CHEMO

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At. Sra. Gabriela Rey
MEGA PHARMA
Ruta 101, Km 23500
Parque de las Ciencias
Edificio Mega Pharma, piso 3
14000, Canelones - Uruguay
Tel.: (+598) 2683 8000

Buenos Aires, 23 de Enero de 2013

De mi mayor consideración:

Por la presente envío:

GMP apostillado Lee Pharma – Lansoprazol pellets.

A la espera de su confirmacion de recepcion,

Cordialmente la saluda,

Veronica Bangerter

GOVERNMENT OF ANDHRAPRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Deputy Director,
Drugs Control Administration,
Visakhapatnam Region,
Visakhapatnam -530 003.

File.No.1788/DD/VSP/2012 Dated: 21-12-2012

G.M.P. CERTIFICATE

This is to certify that M/s Lee Pharma Limited, Plot No.V, Phase-II, VSEZ, Duvvada, Sabbavaram (M), Visakhapatnam District is holding license in Form-25 bearing No. 33/VP/AP/2010/F/G, Dated. 15-07-2010 valid up to 14-07-2015 for manufacture, for sale or distribution of drugs approved by this Department. The firm is subjected to periodical inspection by this Department.

The firm is following GOOD MANUFACTURING PRACTICES as stipulated under the provisions of Schedule 'M' of Drug and Cosmetics Rules, 1945.

The firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.

The Certificate is valid for one year from the date of Issue.

21/12/12

Dy. Director, Govt. of A.P., Visakhapatnam

(L. PRAMOD REDDY)
DEPUTY DIRECTOR & CERTIFYING AUTHORITY
DRUGS CONTROL ADMINISTRATION
VISAKHAPATNAM REGION

DEPUTY DIRECTOR
Drugs Control Administration
Visakhapatnam

To
M/s Lee Pharma Limited,
Plot No.V, Phase-II, VSEZ,
Duvvada, Sabbavaram (M),
Visakhapatnam District, Andhra Pradesh
India.

Copy to: The Joint Director -II, Drugs Control Administration, Hyderabad for favor of information.

NOTARY — Andhra Pradesh INDIA
CH. RAVINDER RAO, B.Sc., LL.B., Hyderabad Dt., In Respect of HYD, G.O.R.T. No. 1105
NOTARIAL

XEROX COPY
ATTESTED

CH. RAVINDER RAO
ADVOCATE B.Sc. LL.B.
NOTARY Appointed by Govt. of A.P.
In Respect of Hyderabad Dist.
3-5-928, Himayathnagar, HYDERABAD-29.

27 DEC 2012

ATTESTED

K.B.V. BHATTAR
Junior Officer

27 DEC 2012

The Federation of Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No.12352/MIB/Mfg/2010 Dated: 10-10-2010.

From.

R.V.S.R.B.Sarma,
Joint Director & Licencing Authority,
O/o the Director General,
Drugs and Copyright,
Drugs Control Administration,
Vengalraonagar, Hyderabad-500 038.

To.

M/s Lee Pharma Limited,
Plot No.V, Phase –II,
VSEZ, Duvvada,
Sabbavaram Mandal,
Visakhapatnam District.

Sirs,

Sub: Drugs and Cosmetic Act.1940 and rules made there under – Grant of additional products in Form-25 – Regarding.

Ref:
1. Your application dated: 15-09-2010.
2. Letter Rc.No.203/DD/VSP/2010 dated: 02-10-2010 of Deputy Director, Visakhapatnam District.
3. Letter Rc.No.991/AD/VSP/2010 dated: 11-10-2010 of Assistant Director, DCA, Visakhapatnam District.
4. Letter Rc.No.485/KR/DI/AKP/2010, dated::08.10.2010 of the Drugs Inspector, Anakapalli, Visakhapatnam District.

With reference to your application cited, you are hereby permitted to manufacture the following products as an additional items under your Drug Licence in Form – 25 bearing **No.33/VP/AP/2010/F/G Dated: 15-07-2010** valid upto 14-07-2015 for the products mentioned in the list enclosed.

The additional products are granted subject to the following conditions.

1. You are informed that on failure to manufacture the drug approved herewith without a reasonable cause during the licensing period the matter will be reviewed and the drug is liable for deletion.
2. The provision of Drugs Price Control Order, 1995 shall be complied with.
3. You should ensure that the drug approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour combination etc., and shall comply with all the provisions relating to the labeling of drug.

