

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: **FI006/001/2019**

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 Portugal confirms the following:

The manufacturer: **Hetero Labs Limited**

Site address: **Unit-V, Block V and V-A, TSIIC - Formulation SEZ, S. Nos 439, 440, 441 & 458, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, 509301, India**

DUNS Number: **65-045-2530**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 and Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:

Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-01-25**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC ³

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.



ATTESTED
Rama Devi
CH. RAMA DEVI
Assistant Secretary



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 44395)





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. APHY0005308120

Seal / Stamp

is issued to HETERO LABS LTD.

Signature



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

Part 2

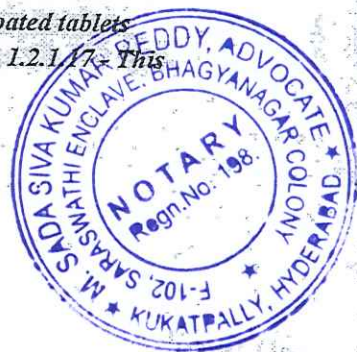
Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.1 Capsules, hard shell
	1.2.1.13 Tablets
	1.2.1.17 Other: powders(en)
1.5	Packaging
	1.5.1 Primary Packing
	1.5.1.1 Capsules, hard shell
	1.5.1.13 Tablets
	1.5.1.17 Other non-sterile medicinal products: powders(en)
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Any restrictions related to the scope of this certificate :

Scope of the inspection included Centrally Authorised Products Entecavir 0.5mg film-coated tablets (EU/1/17/1211/001-003) and Entecavir 1mg film-coated tablets (EU/1/17/1211/004-006) 1.2.1.17 - This dosage form is only manufactured in Unit V-A.

Clarifying remarks (for public users)

Scope of the inspection included Centrally Authorised Products Entecavir 0.5mg film-coated tablets (EU/1/17/1211/001-003) and Entecavir 1mg film-coated tablets (EU/1/17/1211/004-006) 1.2.1.17 - This dosage form is only manufactured in Unit V-A.

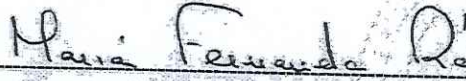


14/12/11



2019-04-01

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



Fernanda Ralha
Diretora da Direção
Inspeção e Licenciamentos

Ms. Maria Fernanda Ralha Henriques Matos
National Authority of Medicines and Health Products,
I.P.

Tel: +351 21 7987278

Fax: +351 21 7987257





DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No. 735/E1/2019

Dated: 31 .07.2019

To

M/s. Hetero Labs Limited Unit-V

Sy.No.439, 440, 441 & 458

TSIIC Formulation SEZ

Polepally Village, Jadcherla Mandal

Mahaboobnagar 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: 14.02.2019.

2. Joint Inspection Report dated: 24.06.2019 to 26.06.2019.

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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

B. Venkateswarlu
31/07/19

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

B. $\frac{1}{31071.9}$



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No. 735/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-V, Sv.No.439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India in Form-25 bearing No.50/MN/AP/2009/F/R, dt:19.12.2009.

9. ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600 mg / 300 mg
Each film coated tablet contains:
Abacavir Sulfate USP 600 mg
Equivalent to Abacavir 600 mg
Lamivudine USP 300 mg
10. ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600 mg / 300 mg
ABAVIR-L 600 / 300
Each film coated tablet contains:
Abacavir Sulfate USP 600 mg
Equivalent to Abacavir 600 mg
Lamivudine USP 300 mg
11. ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600 mg / 300 mg
HEPTAVIR-AB 600 / 300
Each film coated tablet contains:
Abacavir Sulfate USP 600 mg
Equivalent to Abacavir 600 mg
Lamivudine USP 300 mg
12. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 300 mg / 12.5 mg
Each film coated tablet contains:
Irbesartan Ph.Eur 300 mg
Hydrochlorothiazide Ph.Eur 12.5 mg
13. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 300 mg / 25 mg
Each film coated tablet contains:
Irbesartan Ph.Eur 300 mg
Hydrochlorothiazide Ph.Eur 25 mg
14. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 300 mg / 12.5 mg
IRBIGEN-H 300 / 12.5
Each film coated tablet contains:
Irbesartan Ph.Eur 300 mg
Hydrochlorothiazide Ph.Eur 12.5 mg
15. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 300 mg / 25 mg
IRBIGEN- H 300 / 25
Each film coated tablet contains:
Irbesartan Ph.Eur 300 mg
Hydrochlorothiazide Ph.Eur 25 mg



B. Vasu
31.01.19



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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16. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 300 mg / 12.5 mg

IRBIS-HT 300 / 12.5

Each film coated tablet contains:

Irbesartan	Ph.Eur	300 mg
Hydrochlorothiazide	Ph.Eur	12.5 mg

17. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 300 mg / 25 mg

IRBIS-HT 300 / 25

Each film coated tablet contains:

Irbesartan	Ph.Eur	300 mg
Hydrochlorothiazide	Ph.Eur	25 mg

18. ESZOPICLONE TABLETS 1 mg

Each film coated tablet contains:

Eszopiclone		1 mg
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19. ESZOPICLONE TABLETS 1 mg

ESZOP 1

Each film coated tablet contains:

Eszopiclone		1 mg
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20. ESZOPICLONE TABLETS 2 mg

Each film coated tablet contains:

Eszopiclone		2 mg
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21. ESZOPICLONE TABLETS 2 mg

ESZOP 2

Each film coated tablet contains:

Eszopiclone		2 mg
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22. ESZOPICLONE TABLETS 3 mg

Each film coated tablet contains:

Eszopiclone		3 mg
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23. ESZOPICLONE TABLETS 3 mg

ESZOP 3

Each film coated tablet contains:

Eszopiclone		3 mg
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24. LACOSAMIDE TABLETS 50 mg

Each film coated tablet contains:

Lacosamide		50 mg
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B.V.
31/08/19



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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- | | | |
|-----|--|--------|
| 25. | LACOSAMIDE TABLETS 100 mg
Each film coated tablet contains:
Lacosamide | 100 mg |
| 26. | LACOSAMIDE TABLETS 150 mg
Each film coated tablet contains:
Lacosamide | 150 mg |
| 27. | LACOSAMIDE TABLETS 200 mg
Each film coated tablet contains:
Lacosamide | 200 mg |
| 28. | LACOSAMIDE TABLETS 50 mg
LAMIDE 50
Each film coated tablet contains:
Lacosamide | 50 mg |
| 29. | LACOSAMIDE TABLETS 100 mg
LAMIDE 100
Each film coated tablet contains:
Lacosamide | 100 mg |
| 30. | LACOSAMIDE TABLETS 150 mg
LAMIDE 150
Each film coated tablet contains:
Lacosamide | 150 mg |
| 31. | LACOSAMIDE TABLETS 200 mg
LAMIDE 200
Each film coated tablet contains:
Lacosamide | 200 mg |
| 32. | ZIPRASIDONE CAPSULES 20 mg
Each Capsule contains:
Ziprasidone Hydrochloride
Equivalent to Ziprasidone | 20 mg |
| 33. | ZIPRASIDONE CAPSULES 40 mg
Each Capsule contains:
Ziprasidone Hydrochloride
Equivalent to Ziprasidone | 40 mg |



B.V.
31/07/19





DRUGS CONTROL ADMINISTRATION
Government of Telangana



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42. CLOPIDOGREL TABLETS 300 mg
CLOPIGEN 300
Each film coated tablet contains:
Clopidogrel Hydrogen Sulfate Ph.Eur
Equivalent to Clopidogrel 300 mg
43. OLMESARTAN MEDOXOMIL TABLETS 5 mg
Each film coated tablet contains:
Olmesartan Medomoxil Ph.Eur 5 mg
44. OLMESARTAN MEDOXOMIL TABLETS 10 mg
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 10 mg
45. OLMESARTAN MEDOXOMIL TABLETS 20 mg
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 20 mg
46. OLMESARTAN MEDOXOMIL TABLETS 40 mg
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 40 mg
47. OLMESARTAN MEDOXOMIL TABLETS 5 mg
OLMESAR 5
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 5 mg
48. OLMESARTAN MEDOXOMIL TABLETS 10 mg
OLMESAR 10
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 10 mg
49. OLMESARTAN MEDOXOMIL TABLETS 20 mg
OLMESAR 20
Each film coated tablet contains:
Olmesarttan Medoxomil Ph.Eur 20 mg
50. OLMESARTAN MEDOXOMIL TABLETS 40 mg
OLMESAR 40
Each film coated tablet contains:
Olmesarttan Medoxomil Ph.Eur 40 mg



