDINE	USP / Ph.Eur / IP
26.	LEVETIRACETAM	USP / Ph.Eur
27.	LOSARTAN POTASSIUM	USP / Ph.Eur / JP

DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TELANGANA
HYDERABAD JD(FAC)

M. SADA SIVA KUMAR REDDY, ADVOCATE
F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD, A.P. INDIA
NOTARY
Regn. No. 198.

20/06/19

Federation of Indian Micro and Small & Medium Enterprises
Chamber of Commerce & Industry
FISME
No.11(RE-2012)/2008-14
Hyderabad

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 753/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.25/MD/AP/97/B/R, dt:31.01.1997.

Drug Licence No. : **25/MD/AP/97/B/R, dt: 31.01.1997**
in Form–25.

The firm **M/s. Hetero Labs Limited, Unit-I**, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India was jointly inspected by Mr.Naveen Yadav, Drugs Inspector, Zonal Office, CDSCO Bhavan, Hyderabad and Mr.A.N.Kranthi Kumar, Drugs Inspector, Drugs Control Administration, Telangana State on 02.05.2018 & 03.05.2018.

The manufacturer conforms to requirement for **Good Manufacturing Practices** in the manufacturing and quality control (As recommended by the **World Health Organization**) in respect of the products mentioned above **(Forty Nine)** for Export in the international market.

This Certificate is valid for a period of Three years from the date of issue.

DRUGS CONTROL ADMINISTRATION * HYDERABAD JD(FAC) * GOVERNMENT OF TELANGANA

20/06/19

Dr.B.VENKATESWARLU
Joint Director (FAC) & Licensing Authority

To
M/s. HETERO LABS LIMITED, Unit-I
Sy.No.10, I.D.A., Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District,
Telangana State, India.

M. SADA SIVA KUMAR REDDY, ADVOCATE * F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY * KUKATPALLY, HYDERABAD, A.P. INDIA
NOTARY
Regn. No. 198.

Federation of Indian Micro and Small & Medium Enterprises * Chamber of Commerce & Industry * FISME * No.111/RE-2012/2008-14 * Hyderabad