Contd....2

ATTESTED
K.B.V. BHATTAR
Junior Officer

The Federation of Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

27 DEC 2012

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

NOTARY INDIA CH. RAVINDER RAO B.Sc. LL.B. 3rd Dt. 029 HYD-50 NOTARIAL

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CH. RAVINDER RAO

L.Dis.No.12352/M1B/Mfg/2010

4. Specific permission for each export order need not be obtained. However, the details of exports by the exporter shall be furnished immediately after completion of each export in the format mentioned below.

Sl. No.	Date of export.	Names of the drugs exported	Batch No. of the drug.	Quantity of the drug.	Name of the importing country.
1.	2.	3.	4.	5.	6.

5. Detailed particulars of rejects/ returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/disposed of in any other manner.

6. The specification/standards asked for by the Importing Country/firm shall be complied with while exporting the drugs.

7. The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs.

8. While the permissions for export of drugs earlier granted still hold good, the conditions attached for such permissions stand amended as mentioned above.

Further, you are informed that non-compliance of any of the conditions mentioned above the matter will be reviewed and the licences /permission issued herewith are liable for suspension /cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetic Rules. You are therefore requested to plan your production accordingly.

Yours faithfully,

JOINT DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION

Copy to: The Deputy Director, Visakhapatnam District.

NOTARY Andhra Pradesh INDIA
CH. RAVINDER RAO B.Sc., LL.B.
NOTARIAL

DIRECTORATE OF DRUGS CONTROLS ADMINISTRATION
GOVERNMENT OF ANDHRAPRADESH
HYDERABAD

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ATTESTED

CH. RAVINDER RAO
ADVOCATE B.Sc. LL.B.
NOTARY Appointed by Govt. of A.P.
In Respect of Hyderabad Dist.
3-5-928, Himayathnagar, HYDERABAD-29.

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Junior Officer

The Federation of Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

27 DEC 2012

L.Dis.No.12352/M1B/Mfg/2010

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

NAME OF THE ADDITIONAL PRODUCTS UNDER FORM – 25

1. **VENLAFAXINE SR PELLETS 33.0% w/w -** For Export /Domestic

Each 1 gram of Sustained Release Pellets
contains :Venlafaxine Hydrochloride Ph.Eur
equivalent to Venlafaxine 330mg
Excepients: Sugar Spheres, Sodium Starch Glycolate, Sodium Lauryl Sulphate Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

2. **VENLAFAXINE SR PELLETS 33.0% w/w -** For Export

Each 1 gram of Sustained Release Pellets
contains :Venlafaxine Hydrochloride IHS
equivalent to Venlafaxine 330mg
Excepients: Sugar Spheres, Sodium Starch Glycolate,Sodium Lauryl Sulphate Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

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Junior Officer

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No. 1030 of 64 - 65
HYDERABAD

3. **VENLAFAXINE SR PELLETS 35.0% w/w -** For Export /Domestic

Each 1 gram of Sustained Release Pellets
contains Venlafaxine Hydrochloride Ph. Eur
equivalent to Venlafaxine 350 0mg
Excepients: Sugar Spheres, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

27 DEC 2012

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

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ADVOCATE
NOTARY Appointed by Govt. of India
In Respect of Hyderabad Dist.
16-2-738, Himayathnagar, HYDERABAD-29.

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH
HYDERABAD
No of approved products: 3 (Three)

NOTARY INDIA

27 DEC 2012

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

4. **VENLAFAXINE SR PELLETS 35.0% w/w -** For Export

Each 1 gram of Sustained Release Pellets
Contains Venlafaxine Hydrochloride IHS
equivalent to Venlafaxine 350 0mg
Excepients: Sugar Spheres, Sodium Starch Glycolate,Sodium Lauryl Sulphate, Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

5. **VENLAFAXINE SR PELLETS 46.0% w/w -** For Export/Domestic

Each 1 gram of Sustained Release Pellets
Contains :Venlafaxine Hydrochloride Ph.Eur
equivalent to Venlafaxine 460 mg
Excepients: Sugar Spheres, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour:NMT 30.0%
After 4th Hour:30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After12th Hour: 65.0 to 90.0%
After24th Hour: NLT 70.0%

6. **VENLAFAXINE SR PELLETS 46.0% w/w -** For Export

Each 1 gram of Sustained Release Pellets
Contains : Venlafaxine Hydrochloride IHS
equivalent to Venlafaxine 460 mg
Excepients: Sugar Spheres, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

NOTARY ★ INDIA ★ Andhra Pradesh

The Federation of Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

No of approved products: 3 (Three)