B. V. S. R.
31/07/19



DRUGS CONTROL ADMINISTRATION
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51. OLMESARTAN MEDOXOMIL TABLETS 20 mg
OLMETERO 20
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 20 mg
52. OLMESARTAN MEDOXOMIL TABLETS 40 mg
OLMETERO 40
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 40 mg
53. ATORVASTATIN CALCIUM TABLETS 10 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate USP
Equivalent to Atorvastatin 10 mg
54. ATORVASTATIN CALCIUM TABLETS 20 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate USP
Equivalent to Atorvastatin 20 mg
55. ATORVASTATIN CALCIUM TABLETS 40 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate USP
Equivalent to Atorvastatin 40 mg
56. ATORVASTATIN CALCIUM TABLETS 80 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate USP
Equivalent to Atorvastatin 80 mg
57. ATORVASTATIN TABLETS 10 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 10 mg
58. ATORVASTATIN TABLETS 20 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 20 mg
59. ATORVASTATIN TABLETS 40 mg
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 40 mg



B. Venkatesh
31/07/19



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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67. **ATORVASTATIN TABLETS 40 mg**
ATOR 40
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 40 mg
68. **ATORVASTATIN TABLETS 80 mg**
ATOR 80
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 80 mg
69. **TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS USP 40 mg / 12.5 mg**
Each tablet contains:
Telmisartan USP 40 mg
Hydrochlorothiazide USP 12.5 mg
70. **TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS 40 mg / 12.5 mg**
Each tablet contains:
Telmisartan Ph.Eur 40 mg
Hydrochlorothiazide Ph.Eur 12.5 mg
71. **TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS USP 80 mg / 12.5 mg**
Each tablet contains:
Telmisartan USP 80 mg
Hydrochlorothiazide USP 12.5 mg
72. **TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS 80 mg / 12.5 mg**
Each tablet contains:
Telmisartan Ph.Eur 80 mg
Hydrochlorothiazide Ph.Eur 12.5 mg
73. **TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS USP 40 / 12.5 mg**
TELSAR-H 40 / 12.5
Each tablet contains:
Telmisartan USP 40 mg
Hydrochlorothiazide USP 12.5 mg
74. **TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS 40 / 12.5 mg**
TELSAR-H 40 / 12.5
Each tablet contains:
Telmisartan Ph.Eur 40 mg
Hydrochlorothiazide Ph.Eur 12.5 mg



B. Venkatesh
3.10.2019



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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75. TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS USP 80 / 12.5 mg

TELSAR-H 80 / 12.5

Each tablet contains:

Telmisartan	USP	80 mg
Hydrochlorothiazide	USP	12.5 mg

76. TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS 80 / 12.5 mg

TELSAR-H 80 / 12.5

Each tablet contains:

Telmisartan	Ph.Eur	80 mg
Hydrochlorothiazide	Ph.Eur	12.5 mg

77. LAMIVUDINE AND ZIDOVUDINE TABLETS USP 150 mg / 300 mg

Each film coated tablet contains:

Lamivudine	USP	150 mg
Zidovudine	USP	300 mg

78. LAMIVUDINE AND ZIDOVUDINE TABLETS USP 150 mg / 300 mg

ZIDOLAM

Each film coated tablet contains:

Lamivudine	USP	150 mg
Zidovudine	USP	300 mg

79. EFAVIRENZ, EMTRICITABINE AND TENOFOVIR DISPROXIL FUMARATE TABLETS 600 mg / 200 mg / 300 mg

Each film coated tablet contains:

Efavirenz	USP	600 mg
Emtricitabine	USP	200 mg
Tenofovir Disproxil Fumarate		300mg
Equivalent to Tenofovir Disoproxil		245 mg

80. EFAVIRENZ TABLETS 600 mg

HEVAZ 600

Each film coated tablet contains:

Efavirenz	USP	600 mg
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81. TENOFOVIR DISOPROXIL FUMARATE AND LAMIVUDINE TABLETS 300 mg / 300 mg

Each film coated tablet contains:

Tenofovir Disoproxil Fumarate		300 mg
Equivalent to Tenofovir Disoproxil		245 mg
Lamivudine	USP	300 mg



B. V. 31/01/19



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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82. **TENOFOVIR DISOPROXIL FUMARATE AND LAMIVUDINE TABLETS**
300 mg / 300 mg

TENOLAM

Each film coated tablet contains:

Tenofovir Disoproxil Fumarate	300 mg
Equivalent to Tenofovir Disoproxil	245 mg
Lamivudine	300 mg

USP

83. **CELECOXIB CAPSULE 100 mg**

CELOFIN 100

Each capsules contains:

Celecoxib	Ph.Eur	100 mg
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84. **CELECOXIB CAPSULE 200 mg**

CELOFIN 200

Each capsule contains:

Celecoxib	Ph.Eur	200 mg
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85. **VALGANCICLOVIR TABLETS 450 mg**

Each film coated tablet contains:

Valganciclovir Hydrochloride	496.3 mg
Equivalent to Valganciclovir	450 mg

86. **VALGANCICLOVIR TABLETS 450 mg**

VALGOVIR 450

Each film coated tablet contains:

Valganciclovir Hydrochloride	496.43 mg
Equivalent to Valganciclovir	450 mg

87. **VALGANCICLOVIR TABLETS 450 mg**

VALVIR-450

Each film coated tablet contains:

Valganciclovir Hydrochloride	496.43 mg
Equivalent to Valganciclovir	450 mg

88. **VALGANCICLOVIR TABLETS 450 mg**

VALGAN-450

Each film coated tablet contains:

Valganciclovir Hydrochloride	496.43 mg
Equivalent to Valganciclovir	450 mg



B. V. 31/07/19



DRUGS CONTROL ADMINISTRATION
Government of Telangana



1.Dis.No. 735/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-V, Sy.No.439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India in Form-25 bearing No.50/MN/AP/2009/F/R, dt:19.12.2009.

89. **ATORVASTATIN TABLETS 10 mg**
HYPOLIP 10
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 10 mg
90. **ATORVASTATIN TABLETS 20 mg**
HYPOLIP 20
Each film coated tablet contains:
Atorvastatin Calcium Trihydrate Ph.Eur
Equivalent to Atorvastatin 20 mg
91. **EFAVIRENZ, EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE**
TABLETS 600 mg / 200 mg / 300 mg
EFTEM
Each film coated tablet contains:
Efavirenz USP 600 mg
Emtricitabine USP 200 mg
Tenofovir Disoproxil Fumarate 300 mg
Equivalent to Tenofovir Disoproxil 245 mg
92. **VALACYCLOVIR HYDROCHLORIDE TABLETS 1000 mg**
Each film coated tablet contains:
Valacyclovir Hydrochloride 1112 mg
Equivalent to Valacyclovir 1000 mg
93. **VALACYCLOVIR HYDROCHLORIDE TABLETS 500 mg**
Each film coated tablet contains:
Valacyclovir Hydrochloride 556 mg
Equivalent to Valacyclovir 500 mg
94. **EFAVIRENZ TABLETS 600 mg**
Each film coated tablet contains:
Efavirenz 600 mg
95. **EFAVIRENZ TABLETS 600 mg**
ESVITA 600
Each film coated tablet contains:
Efavirenz 600 mg
96. **LEVOFLOXACIN TABLETS 250 mg**
Each film coated tablet contains:
Levofloxacin Hemihydrate 256.24 mg
Equivalent to Levofloxacin 250 mg