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

7. **VENLAFAXINE SR PELLETS 50. 0% w/w** - For Export/Domestic
Each 1 gram of Sustained Release Pellets
Contains : Venlafaxine Hydrochloride Ph.Eur.
equivalent to Venlafaxine 500 mg
Excepients: Sugar Spheres, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

8. **VENLAFAXINE SR PELLETS 50. 0% w/w** - For Export
Each 1 gram of Sustained Release Pellets
Contains : Venlafaxine Hydrochloride IHS
equivalent to Venlafaxine 500 mg
Excepients: Sugar Spheres, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Microcrystalline Cellulose, Sucrose, Povidone, Hypromellose 3cps and 6cps, Ethyl Cellulose, Triethyl Citrate.

DISSOLUTION
USP Apparatus II
RPM: 100
1000ml DM Water

RELEASE PROFILE
After 2nd Hour: NMT 30.0%
After 4th Hour: 30.0 to 55.0%
After 8th Hour: 55.0 to 80.0%
After 12th Hour: 65.0 to 90.0%
After 24th Hour: NLT 70.0%

9. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.12% w/w** For Export
Each 1 gram of Sustained Release Pellets
Contains: Tamsulosin Hydrochloride Ph. Eur 1.20 mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)
RPM100

RELEASE PROFILE
After 2 Hours : 13%to34%

After 3 Hours : 47.0 to 68.0%
After 8 Hours : NLT 80.0%

No of approved products: 3 (Three)

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVT OF ANDHRA PRADESH HYDERABAD

The Federation of Andhra Pradesh Chambers of Commerce & Industry No. 1030 of 64 - 65 HYDERABAD

10. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.12% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains: Tamsulosin Hydrochloride U.S.P 1.20 mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)
RPM 100

RELEASE PROFILE
After 2 Hours : 13%to34%
After 3 Hours : 47.0 to 68.0%
After 8 Hours : NLT 80.0%

11. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.12% w/w - For Export**
Each 1 gram of Sustained Release Pellets
Contains :Tamsulosin Hydrochloride I.H.S 1.20 mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)
RPM 100

RELEASE PROFILE
After 2 Hours : NMT 10.0%
After 2 Hours : 35.0 to 70.0%
After 4 Hours: NLT 65.0%
After 8 Hours : NLT 70.0%

12. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.2% w/w - For Export**
Each 1 gram of Sustained Release Pellets
Contains : Tamsulosin Hydrochloride B.P 2mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)
RPM 100

RELEASE PROFILE
After 2 Hours: 13%. to 34.0%
After 3 Hours : 47.0 to 68.0%
After 8 Hours : NLT 80.0%

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH

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No.of approved products: 3 (Three)

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

13. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.2% w/w** For Export

Each 1 gram of Sustained Release Pellets
Contains : Tamsulosin Hydrochloride Ph. Eur 2mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)
RPM 100

RELEASE PROFILE
After 2 Hours: 13.% to 34.0%
After 3 Hours : 47.0 to 68.0%
After 8 Hours : NLT 80.0%

14. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.2% w/w** For Export

Each 1 gram of Sustained Release Pellets
Contains :Tamsulosin Hydrochloride U.S.P 2 mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)
RPM 100

RELEASE PROFILE
After 2 Hours: 13.0 to 34.0%
After 3 Hours : 47.0 to 68.0%
After 8 Hours : NLT 80.0%

15. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.2% w/w** – For Export

Each 1 gram of Sustained Release Pellets
Contains :Tamsulosin Hydrochloride I.H.S 2mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION
A) Acid Stage
(0.1 N HCl 500 ml)
B) Buffer Stage
(Phosphate Buffer, pH 7.2, 500ml)

RELEASE PROFILE
After 2 Hours : NMT 10.0%
After 2 Hours : 35.0 to 70.0%
After 4 Hours : NLT 65.0%
After 8 Hours : NLT 70.0%

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

The Federation of Andhra Pradesh Chambers of Commerce & Industry No. 1030 of 64 - 65 HYDERABAD

No of approved products: 3 (Three)

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

16. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.4% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains :Tamsulosin Hydrochloride Ph. Eur 4mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION	**RELEASE PROFILE**
A) Acid Stage	After 2 Hours : 13% to 34%
(0.1 N HCl 500 ml)	
B) Buffer Stage	After 4 Hours : 47.0 to 68
(Phosphate Buffer, pH 7.2, 500ml)	After 8 Hours : NLT 80.0%
RPM 100	