B. Venkatesh
31/07/19



DRUGS CONTROL ADMINISTRATION
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97. LEVOFLOXACIN TABLETS 500 mg
Each film coated tablet contains:
Levofloxacin Hemihydrate 512.47 mg
Equivalent to Levofloxacin 500 mg
98. IRBESARTAN TABLETS 75 mg
Each uncoated tablet contains:
Irbesartan 75 mg
99. IRBESARTAN TABLETS 150 mg
Each uncoated tablet contains:
Irbesartan 150 mg
100. IRBESARTAN TABLETS 300 mg
Each uncoated tablet contains:
Irbesartan 300 mg
101. MONTELUKAST SODIUM CHEWABLE TABLETS 4 mg
Each tablet contains:
Montelukast Sodium
Equivalent to Montelukast 4 mg
102. MONTELUKAST SODIUM CHEWABLE TABLETS 5 mg
Each tablet contains:
Montelukast Sodium
Equivalent to Montelukast 5 mg
103. MONTELUKAST SODIUM TABLETS 10 mg
Each film coated tablet contains:
Montelukast Sodium
Equivalent to Montelukast 10 mg
104. PANTOPRAZOLE GASTRO RESISTANT TABLETS 20 mg
Each Gastro Resistance Tablets contains:
Pantoprazole Sodium Sesquihydrate
Equivalent to Pantoprazole 20 mg
105. PANTOPRAZOLE GASTRO RESISTANT TABLETS 40 mg
Each Gastro Resistance Tablets contains:
Pantoprazole Sodium Sesquihydrate
Equivalent to Pantoprazole 40 mg



B. V. 3110719



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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106. SAQUINAVIR MESILATE TABLETS 500 mg
Each film coated Tablets contains ·
Saquinavir Mesilate Ph.Eur
Equivalent to Saquinavir 500 mg
107. SILDENAFIL CITRATE TABLETS 25 mg
GIAGRA 25
Each film coated tablet contains:
Sildenafil Citrate 35.12 mg
Equivalent to Sildenafil 25 mg
108. SILDENAFIL CITRATE TABLETS 50 mg
GIAGRA 50
Each film coated tablet contains:
Sildenafil Citrate 70.24 mg
Equivalent to Sildenafil 50 mg
109. SILDENAFIL CITRATE TABLETS 100 mg
GIAGRA 100
Each film coated tablet contains:
Sildenafil Citrate 140.48 mg
Equivalent to Sildenafil 100 mg
110. AMLODIPINE TABLETS 5 mg
AMLO 5
Each uncoated tablet contains:
Amlodipine 5 mg
Equivalent to Amlodipine Besilate 6.934 mg
111. AMLODI PINE TABLETS 10 mg
AMLO 10
Each uncoated tablet contains:
Amlodipine 10 mg
Equivalent to Amlodipine Besilate 13.868 mg
112. MEMANTINE HYDROCHLORIDE TABLETS 5 mg
MENTINE 5
Each film coated tablet contains:
Memantine Hydrochloride 5 mg
113. MEMANTINE HYDROCHLORIDE TABLETS 10 mg
MENTINE 10
Each film coated tablet contains:
Memantine Hydrochloride 10 mg



Signature
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DRUGS CONTROL ADMINISTRATION
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114. EFAVIRENZ 600 mg, EMTRICITABINE 200 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS

RIZENE

Each film coated tablet contains:

Efavirenz	USP	600 mg
Emtricitabine	USP	200 mg
Tenofovir Disoproxil Fumarate		300 mg
Equivalent to Tenofovir Disoproxil		245 mg

115. SILDENAFIL CITRATE TABLETS 50 mg

SILDENAMED 50

Each film coated tablet contains:

Sildenafil Citrate	Ph.Eur	70.24 mg
Equivalent to Sildenafil		50 mg

116. SILDENAFIL CITRATE TABLETS 100 mg

SILDENAMED 100

Each film coated tablet contains:

Sildenafil Citrate	Ph.Eur	140.48 mg
Equivalent to Sildenafil		100 mg

117. PERINDOPRIL TABLETS 8 mg

DOPRIL 8

Each uncoated tablet contains:

Perindopril Tert-Butylamine	Ph.Eur	8 mg
Equivalent to Perindopril		6.676 mg

118. PERINDOPRIL ERBUMINE TABLETS 8 mg

DOPRIL 8

Each uncoated tablet contains:

Perindopril Erbumine		8 mg
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119. ENTECAVIR TABLETS 0.5 mg

ENTECAVIR SANDOZ TABLET 0.5 mg

Each film coated tablet contains:

Entecavir (as Monohydrate)		0.5 mg
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120. ENTECAVIR TABLETS 1 mg

ENTECAVIR SANDOZ TABLET 1 mg

Each film coated tablet contains:

Entecavir (as Monohydrate)		1 mg
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121. SAQUINAVIR MESILATE TABLETS 500 mg
SAQUINAVIR SANDOZ 500 mg
Each film coated tablet contains:
Saquinavir Mesilate Ph.Eur
Equivalent to Saquinavir 500 mg
122. SAQUINAVIR MESILATE TABLETS 500 mg
SAQUINAVIR FARMOZ 500 mg
Each film coated tablet contains:
Saquinavir Mesilate Ph.Eur
Equivalent to Saquinavir 500 mg
123. ARIPIRAZOLE TABLETS 10 mg
ARIPIRAZOL ALPHA 10 mg [ARIPIRAZOLUM]
Each tablet contains:
Aripiprazole 10 mg
124. ARIPIRAZOLE TABLETS 15 mg
ARIPIRAZOL ALPHA 15 mg [ARIPIRAZOLUM]
Each tablet contains:
Aripiprazole 15 mg
125. SILDENAFIL CITRATE TABLETS 50 mg
SILDENAFIL LYFIS 50 mg
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur 70.24 mg
Equivalent to Sildenafil Ph.Eur 50 mg
126. ABIRATERONE ACETATE TABLETS 250 mg
Each tablet contains:
Abiraterone Acetate 250 mg
127. SILDENAFIL CITRATE TABLETS 100 mg
SILDENAFIL LYFIS 100 mg
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur 140.48 mg
Equivalent to Sildenafil Ph.Eur 100 mg
128. QUETIAPINE FUMARATE TABLETS USP 25 mg
Each film coated tablet contains:
Quetiapine Fumarate USP
Equivalent to Quetiapine 25 mg

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139. TELMISARTAN AND HYDROCHLOROTHIAZIDE 80 mg / 12.5 mg

TELIDURIEV 80 mg/12.5 mg

Each tablet contains:

Telmisartan	Ph.Eur	80 mg
Hydrochlorothiazide	Ph.Eur	12.5 mg

140. TELMISARTAN AND HYDROCHLOROTHIAZIDE 80 mg / 12.5 mg

TEPRECOM 80 mg/ 12.5 mg

Each tablet contains:

Telmisartan	Ph.Eur	80 mg
Hydrochlorothiazide	Ph.Eur	12.5 mg

141. TELMISARTAN AND HYDROCHLOROTHIAZIDE 80 mg / 12.5 mg

FREPADAN-PRO 80 mg/ 12.5 mg

Each tablet contains:

Telmisartan	Ph.Eur	80 mg
Hydrochlorothiazide	Ph.Eur	12.5 mg

142. TELMISARTAN AND HYDROCHLOROTHIAZIDE 80 mg / 12.5 mg

ARMILARE-HOS 80 mg / 12.5 mg

Each tablet contains:

Telmisartan	Ph.Eur	80 mg
Hydrochlorothiazide	Ph.Eur	12.5 mg

143. LAMIVUDINE TABLETS 100 mg

LAMIVIR 100 mg

Each film coated tablet contains:

Lamivudine	Ph.Eur	100 mg
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144. ABACAVIR AND LAMIVUDINE TABLETS 600 mg / 300 mg

Each film coated tablet contains:

Abacavir (As Sulfate)	Ph.Eur	600 mg
Lamivudine	Ph.Eur	300 mg

145. SILDENAFIL CITRATE TABLETS 100 mg

ZED 100 mg

Each film coated tablet contains:

Sildenafil Citrate	Ph.Eur	140.48 mg
Equivalent to Sildenafil		100 mg

146. VALGANCICLOVIR TABLETS 450 mg

VALGANCICLOVIR ACCORD

Each film coated tablet contains:

Valganciclovir Hydrochloride		496.3 mg
Equivalent to Valganciclovir		450 mg



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147. LEDIPASVIR AND SOFOSBUVIR TABLETS 90 mg / 400 mg

SOFOVIR-L

Each film coated tablet contains:

Ledipasvir	90 mg
Sofosbuvir	400 mg

148. LEDIPASVIR AND SOFOSBUVIR TABLETS 90 mg / 400 mg

SOSVIR-L

Each film coated tablet contains:

Ledipasvir	90 mg
Sofosbuvir	400 mg

149. LEDIPASVIR AND SOFOSBUVIR TABLETS 90 mg / 400 mg

SOFGEN-L

Each film coated tablet contains:

Ledipasvir	90 mg
Sofosbuvir	400 mg

150. LINEZOLID TABLETS 600 mg

LINEZOLIDE KABI 600 mg

Each film coated tablet contains:

Linezolid	600 mg
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151. CELECOXIB CAPSULES 200 mg

CELECOXIB 200 mg CAPSULES HARD

Each capsule contains:

Celecoxib	Ph.Eur	200 mg
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152. SOFOSBUVIR TABLETS 400 mg

CAPRIBUVIR

Each film coated tablet contains:

Sofosbuvir	400 mg
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153. SOFOSBUVIR TABLETS 400 mg

CAPRISOPOS

Each film coated tablet contains:

Sofosbuvir	400 mg
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154. MYCOPHENOLATE MOFETIL CAPSULES 250 mg

MYCOPE 250

Each capsule contains:

Mycophenolate Mofetil	Ph.Eur	250 mg
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155. MYCOPHENOLATE MOFETIL CAPSULES 500 mg
MYCOPE 500
Each Tablet contains:
Mycophenolate Mofetil Ph.Eur 500 mg
156. ABIRATERONE ACETATE TABLETS 250mg
ABIRAT
Each tablet contains:
Abiraterone Acetate 250 mg
157. QUETIAPINE FUMARATE TABLETS 100 mg
TIAQUEL 100
Each film coated tablet contains
Quetiapine Fumarate
Equivalent to Quetiapine 100 mg
158. QUETIAPINE FUMARATE TABLETS 200 mg
TIAQUEL 200
Each film coated tablet contains
Quetiapine Fumarate
Equivalent to Quetiapine 200 mg
159. QUETIAPINE FUMARATE TABLETS 300 mg
TIAQUEL 300
Each film coated tablet contains
Quetiapine Fumarate
Equivalent to Quetiapine 300 mg
160. MYCOPHENOLATE MOFETIL CAPSULES USP 250 mg
TRANSTERO
Each capsule contains
Mycophenolate Mofetil USP 250 mg
161. TOLTERODINE TARTRATE TABLETS 1mg
Each film coated tablet contains
Tolterodine Tartrate USP 1 mg
162. TOLTERODINE TARTRATE TABLETS 2 mg
Each film coated tablet contains
Tolterodine Tartrate USP 2 mg



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163. VALACYCLOVIR TABLETS USP 1000 mg
VALTERO® 1000 mg
Each film coated tablets contains:
Valacyclovir Hydrochloride USP 1112 mg
Equivalent to Valacyclovir 1000 mg
164. VALACYCLOVIR TABLETS USP 500 mg
VALTERO® 500 mg
Each film coated tablets contains:
Valacyclovir Hydrochloride USP 556 mg
Equivalent to Valacyclovir 500 mg
165. ERLOTINIB TABLETS 25 mg
Each film coated tablet contains:
Erlotinib Hydrochloride
Equivalent to Erlotinib 25 mg
Colour: Titanium Dioxide
166. ERLOTINIB TABLETS 100 mg
Each film coated tablet contains:
Erlotinib Hydrochloride
Equivalent to Erlotinib 100 mg
Colour: Titanium Dioxide
167. ERLOTINIB TABLETS 150 mg
Each film coated tablet contains:
Erlotinib Hydrochloride
Equivalent to Erlotinib 150 mg
Colour: Titanium Dioxide
168. **ESCITALOPRAM TABLETS 10 mg**
ESOLEX 10 mg
Each film coated tablet contains:
Escitalopram Oxalate
Equivalent to Escitalopram 10 mg
169. ESCITALOPRAM TABLETS 20 mg
ESOLEX 20 mg
Each film coated tablet contains:
Escitalopram Oxalate
Equivalent to Escitalopram 20 mg

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170. QUETIAPINE FUMARATE TABLETS 25 mg
TIQUEPIN® 25 mg
Each film coated tablet contains
Quetiapine Fumarate 28.78 mg
Equivalent to Quetiapine 25 mg
171. QUETIAPINE FUMARATE TABLETS 100 mg
TIQUEPIN® 100 mg
Each film coated tablet contains
Quetiapine Fumarate 115.12 mg
Equivalent to Quetiapine 100 mg
172. QUETIAPINE FUMARATE TABLETS 200 mg
TIQUEPIN® 200 mg
Each film coated tablet contains
Quetiapine Fumarate 230.4 mg
Equivalent to Quetiapine 200 mg
173. QUETIAPINE FUMARATE TAB LETS 300 mg
TIQUEPIN® 300 mg
Each film coated tablet contains
Quetiapine Fumarate 345.6 mg
Equivalent to Quetiapine 300 mg
174. IRBESARTAN TABLETS 75 mg
IRMEGLOL 75 mg
Each film coated tablet contains
Irbesartan Ph.Eur 75 mg
175. IRBESARTAN TABLETS 150 mg
IRMEGLOL 150 mg
Each film coated tablet contains
Irbesartan Ph.Eur 150 mg
176. IRBESARTAN TABLETS 300 mg
IRMEGLOL 300 mg
Each film coated tablet contains
Irbesartan Ph.Eur 300 mg
177. ABIRATERONE ACETATE TABLETS 250 mg
ATERON
Each tablet Contains
Abiraterone Acetate 250 mg



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178. QUETIAPINE FUMARATE TABLETS 25 mg
APEGO 25 mg
Each film coated tablet contains
Quetiapine Fumarate
Equivalent to Quetiapine 25 mg
179. QUETIAPINE FUMARATE TABLETS 100 mg
APEGO 100 mg
Each film coated tablet contains
Quetiapine Fumarate
Equivalent to Quetiapine 100 mg
180. PANTOPRAZOLE GASTRO-RESISTANT TABLETS 20 mg
PANTOZYN 20 mg
Each Gastro-resistant tablet contains
Pantoprazole Sodium Sesquihydrate Ph.Eur
Equivalent to Pantoprazole 20 mg
181. PANTOPRAZOLE GASTRO-RESISTANT TABLETS 40 mg
PANTOZYN 40 mg
Each Gastro-resistant tablet contains
Pantoprazole Sodium Sesquihydrate Ph.Eur
Equivalent to Pantoprazole 40 mg
182. VALGANCICLOVIR TABLETS 450 mg
VIREXAN 450 mg
Each film coated tablet contains:
Valganciclovir Hydrochloride 496.3 mg
Equivalent to Valganciclovir 450 mg
183. VALGANCICLOVIR TABLETS 450 mg
VALHIT 450 mg
Each film coated tablet contains:
Valganciclovir Hydrochloride 496.3 mg
Equivalent to Valganciclovir 450 mg
184. LAMIVUDINE TABLETS 100 mg
RIVIRON-100
Each film coated tablet contains:
Lamivudine Ph.Eur 100 mg
185. LEVOFLOXACIN TABLETS 250 mg
Each film coated tablet contains:
Levofloxacin Hemihydrate 256.24 mg
Equivalent to Levofloxacin 250 mg



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186. LEVOFLOXACIN TABLETS 500 mg
Each film coated tablet contains:
Levofloxacin Hemihydrate 512.47 mg
Equivalent to Levofloxacin 500 mg
187. LEVOFLOXACIN TABLETS USP 250 mg
Each film coated tablet contains:
Levofloxacin Hemihydrate USP 256.24 mg
Equivalent to Levofloxacin 250 mg
188. LEVOFLOXACIN TABLETS USP 500 mg
Each film coated tablet contains:
Levofloxacin Hemihydrate USP 512.47 mg
Equivalent to Levofloxacin 500 mg
189. IRBESARTAN TABLETS 75 mg
Each film coated tablet contains:
Irbesartan 75 mg
190. IRBESARTAN TABLETS 150 mg
Each film coated tablet contains:
Irbesartan 150 mg
191. IRBESARTAN TABLETS 300 mg
Each film coated tablet contains:
Irbesartan 300 mg
192. AFATINIB TABLETS 40 mg
Each film coated tablet contains:
Afatinib Dimaleate 59.12 mg
Equivalent to Afatinib 40 mg
193. AFATINIB TABLETS 30 mg
Each film coated tablet contains:
Afatinib Dimaleate 44.34 mg
Equivalent to Afatinib 30 mg
194. AFATINIB TABLETS 20 mg
Each film coated tablet contains:
Afatinib Dimaleate 29.56 mg
Equivalent to Afatinib 20 mg