17. **TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.4% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains: Tamsulosin Hydrochloride U.S.P 4 mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION	**RELEASE PROFILE**
A) Acid Stage	After 2 Hours: 13 % to 34%
(0.1 N HCl 500 ml)	
B) Buffer Stage	
(Phosphate Buffer, pH 7.2, 500ml)	After 3 Hours : 47.0 to 68
RPM 100	After 8 Hours :NLT 80.0%

18. **TAMSULOSIN HCl SR PELLETS 0.4% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains: Tamsulosin Hydrochloride I.H.S 4 mg
Excepients: Sugar Spheres, Hypromellose, Talc, Colloidal Silicon Dioxide, Propylene Glycol, Tween-80, Methacrylic Acid Co-polymer Dispersion, Polyethylene Glycol 6000, Titanium Dioxide, Sodium Hydroxide, Ethyl Cellulose, Diethyl Phthalate.

DISSOLUTION	**RELEASE PROFILE**
A) Acid Stage	After 2 Hours : NMT 10.0%
(0.1 N HCl 500 ml)	
	After 2 Hours : 35.0 to 70.0%
B) Buffer Stage	After 4 Hours : NLT 65.0%
(Phosphate Buffer, pH 7.2, 500ml)	After 8 Hours : NLT 70.0%
RPM 100	

No of approved products: 3 (Three)

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

The Federation of Andhra Pradesh Chambers of Commerce & Industry No. 1030 of 64 - 65 HYDERABAD

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

19. **DOMPERIDONE SUSTAINED RELEASE PELLETS 19.2% w/w –** For Export
Each 1 gram of Sustained Release Pellets .
Contains: Domperidone B.P 192 mg
Colour: Sunset Yellow FCF
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION	**RELEASE PROFILE**
USP Apparatus II	After 1st Hour: 15.0 to 40.0%
RPM: 100, 0.1N HCl	After 4th Hour: 30.0 to 60.0%
	After 8th Hour: 55.0 to 85.0%
	After 12th Hour: NLT 70.0%

20. **DOMPERIDONE SUSTAINED RELEASE PELLETS 19.2% w/w –** For Export
Each 1 gram of Sustained Release Pellets
Contains: Domperidone I.H.S 192 mg
Colour: Sunset Yellow FCF
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION	**RELEASE PROFILE**
USP Apparatus II	After 1st Hour: 15.0 to 40.0%
RPM: 100, 0.1N HCl	After 4th Hour: 30.0 to 60.0%
	After 8th Hour: 55.0 to 85.0%
	After 12th Hour: NLT 70.0%

21. **DOMPERIDONE SUSTAINED RELEASE PELLETS 17.0% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains : Domperidone B.P. 170 mg
Colour: Sunset Yellow FCF
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION	**RELEASE PROFILE**
USP Apparatus II	After 1st Hour: 15.0 to 40.0%
RPM: 100, 0.1N HCl	After 4th Hour: 30.0 to 60.0%
	After 8th Hour: 55.0 to 85.0%
	After 12th Hour: NLT 70.0%

22. **DOMPERIDONE SUSTAINED RELEASE PELLETS 17.0% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains : Domperidone IHS. 170 mg
Colour: Sunset Yellow FCF
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION	**RELEASE PROFILE**
USP Apparatus II	After 1st Hour: 15.0 to 40.0%
RPM: 100, 0.1N HCl	After 4th Hour: 30.0 to 60.0%
	After 8th Hour: 55.0 to 85.0%
	After 12th Hour: NLT 70.0%

No of approved products: 4 (Four)

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

23. **DOMPERIDONE SUSTAINED RELEASE PELLETS 20.0% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains : Domperidone B.P. 200 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION
USP Apparatus II
RPM: 100, 0.1N HCl

RELEASE PROFILE
After 1st Hour: 15.0 to 40.0%
After 4th Hour: 30.0 to 60.0%
After 8th Hour: 55.0 to 85.0%
After 12th Hour: NLT 70.0%

24. **DOMPERIDONE SUSTAINED RELEASE PELLETS 20.0% w/w -** For Export
Each 1 gram of Sustained Release Pellets
Contains : Domperidone IHS. 200 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION
USP Apparatus II
RPM: 100, 0.1N HCl

RELEASE PROFILE
After 1st Hour: 15.0 to 40.0%
After 4th Hour: 30.0 to 60.0%
After 8th Hour: 55.0 to 85.0%
After 12th Hour: NLT 70.0%