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195. TEMOZOLOMIDE CAPSULES 20 mg
TEMOZ 20 mg
Each Hard Gelatin capsule contains
Temozolomide USP 20 mg
196. TEMOZOLOMIDE CAPSULES 100 mg
TEMOZ 100 mg
Each Hard Gelatin capsule contains
Temozolomide USP 100 mg
197. TEMOZOLOMIDE CAPSULES 250 mg
TEMOZ 250 mg
Each Hard Gelatin capsule contains
Temozolomide USP 250 mg
198. ROSUVASTATIN TABLETS 5 mg
ROST 5 mg
Each film coated tablet contains
Rosuvastatin Calcium
Equivalent to Rosuvastatin 5 mg
199. ROSUVASTATIN TABLETS 40 mg
ROST 40 mg
Each film coated tablet contains
Rosuvastatin 40 mg
(As Rosuvastatin Calcium)
200. GLIPIZIDE EXTENDED RELEASE TABLETS 5 mg
Each extended release tablet contains:
Glipizide 5 mg
201. OSELTAMIVIR FOR ORAL SUSPENSION 6 mg/ mL
Each mL contains:
Oseltamivir Phosphate USP 7.882 mg
Equivalent to Oseltamivir 6 mg
202. LINEZOLID FOR ORAL SUSPENSION 100 mg/ 5 mL
Each 5mL contains:
Linezolid 100 mg
203. VORICONAZOLE FOR ORAL SUSPENSION 40 mg/ mL
Each mL of suspension contains:
Voriconazole USP 40 mg
After reconstitution



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204. LENALIDOMIDE CAPSULES 5 mg
Each hard gelatin capsule contains
Lenalidomide 5 mg
205. LENALIDOMIDE CAPSULES 10 mg
Each hard gelatin capsule contains
Lenalidomide 10 mg
206. LENALIDOMIDE CAPSULES 25 mg
Each hard gelatin capsule contains
Lenalidomide 25 mg
207. MEMANTINE HYDROCHLORIDE TABLETS 5 mg
Each film coated tablet contains:
Memantine Hydrochloride 5 mg
208. MEMANTINE HYDROCHLORIDE TABLETS 10 mg
Each film coated tablet contains:
Memantine Hydrochloride 10 mg
209. MEMANTINE HYDROCHLORIDE TABLETS 15 mg
Each film coated tablet contains:
Memantine Hydrochloride 15 mg
210. MEMANTINE HYDROCHLORIDE TABLETS 20 mg
Each film coated tablet contains:
Memantine Hydrochloride 20 mg
211. ATOVAQUONE 62.5 mg + PROGUANIL HYDROCHLORIDE 25 mg TABLETS
Each film coated tablet contains
Atovaquone 62.5 mg
Proguanil Hydrochloride Ph.Eur. 25 mg
212. ATOVAQUONE 250 mg + PROGUANIL HYDROCHLORIDE 100 mg TABLETS
Each film coated tablet contains
Atovaquone 250 mg
Proguanil Hydrochloride Ph.Eur. 100 mg
213. POMALIDOMIDE CAPSULES 1 mg
Each hard gelatin capsule contains
Pomalidomide 1 mg

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3.1.2019





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214. POMALIDOMIDE CAPSULES 2 mg
Each hard gelatin capsule contains
Pomalidomide 2 mg
215. POMALIDOMIDE CAPSULES 3 mg
Each hard gelatin capsule contains
Pomalidomide 3 mg
216. POMALIDOMIDE CAPSULES 4 mg
Each hard gelatin capsule contains
Pomalidomide 4 mg
217. DACLATASVIR TABLETS 30 mg
DACLAHEP
Each film coated tablet contains
Daclatasvir Dihydrochloride
Equivalent to Daclatasvir 30 mg
218. SITAGLIPTIN FILM COATED TABLETS 25 mg
Each film coated tablet contains:
Sitagliptin 25 mg
(as Hydrochloride Monohydrate)
219. SITAGLIPTIN FILM COATED TABLETS 50 mg
Each film coated tablet contains:
Sitagliptin 50 mg
(as Hydrochloride Monohydrate)
220. SITAGLIPTIN FILM COATED TABLETS 100 mg
Each film coated tablet contains:
Sitagliptin 100 mg
(as Hydrochloride Monohydrate)
221. SITAGLIPTIN AND METFORMIN HYDROCHLORIDE 50 mg/ 850 mg FILM COATED TABLETS
Each film coated tablet contains:
Sitagliptin (as Hydrochloride) 50 mg
Metformin Hydrochloride 850 mg
222. SITAGLIPTIN AND METFORMIN HYDROCHLORIDE 50 mg/ 1000 mg FILM COATED TABLETS
Each film coated tablet contains:
Sitagliptin (as Hydrochloride) 50 mg
Metformin Hydrochloride 1000 mg



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223. IBRUTINIB CAPSULES 140 mg
Each hard gelatin capsule contains:
Ibrutinib 140 mg
224. CINACALCET TABLETS 30 mg
Each film coated tablet contains:
Cinacalcet Hydrochloride
Equivalent to Cinacalcet 30 mg
225. ARIPIRAZOLE TABLETS 5mg
Each un coated tablet contains:
Aripiprazole 5 mg
226. TENOFOVIR ALAFENAMIDE TABLETS 25 mg
Each film coated tablet contains:
Tenofovir Alafenamide 25 mg
Equivalent to Tenofovir Alafenamide Hemifumarate 28.043 mg
227. GEFITINIB TABLETS 250 mg
Each film coated tablet contains:
Gefitinib 250 mg
228. EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE
TABLETS 600/300/300 mg
Each film coated tablet contains:
Efavirenz USP 600 mg
Lamivudine USP 300 mg
Tenofovir Disoproxil Fumarate 300 mg
Equivalent to Tenofovir Disoproxil 245 mg
229. Olmesartan Medoxomil and Hydrochlorothiazide Tablets 20mg/12.5mg
Each film coated tablet contains:
Olmesartan Medoxomil USP 20 mg
Hydrochlorothiazide USP 12.5 mg
230. Olmesartan Medoxomil and Hydrochlorothiazide Tablets 40mg/12.5mg
Each film coated tablet contains:
Olmesartan Medoxomil USP 40 mg
Hydrochlorothiazide USP 12.5 mg
231. Olmesartan Medoxomil and Hydrochlorothiazide Tablets 40mg/25mg
Each film coated tablet contains:
Olmesartan Medoxomil USP 40 mg
Hydrochlorothiazide USP 25 mg



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232. Olmesartan Medoxomil and Hydrochlorothiazide Tablets 20mg/12.5mg
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur 20 mg
Hydrochlorothiazide Ph.Eur 12.5 mg
233. Olmesartan Medoxomil and Hydrochlorothiazide Tablets 40mg/12.5mg
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur. 40 mg
Hydrochlorothiazide Ph.Eur. 12.5 mg
234. Olmesartan Medoxomil and Hydrochlorothiazide Tablets 40mg/25mg
Each film coated tablet contains:
Olmesartan Medoxomil Ph.Eur. 40 mg
Hydrochlorothiazide Ph.Eur. 25 mg
235. ROSUVASTATIN CALCIUM TABLETS 5 mg
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 5 mg
236. ROSUVASTATIN CALCIUM TABLETS 10 mg
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 10 mg
237. ROSUVASTATIN TABLETS 10 mg
ROST 10
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 10 mg
238. ROSUVASTATIN CALCIUM TABLETS 20 mg
Each film coated tablet contains:
Rosuvastatin Calcium.
Equivalent to Rosuvastatin 20 mg
239. ROSUVASTATIN TABLETS 20 mg
ROST 20
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 20 mg



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240. ROSUV ASTATIN CALCIUM TABLETS 40 mg
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 40 mg
241. PRASUGREL TABLETS 5mg
Each Film-Coated tablet contains:
Prasugrel Hydrochloride
Equivalent to Prasugrel 5 mg
242. PRASUGREL TABLETS 10mg
Each Film-Coated tablet contains:
Prasugrel hydrochloride
Equivalent to Prasugrel 10 mg
243. Mycophenolate Mofetil Capsules 250mg
Each capsule contains
Mycophenolate Mofetil Ph.Eur 250 mg
244. Mycophenolate Mofetil Tablets 500mg
Each Tablets contains
Mycophenolate Mofetil, Ph.Eur 500 mg
245. ABACAVIR TABLETS 300mg
Each Film Coated tablet contains
Abacavir 300mg
246. EFAVIRENZ, EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE
TABLETS 600 mg/200 mg/300 mg
TRUSTIVA
Each film coated tablet contains:
Efavirenz USP 600 mg
Emtricitabine USP 200 mg
Tenofovir Disoproxil Fumarate 300 mg
Equivalent to Tenofovir Disoproxil 245mg
247. FEXOFENADINE HYDROCHLORIDE TABLETS 180 mg
FEXOGEN 180
Each film coated tablet contains:
Fexofenadine Hydrochloride Ph.Eur. 180 mg