25. **DOMPERIDONE SUSTAINED RELEASE PELLETS 30.0% w/w** -For Export
Each 1 gram of Sustained Release Pellets contains
Domperidone B.P 300 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION
USP Apparatus II
RPM: 100, 0.1N HCl

RELEASE PROFILE
After 1st Hour: 15.0 to 40.0%
After 4th Hour: 30.0 to 60.0%
After 8th Hour: 55.0 to 85.0%
After 12th Hour: NLT 70.0%

26. **DOMPERIDONE SUSTAINED RELEASE PELLETS 30.0% w/w** -For Export
Each 1 gram of Sustained Release Pellets contains
Domperidone IHS 300 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION
USP Apparatus II
RPM: 100, 0.1N HCl

RELEASE PROFILE
After 1st Hour: 15.0 to 40.0%
After 4th Hour: 30.0 to 60.0%
After 8th Hour: 55.0 to 85.0%
After 12th Hour: NLT 70.0%

No of approved products: 4 (Four)

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List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

27. **DOMPERIDONE SUSTAINED RELEASE PELLETS 40.0% w/w** - For Export
Each 1 gram of Sustained Release Pellets contains
Domperidone B.P 400 mg
Colour: Sunset Yellow FCF
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION	**RELEASE PROFILE**
USP Apparatus II	After 1st Hour: 15.0 to 40.0%
RPM: 100, 0.1N HCl	After 4th Hour: 30.0 to 60.0%
	After 8th Hour: 55.0 to 85.0%
	After 12th Hour: NLT 70.0%

28. **DOMPERIDONE SUSTAINED RELEASE PELLETS 40.0% w/w** - For Export
Each 1 gram of Sustained Release Pellets contains
Domperidone I H S 400 mg
Colour: Sunset Yellow FCF
Excepients: Sugar Spheres, Sucrose, Starch, Povidone, Ethyl Cellulose, Diethyl Phthalate, Methylene Dichloride, Isopropyl Alcohol.

DISSOLUTION	**RELEASE PROFILE**
USP Apparatus II	After 1st Hour: 15.0 to 40.0%
RPM: 100, 0.1N HCl	After 4th Hour: 30.0 to 60.0%
	After 8th Hour: 55.0 to 85.0%
	After 12th Hour: NLT 70.0%

29. **DULOXETINE HCl ENTERIC COATED PELLETS 17.0% w/w** - For Export
Each 1 gram of Enteric Coated Pellets contains
Duloxetine HCl
equivalent to Duloxetine I.H.S 170 mg
Colour: Red Oxide of Iron
Excepients: Sugar Spheres, Sodium Carbonate, Talc, Titanium Dioxide,Hypromellose Crospovidone, Cetyl Alcohol, Iron Oxide Red, Hypromellose Phthalate.

30. **PSEUDOEPHEDRINE HCL SR PELLETS - 42.% W/W (for Domestic)**
Each 1 gram SR Pellets contains:
Psedoephedrine Hydrochloride I.P 420.00 mg.
Colour: Titanium Dioxide
Excepients: Starch, Sugar, PVPK-30, Ethyl Cellulose, Triethyl Citrate IPA, Methylene Dichloride

DISSOLUTION	RELEASE PROFILE
Buffer stage	After 3 Hours: 20.0-50.0%
(water,900ml)	After 6 Hours: 45.0-75.0%

No of approved products: 4 (Four)

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31. **PSEUDOEPHEDRINE HCL SR PELLETS - 42.% W/W (for Export)**
Each 1 gram SR Pellets contains:
Psedoephedrine Hydrochloride U.S.P. 420.00 mg.
Colour: Titanium Dioxide
Excepients: Starch, Sugar, PVPK-30, Ethyl Cellulose, Triethyl Citrate IPA, Methylene Dichloride

DISSOLUTION	RELEASE PROFILE
Buffer stage (water,900ml)	After 3 Hours: 20.0-50.0% After 6 Hours: 45.0-75.0%

32. **OMEPRAZOLE PELLETS 8.5% w/w-** For Domestic
Each 1 gram of Enteric Coated Pellets
Contain: Omeprazole I.P 85 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Hypromellose Phthalate, Cetyl Alcohol, Acetone, Isopropyl Alcohol.

33. **OMEPRAZOLE PELLETS 8.5% w/w-** For Export
Each 1 gram of Enteric Coated Pellets
Contains: Omeprazole Ph. Eur 85 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Hypromellose Phthalate, Cetyl Alcohol Acetone, Isopropyl Alcohol.