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248. IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS 150mg/12.5mg

IRBIGEN-H 150mg/12.5 mg

Each film coated tablet contains:

Irbesartan	Ph.Eur.	150 mg
Hydrochlorothiazide	Ph.Eur.	12.5 mg

249. ARIPIPRAZOLE TABLETS 10mg

DERIPEX 10

Each tablet contains:

Aripiprazole		10mg
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250. ARIPIPRAZOLE TABLETS 15mg

DERIPEX 15

Each tablet contains:

Aripiprazole		15mg
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251. TELMISARTAN TABLETS 40mg

TELCARD 40

Each tablet contains:

Telmisartan	Ph.Eur.	40 mg
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252. TELMISARTAN TABLETS 80mg

TELCARD 80

Each tablet contains:

Telmisartan	Ph.Eur.	80 mg
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253. OLMESARTAN MEDOXOMIL TABLETS 20mg

OLMICARD 20

Each film coated tablet contains:

Olmesartan Medoxomil	Ph.Eur.	20 mg
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254. OLMESARTAN MEDOXOMIL TABLETS 40mg

OLMICARD 40

Each film coated tablet contains:

Olmesartan Medoxomil	Ph.Eur.	40 mg
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255. VALGANCICLOVIR TABLETS 450 mg

GANCIL 450

Each Film- Coated tablet contains:

Valganciclovir Hydrochloride		496.3 mg
Equivalent to Valganciclovir		450 mg

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256. OLANZAPINE TABLETS 5mg
OLANZA 5 mg
Each film coated tablet contains:
Olanzapine Ph.Eur 5 mg
257. OLANZAPINE TABLETS 10mg
OLANZA 10 mg
Each film coated tablet contains:
Olanzapine Ph.Eur 10 mg
258. MONTELUKAST SODIUM TABLETS 10mg
MONTIKAR 10
Each film coated tablet contains:
Montelukast Sodium Ph.Eur.
Equivalent to Montelukast 10 mg
259. LEVOFLOXACIN TABLETS 250mg
LIVA 250
Each film coated tablet contains:
Levofloxacin Hemihydrate 256.24 mg
Equivalent to Levofloxacin 250mg
260. LEVOFLOXACIN TABLETS 500mg
LIVA 500
Each film coated tablet contains:
Levofloxacin Hemihydrate 512.47 mg
Equivalent to Levofloxacin 500mg
261. CLOPIDOGREL TABLETS 75mg
THINRIN 75
Each film coated tablet contains:
Clopidogrel Hydrogen Sulfate Ph.Eur.
Equivalent to Clopidogrel 75mg
262. AMLODIPINE TABLETS 10mg
ACT 10
Each uncoated tablet contains:
Amlodipine Besilate Ph.Eur 13.868 mg
Equivalent to Amlodipine 10mg
263. PANTOPRAZOLE GASTRO RESISTANT TABLETS 20mg
PAN 20
Each gastro resistant tablet contains:
Pantoprazole Sodium Sesquihydrate Ph.Eur.
Equivalent to Pantoprazole 20mg



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264. PANTOPRAZOLE GASTRO RESISTANT TABLETS 40mg

PAN 40

Each gastro resistant tablet contains:

Pantoprazole Sodium Sesquihydrate Ph.Eur.

Equivalent to Pantoprazole

40mg

265. AMLODIPINE TABLETS 5 mg

CARZODINE 5

Each uncoated tablet contains:

Amlodipine Besilate

Ph.Eur.

6.934 mg

Equivalent to Amlodipine

5mg

266. AMLODIPINE TABLETS 10mg

CARZODINE 10

Amlodipine Besilate Ph.Eur.

13.869 mg

Equivalent to Amlodipine

10 mg

267. IRBESARTAN TABLETS 150 mg

WINSARTAN 150

Each film coated tablet contains:

Irbesartan

Ph.Eur

150mg

268. IRBESARTAN TABLETS 300 mg

WINSARTAN 300

Each film coated tablet contains:

Irbesartan

Ph.Eur

300mg

269. Clopidogrel Tablets 75 mg

CLOVAX 75

Each film coated tablet contains:

Clopidogrel Hydrogen Sulfate

Ph.Eur

Equivalent to Clopidogrel

75mg

270. SILDENAFIL CITRATE TABLETS 25 mg

HETAGRA-25

Each film coated tablet contains:

Sildenafil Citrate

Ph.Eur.

Equivalent to Sildenafil

25 mg

271. SILDENAFIL CITRATE TABLETS 50 mg

HETAGRA-50

Each film coated tablet contains:

Sildenafil Citrate

Ph.Eur.

Equivalent to Sildenafil

50 mg



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272. SILDENAFIL CITRATE TABLETS 100 mg
HETAGRA-100
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur.
Equivalent to Sildenafil 100 mg
273. SILDENAFIL CITRATE TABLETS 25 mg
SILDENAFILORIFARM 25
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 35.12 mg
Equivalent to Sildenafil 25 mg
274. SILDENAFIL CITRATE TABLETS 50 mg
SILDENAFILORIFARM 50
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24mg
Equivalent to Sildenafil 50 mg
275. SILDENAFIL CITRATE TABLETS 100 mg
SILDENAFILORIFARM 100
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 140.48mg
Equivalent to Sildenafil 100 mg
276. SILDENAFIL CITRATE TABLETS 25 mg
SILDENOVA 25 mg
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 35.12 mg
Equivalent to Sildenafil 25 mg
277. SILDENAFIL CITRATE TABLETS 50 mg
SILDENOVA 50 mg
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24mg
Equivalent to Sildenafil 50 mg
278. SILDENAFIL CITRATE TABLETS 100 mg
SILDENOVA 100 mg
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 140.48mg
Equivalent to Sildenafil 100 mg



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279. SILDENAFIL CITRATE TABLETS 25 mg
SIFE 25 mg
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 35.12 mg
Equivalent to Sildenafil 25 mg
280. SILDENAFIL CITRATE TABLETS 50 mg
SIFE 50
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24mg
Equivalent to Sildenafil 50 mg
281. SILDENAFIL CITRATE TABLETS 100 mg
SIFE 100
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 140.48mg
Equivalent to Sildenafil 100 mg
282. SILDENAFIL CITRATE TABLETS 25 mg
GIAGRA 25
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 35.12 mg
Equivalent to Sildenafil 25 mg
283. SILDENAFIL CITRATE TABLETS 50 mg
GIAGRA 50
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24mg
Equivalent to Sildenafil 50 mg
284. SILDENAFIL CITRATE TABLETS 100 mg
GIAGRA 100
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 140.48mg
Equivalent to Sildenafil 100 mg
285. SILDENAFIL CITRATE TABLETS 25 mg
CAMASTIL 25
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 35.12 mg
Equivalent to Sildenafil 25 mg



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286. SILDENAFIL CITRATE TABLETS 50 mg
CAMASTIL 50
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24mg
Equivalent to Sildenafil 50 mg
287. SILDENAFIL CITRATE TABLETS 100 mg
CAMASTIL 100
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 140.48mg
Equivalent to Sildenafil 100 mg
288. ABACAVIR AND LAMIVUDINE TABLETS 600/300 mg
Each film coated tablet contains:
Abacavir 600mg
Lamivudine Ph.Eur. 300mg
289. LAMIVUDINE AND ZIDOVUDINE TABLETS USP 150/300 mg
LAVUZID
Each film coated tablet contains
Lamivudine USP 150mg
Zidovudine USP 300 mg
290. LAMIVUDINE AND ZIDOVUDINE TABLETS 150/300 mg
LAZID 150/300 mg
Each film coated tablet contains:
Lamivudine Ph.Eur. 150mg
Zidovudine Ph.Eur. 300mg
291. ABACAVIR SULFATE & LAMIVUDINE TABLETS 600mg/300 mg
ABCAR-L 600/300
Each film coated tablet contains:
Abacavir Sulfate USP 600mg
Equivalent to Abacavir 600mg
Lamivudine USP 300mg
292. ARIPIPRAZOLE TABLETS 10 mg
ARIPIFY 10
Each tablet contains:
Aripiprazole 10mg
293. OLANZAPINE TABLETS 10 mg
ZYPIN 10
Each film coated tablet contains:
Olanzapine Ph.Eur 10mg



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294. **ESCITALOPRAM TABLETS 10 mg**
ESILEX 10
Each film coated tablets contains:
Escitalopram Oxalate
Equivalent to Escitalopram 10mg
295. **CELECOXIB CAPSULES 200 mg**
Each capsule contains:
Celecoxib Ph.Eur 200mg
296. **CELECOXIB CAPSULES 200 mg**
SIBREX 200
Each capsule contains:
Celecoxib Ph.Eur 200mg
297. **ABACAVIR SULFATE & LAMIVUDINE TABLETS 600/300 mg**
ABALAM
Each film coated tablet contains:
Abacavir Sulfate USP 600mg
Equivalent to Abacavir
Lamivudine USP 300mg
298. **MYCOPHENOLATE MOFETIL CAPSULES USP 250 mg**
Each capsule contains
Mycophenolate Mofetil USP 250 mg
299. **MYCOPHENOLATE MOFETIL TABLETS USP 500 mg**
Each tablet contains
Mycophenolate Mofetil USP 500 mg
300. **ROSUVASTATIN CALCIUM TABLETS 5 mg**
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 5 mg
301. **ROSUVASTATIN CALCIUM TABLETS 10 mg**
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 10 mg
302. **ROSUVASTATIN CALCIUM TABLETS 20 mg**
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 20 mg



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- 303. ROSUVASTATIN CALCIUM TABLETS 40 mg**
Each film coated tablet contains:
Rosuvastatin Calcium
Equivalent to Rosuvastatin 40 mg
- 304. EPROSARTAN TABLETS 400 mg**
Each film coated tablet contains:
Eprosartan Mesylate
Equivalent to Eprosartan 400mg
- 305. EPROSARTAN TABLETS 600 mg**
Each film coated tablet contains:
Eprosartan Mesylate
Equivalent to Eprosartan 600mg
- 306. QUETIAPINE FUMARATE TABLETS 25 mg**
Each film coated tablet contains:
Quetiapine Fumarate 28.78 mg
Equivalent to Quetiapine 25 mg
- 307. QUETIAPINE FUMARATE TABLETS 100 mg**
Each film coated tablet contains:
Quetiapine Fumarate 115.12mg
Equivalent to Quetiapine 100 mg
- 308. QUETIAPINE FUMARATE TABLETS 200 mg**
Each film coated tablet contains:
Quetiapine Fumarate 230.24 mg
Equivalent to Quetiapine 200 mg
- 309. QUETIAPINE FUMARATE TABLETS 300 mg**
Each film coated tablet contains:
Quetiapine Fumarate 345.36 mg
Equivalent to Quetiapine 300mg
- 310. OLANZAPINE TABLETS 5 mg**
Each film coated tablet contains
Olanzapine Ph.Eur. 5 mg
- 311. OLANZAPINE TABLETS 7.5 mg**
Each film coated tablet contains
Olanzapine Ph.Eur. 7.5 mg



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- 312. OLANZAPINE TABLETS 15 mg**
Each film coated tablet contains
Olanzapine Ph .Eur. 15 mg
- 313. FEXOFENADINE HYDROCHLORIDE TABLETS 180 mg**
Each film coated tablet contains:
Fexofenadine Hydrochloride Ph.Eur. 180 mg
- 314. SILDENAFIL CITRATE TABLETS 25 mg**
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 35.12 mg
Equivalent to Sildenafil 25 mg
- 315. SILDENAFIL CITRATE TABLETS 50 mg**
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24 mg
Equivalent to Sildenafil 50 mg
- 316. SILDENAFIL CITRATE TABLETS 100 mg**
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 140.48 mg
Equivalent to Sildenafil 100 mg
- 317. SILDENAFIL CITRATE TABLETS 20 mg**
Each film coated tablet contains
Sildenafil Citrate
Equivalent to Sildenafil 20 mg
- 318. CLOPIDOGREL TABLETS 75mg**
Each film coated tablet contains:
Clopidogrel Hydrogen Sulfate Ph.Eur.
Equivalent to Clopidogrel 75mg
- 319. RABEPRAZOLE SODIUM DELAYED RELEASE TABLETS 10 mg**
Each Delayed Release tablet contains
Rabeprazole Sodium 10 mg
- 320. RABEPRAZOLE SODIUM DELAYED RELEASE TABLETS 20 mg**
Each Delayed Release tablet contains
Rabeprazole Sodium 20 mg
- 321. ENTECAVIR TABLETS 0.5 mg**
Each film coated tablet contains
Entecavir (as monohydrate) 0.5 mg



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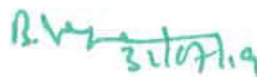


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- 322. ENTECAVIR TABLETS 1 mg**
Each film coated tablet contains
Entecavir (as monohydrate) 1 mg
- 323. OLMESARTAN MEDOXOMIL TABLETS 5 mg**
Each Film - Coated tablet contains:
Olmesartan Medoxomil USP 5mg
- 324. OLMESARTAN MEDOXOMIL TABLETS 20 mg**
Each Film - Coated tablet contains:
Olmesartan Medoxomil USP 20 mg
- 325. OLMESARTAN MEDOXOMIL TABLETS 40 mg**
Each Film - Coated tablet contains:
Olmesartan Medoxomil USP 40mg
- 326. CELECOXIB CAPSULES 100 mg**
Each capsule contains:
Celecoxib Ph.Eur. 100 mg
- 327. PERINDOPRIL TABLETS 8 mg**
Each tablet contains:
Perindopril tert-Butylamine Ph.Eur 8 mg
Equivalent to Perindopril 6.676 mg
- 328. VALACYCLOVIR HYDROCHLORIDE TABLETS USP 500 mg**
Each film coated tablet contains:
Valacyclovir Hydrochloride USP 556 mg
Equivalent to Valacyclovir 500 mg
- 329. VALACYCLOVIR HYDROCHLORIDE TABLETS USP 1000 mg**
Each film coated tablet contains
Valacyclovir Hydrochloride USP 1112 mg
Equivalent to Valacyclovir 1000 mg
- 330. EFAVIRENZ TABLETS USP 600 mg**
Each film coated tablet contains
Efavirenz USP 600 mg
- 331. DONEPEZIL HYDROCHLORIDE TABLETS USP 5 mg**
Each film coated tablet contains:
Donepezil Hydrochloride USP 5 mg



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340. ENTECAVIR TABLETS 1 mg
BENVIR Film Coated tablets 1mg
Each film coated tablet contains:
Entecavir 1mg
341. VALGANCICLOVIR TABLETS 450 mg
XANVOR Film coated tablets 450 mg
Each film coated tablet contains:
Valganciclovir Hydrochloride USP 496.3mg
Equivalent to Valganciclovir 450mg
342. ABACAVIR SULFATE & LAMIVUDINE TABLETS 600 mg/300 mg
ABCAR-L 600/300
Each film coated tablet contains:
Abacavir Sulfate USP 600mg
Equivalent to Abacavir 600mg
Lamivudine USP 300mg
343. OLANZAPINE TABLETS 2.5 mg
OLANTERO 2.5 mg
Each film coated tablet contains:
Olanzapine Ph.Eur. 2.5mg
344. OLANZAPINE TABLETS 5 mg
OLANTERO 5 mg
Each film coated tablet contains:
Olanzapine Ph.Eur. 5mg
345. OLANZAPINE TABLETS 10 mg
OLANTERO 10
Each film coated tablet contains:
Olanzapine Ph.Eur. 10mg
346. OLANZAPINE TABLETS 15 mg
OLANTERO 15 mg
Each film coated tablet contains:
Olanzapine Ph.Eur. 15mg
347. Donepezil Hydrochloride Tablets 5 mg
DEMIZEPT 5
Each film coated tablet contains
Donepezil Hydrochloride USP 5 mg