34. **OMEPRAZOLE PELLETS 8.5% w/w -** For Export
Each 1 gram of Enteric Coated Pellets
Contains: Omeprazole U.S.P 85 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Hypromellose Phthalate, Cetyl Alcohol Acetone, Isopropyl Alcohol.

35. **OMEPRAZOLE PELLETS 9.0% w/w -** For Domestic
Each 1 gram of Enteric Coated Pellets
Contains: Omeprazole I.P 90 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Methacrylic Acid Co-polymer Dispersion, Talc, Tween-80, Sodium Hydroxide, Diethyl Phthalate,

No of approved products: 5 (Five)

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

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L.Dis.No.12352/M1B/Mfg/2010

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

36. **OMEPRAZOLE PELLETS 9.0% w/w -** For Export
Each 1 gram of Enteric Coated Pellets
Contains: Omeprazole Ph .Eur 90 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Methacrylic Acid Co-polymer Dispersion, Talc, Tween-80, Sodium Hydroxide, Diethyl Phthalate,

37. **OMEPRAZOLE PELLETS 9.0% w/w -** For Export
Each 1 gram of Enteric Coated Pellets
Contains: Omeprazole U.S.P 90 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Methacrylic Acid Co-polymer Dispersion, Talc, Tween-80, Sodium Hydroxide, Diethyl Phthalate,

38. **OMEPRAZOLE PELLETS 9.5% w/w -** For Export
Each 1 gram of Enteric Coated Pellets
Contains: Omeprazole Ph .Eur 95 mg
Excepients: Sugar Spheres, Hypromellose, Dimethicone Emulsion, Polysorbate 80, Mannitol, Diacetylated monoglycerides, Talc, Methacrylic acid-ethyl acrylate copolymer (1:1), Triethyl Citrate, Stearyl Macroglycerides.

ATTESTED
K.B.V. BHATTAR
Junior Officer

39. **LANSOPRAZOLE PELLETS 8.5% w/w-** For Export
Each 1 gram of Enteric Coated Pellets
Contain: Lansoprazole U S P 85 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Hypromellose Phthalate, Cetyl Alcohol, Acetone, Isopropyl Alcohol.

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40. **LANSOPRAZOLE PELLETS 8.5% w/w-** For Export
Each 1 gram of Enteric Coated Pellets
Contain: Lansoprazole I.P 85 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Hypromellose Phthalate, Cetyl Alcohol, Acetone, Isopropyl Alcohol.

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

No. of approved products: 5 (Five)

XEROX COPY ATTESTED

NOTARY
CH. RAVINDER RAO
ADVOCATE B.Sc. LL.B.
NOTARY Appointed by Govt. of A.P
In Respect of Hyderabad Dist.
5-928, Himayathnagar, HYDERABAD-29

NOTARIAL

L.Dis.No.12352/M1B/Mfg/2010

List of the additional products approved to be manufactured by M/s.Lee Pharma Ltd., Plot No.V, Phase-II, Visakhapatnam Special Economic Zone, Duvvada, Sabbavaram (M), Visakhapatnam under their Licence in Form – 25 bearing No.33/VP/AP/2010/F/G dt:15.07.10 valid upto 14.07.2015

For Export

41. **LANSOPRAZOLE PELLETS 8.5% w/w-**
Each 1 gram of Enteric Coated Pellets
Contain: Lansoprazole B P 85 mg
Colour: Titanium Dioxide
Excepients: Sugar Spheres, Sucrose, Mannitol, Calcium Carbonate, Sodium Lauryl Sulphate, Disodium Hydrogen Orthophosphate, Povidone, Hypromellose, Hypromellose Phthalate, Cetyl Alcohol, Acetone, Isopropyl Alcohol.

DIRECTORATE OF DRUGS CONTROLS ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

JOINT DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION

XEROX COPY ATTESTED

CH. RAVINDER RAO B.Sc. LL.B.
ADVOCATE
NOTARY Appointed by Govt. of A.P.
In Respect of Hyderabad Dist.
3-5-928, Himayathnagar, HYDERABAD-29.

NOTARY Andhra Pradesh INDIA CH. RAVINDER RAO NOTARIAL

27 DEC 2012

ATTESTED

K.B.V. BHATTAR
Junior Officer

The Federation of Andhra Pradesh Chambers of Commerce & Industry
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27 DEC 2012