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348. Donepezil Hydrochloride Tablets 10 mg
DEMIZEPT 10
Each film coated tablet contains
Donepezil Hydrochloride USP 10 mg
349. Escitalopram Tablets 10 mg
ALVODEP 10
Each film coated tablet contains:
Escitalopram Oxalate
Equivalent to Escitalopram 10 mg
350. Escitalopram Tablets 20 mg
ALVODEP 20
Each film coated tablet contains:
Escitalopram Oxalate
Equivalent to Escitalopram 20 mg
351. Aripiprazole Tablets 10 mg
ALVOPIP 10
Each tablet contains
Aripiprazole 10 mg
352. Aripiprazole Tablets 15 mg
ALVOPIP 15
Each tablet contains
Aripiprazole 15 mg
353. Alfuzosin Hydrochloride Extended Release Tablets 10 mg
UROZEEN 10
Each tablet contains:
Alfuzosin Hydrochloride Ph.Eur. 10 mg
354. Levofloxacin Tablets 500 mg
CIDIQUIN 500
Each film coated tablet contains:
Levofloxacin Hemihydrate 512.47 mg
Equivalent to Levofloxacin 500 mg
355. SILDENAFIL CITRATE TABLETS 50 mg
FREEXA 50
Each film coated tablet contains:
Sildenafil Citrate Ph.Eur. 70.24 mg
Equivalent to Sildenafil 50 mg



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356. SILDENAFIL CITRATE TABLETS 100 mg
FREEXA 100
Each film coated tablet contains:
Sildenafil citrate Ph.Eur. 140.48 mg
Eq. to Sildenafil 100mg
357. LAMIVUDINE TABLETS 100 mg
Each film coated tablet contains:
Lamivudine Ph.Eur 100 mg
358. PANTOPRAZOLE SODIUM DELAYED RELEASE TABLETS USP 20 mg
PANTIN 20
Each delayed release tablet contains:
Pantoprazole sodium Sesquihydrate USP
Equivalent to Pantoprazole 20 mg
359. PANTOPRAZOLE SODIUM DELAYED RELEASE TABLETS USP 40 mg
PANTIN 40
Each delayed release tablet contain:
Pantoprazole sodium Sesquihydrate USP
Equivalent to Pantoprazole 40 mg
360. QUETIAPINE FUMARATE TABLETS 150 mg
QUTERO 150
Each film coated tablet contains
Quetiapine Fumarate 172.68 mg
Equivalent to Quetiapine 150 mg
361. LINEZOLID TABLETS 600 mg
LINEZOLE 600 mg
Each film coated tablet contains:
Linezolid 600mg
362. ROSUVASTATIN TABLETS 5mg
CAROZA 5
Each film coated tablet contains:
Rosuvastatin 5mg
(As Rosuvastatin Calcium)
363. ROSUVASTATIN TABLETS 10mg
CAROZA 10
Each film coated tablet contains:
Rosuvastatin 10mg
(As Rosuvastatin Calcium)



B. V. 31/01/19



DRUGS CONTROL ADMINISTRATION
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364. ROSUVASTATIN TABLETS 20 mg
CAROZA 20
Each film coated tablet contains:
Rosuvastatin 20mg
(As Rosuvastatin Calcium)
365. ROSUVASTATIN TABLETS 40 mg
CAROZA 40
Each film coated tablet contains:
Rosuvastatin 40mg
(As Rosuvastatin Calcium)
366. LACOSAMIDE TABLETS 50 mg
LACOX 50
Each film coated tablet contains:
Lacosamide 50mg
367. LACOSAMIDE TABLETS 100mg
LACOX 100
Each film coated tablet contains:
Lacosamide 100 mg
368. LACOSAMIDE TABLETS 150mg
LACOX 150
Each film coated tablet contains:
Lacosamide 150mg
369. LACOSAMIDE TABLETS 200mg
LACOX 200
Each film coated tablet contains:
Lacosamide 200mg
370. **PIOGLITAZONE HYDROCHLORIDE TABLETS 15 mg**
Each tablet contains:
Pioglitazone Hydrochloride
Equivalent to Pioglitazone 15 mg
371. **PIOGLITAZONE HYDROCHLORIDE TABLETS 30 mg**
Each tablet contains:
Pioglitazone Hydrochloride
Equivalent to Pioglitazone 30 mg



B. Venkatesh
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DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No. 735/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-V, Sy.No.439, 440, 441 & 458, TSIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India in Form-25 bearing No.50/MN/AP/2009/F/R, dt:19.12.2009.

- 372. PIOGLITAZONE HYDROCHLORIDE TABLETS 45 mg**
Each tablet contains:
Pioglitazone Hydrochloride
Equivalent to Pioglitazone 45 mg
- 373. ACYCLOVIR TABLETS USP 400 mg**
Each tablet contains:
Acyclovir USP 400 mg
- 374. ACYCLOVIR TABLETS USP 800 mg**
Each tablet contains:
Acyclovir USP 800 mg
- 375. CELECOXIB CAPSULES 100 mg**
Each capsule contains:
Celecoxib 100 mg
- 376. CELECOXIB CAPSULES 200 mg**
Each capsule contains:
Celecoxib 200 mg
- 377. PERINDOPRIL ERBUMINE TABLETS 8 mg**
Each tablet contains:
Perindopril Erbumine 8 mg
- 378. DONEPEZIL HYDROCHLORIDE TABLETS 5 mg**
Each film coated tablet contains:
Donepezil Hydrochloride USP 5 mg
- 379. DONEPEZIL HYDROCHLORIDE TABLETS 10 mg**
Each film coated tablet contains:
Donepezil 10 mg
- 380. Efavirenz, Emtricitabine & Tenofovir Disoproxil Fumarate Tablets 600mg/ 200 mg/ 300 mg**
Each film coated tablet contains:
Efavirenz USP 600 mg
Emtricitabine 200 mg
Tenofovir Disoproxil fumarate 300 mg
Equivalent to Tenofovir Disoproxil 245 mg



B. Venkata
3.10.19

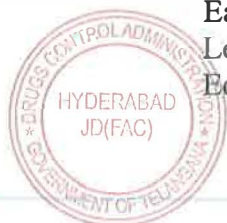


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388. Famciclovir Tablets 250 mg
PENVIR 250
Each film coated tablet contains
Famciclovir 250 mg
389. Famciclovir Tablets 500 mg
PENVIR 500
Each film coated tablet contains
Famciclovir 500 mg
390. Famciclovir Tablets 750 mg
PENVIR 750
Each film coated tablet contains
Famciclovir 750 mg
391. Montelukast Sodium Paediatric Chewable Tablets 4 mg
MONTE-H 4
Each tablet contains
Montelukast Sodium
Equivalent to Montelukast 4 mg
392. Montelukast Sodium Paediatric Chewable Tablets 5 mg
MONTE-H 5
Each tablet contains
Montelukast Sodium
Equivalent to Montelukast 5 mg
393. Montelukast Sodium Tablets 10 mg
MONTE-H 10
Each film coated tablet contains
Montelukast Sodium
Equivalent to Montelukast 10 mg
394. Zidovudine, Lamivudine and Nevirapine Tablets 300mg/150mg/200mg
ZIDOLAM-N
Each film coated tablet contains:
Zidovudine USP 300 mg
Lamivudine USP 150 mg
Nevirapine USP 200 mg
395. LEVOFLOXACIN TABLETS 500 mg
HETLOX-500
Each film coated tablet contains:
Levofloxacin Hemihydrate 512.47 mg
Equivalent to Levofloxacin 500 mg



R. M. 3.10.19



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396. LETROZOLE TABLETS USP 2.5 mg

Each film coated tablet contains:

Letrozole USP 2.5 mg

Manufacturer : **M/s. Hetero Labs Limited Unit-V**
Sy.No.439, 440, 441 & 458
TSIIC Formulation SEZ, Polepally Village,
Jadcherla Mandal, Mahaboobnagar District,
Telangana State, India.

When applicable : Placing the product on the market as
detailed above.

It is certified that these products has been authorized to be placed on the market for use in the country and exporting countries.

Drug Licence No. : **50/MN/AP/2009/F/R, dt: 19.12.2009**
in Form- 25.

The firm **M/s. Hetero Labs Limited Unit-V**, Sy.No.439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India was jointly inspected by Mr. V. Anjaneya Mithra, Drugs Inspector, CDSCO Zonal Office, S.R.Nagar, Hyderabad and Dr. B. Lakshmi Narayana, Drugs Inspector, Drugs Control Administration, Telangana, Hyderabad from 24.06.2019 to 26.06.2019.

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 (**Three Hundred and Ninety Six**) for Export in the international market.

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



To
M/s. HETERO LABS LIMITED Unit-V
Sy.No.439, 440, 441 & 458
TSIIC Formulation SEZ, Polepally Village
Jadcherla Mandal, Mahaboobnagar District
Telangana State, India


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