



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.326/A3/2019

Dated: -11-2019

To

M/s. GRANULES INDIA LIMITED,
Sy.No.160/A, 161/E, 162, & 174/A,
Gagillapur Village, Dundigal-Gandimaisamma Mandal,
Medchal-Malkajgiri District – 500043,
Telangana, INDIA.

Sirs

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of **WORLD HEALTH ORGANIZATION G.M.P. CERTIFICATE** – Regarding.

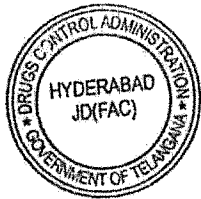
Ref: 1. Your letter dated: 21.01.2019
2. Joint Inspection report dt: 03.07.2019 & 04.07.2019.
3. Lr.No. 5-6(470-A3)/2019/5698, dated 11.11.2019 of Deputy
Drugs Controller (India), CDSCO, Hyderabad.

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With reference to your application cited, I forward herewith “**WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE**” **CERTIFICATE** for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Telangana State and CDSCO, Zonal Office, Hyderabad vide reference 2nd cited.

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

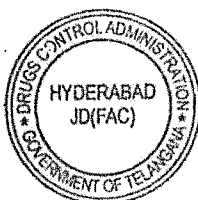
Yours faithfully,



B. Venkaeshwarlu
26/11/19
Dr. B. VENKAESHWARLU
JOINT DIRECTOR (FAC)
LICENSING & CONTROLLING AUTHORITY

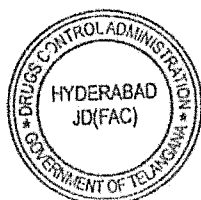
**LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION SCHEME FOR
EXPORT PURPOSE**

1. **ACETAMINOPHEN DC GRANULES**
COMPRESSO PAP 90CPL
Each gram of granules contains Acetaminophen USP 900 mg
2. **PARACETAMOL DC GRANULES**
COMPRESSO PAP 90CPL
Each gram of granules contains Paracetamol Ph.Eur 900 mg
3. **Acetaminophen DC Granules**
COMPRESSO PAP 90 CPF
Each gram of granules contains Acetaminophen USP 900 mg
4. **Paracetamol DC Granules**
COMPRESSO PAP 90 CPF
Each gram of granules contains Paracetamol Ph.Eur 900 mg
5. **Compresso PAP 90 CPC**
Acetaminophen directly compressible granules
Each gram of granules contains Acetaminophen USP 900 mg
6. **Paracetamol DC Granules**
COMPRESSO PAP 90 CPC
Each gram of granules contains Paracetamol Ph.Eur 900 mg
7. **ACETAMINOPHEN DC GRANULES**
COMPRESSO PAP 96P
Each gram of granules contains Acetaminophen USP 960 mg
8. **PARACETAMOL DC GRANULES**
COMPRESSO PAP 96P
Each gram of granules contains Paracetamol Ph.Eur 960 mg
9. **Acetaminophen DC Granules**
COMPRESSO PAP 90P
Each gram of granules contains Acetaminophen USP 900 mg
10. **Paracetamol DC Granules**
COMPRESSO PAP 90P
Each gram of granules contains Paracetamol Ph.Eur 900 mg
11. **Compresso PAP 90 CPU**
Acetaminophen Directly Compressible Granules
Each gram of granules contains Acetaminophen USP 896.0 mg
12. **Compresso PAP 90 CPU**
Paracetamol Directly Compressible Granules
Each gram of granules contains Paracetamol Ph.Eur 896.0 mg
13. **IBUPROFEN DC GRANULES**
COMPRESSO IBU 90CP
Each gram of granules contains Ibuprofen USP 900mg
14. **IBUPROFEN DC GRANULES**
COMPRESSOIBU90CP
Each gram of granules contains Ibuprofen Ph.Eur 900mg

B. Venkatesh
26/11/19

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

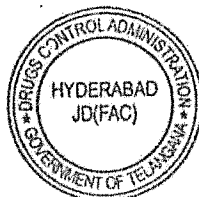
15. **IBUPROFEN DC GRANULES**
COMPRESSO IBU 66S
Each gram of granules contains Ibuprofen USP 660 mg
16. **Compresso IBU 66S (Ibuprofen Directly Compressible Granules)**
Each gram of granules contains Ibuprofen Ph.Eur 660 mg
17. **Compresso MF 95P (Metformin Hydrochloride Directly Compressible Granules)**
Each gram of granules contains Metformin Hydrochloride USP 950 mg
18. **Compresso MF 95P (Metformin Hydrochloride Directly Compressible Granules)**
Each gram of granules contains Metformin Hydrochloride Ph.Eur 950mg
19. **Metformin Hydrochloride DC Granules**
Compresso MF 90 P
Each gram of granules contains Metformin Hydrochloride Ph.Eur 900 mg
20. **Metformin Hydrochloride DC Granules**
Compresso MF 90 P
Each gram of granules contains Metformin Hydrochloride USP 900 mg
21. **Guaifenesin Directly compressible Granules**
COMPRESSO GGF 95SA
Each gram of granules contains Guaifenesin USP 950mg
22. **Guaifenesin Directly compressible Granules**
COMPRESSO GGF 95SA
Each gram of granules contains Guaifenesin Ph.Eur 950mg
23. **Compresso PAP 90 CPM (Acetaminophen 90%&Chlorpheniramine Maleate 0.55% GranulesDC)**
Directly compressible granules contains Acetaminophen USP 90% Chlorpheniramine Maleate 0.55%
24. **Paracetamol tablets**
Pangran Granules
Directly compressible granules containing Paracetamol Ph. Eur - 84.18%
25. **Compresso MF 95P (Metformin Hydrochloride Directly Compressible Granules)**
Each gram of granules contains Metformin Hydrochloride USP 950 mg



B. V. S. R. J. S.
26/11/19

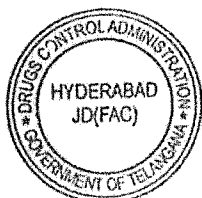
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EXPORT PURPOSE**

26. **Compresso MF 95P (Metformin Hydrochloride Directly Compressible Granules)**
Each gram of granules contains Metformin Hydrochloride Ph.Eur 950mg
27. **Acetaminophen Rapid Release Gel caps 500mg (Gray)**
Each Rapid Release Gelcaps contains Acetaminophen USP 500mg
28. **Paracetamol 500 mg TevaTabletter**
Paracetamol Tablets 500 mg
Each uncoated tablet contains Paracetamol Ph.Eur 500 mg
29. **Paracetamol EG 500 mg FilmohuldeTabletten**
Paracetamol Tablets 500 mg
Each film coated tablet contains Paracetamol Ph.Eur 500 mg
30. **PARACETAMOL TABLETS Ph.Eur 500 mg**
Paracetamol 500 mg coated tablets
Each film coated tablet contains Paracetamol Ph.Eur 500mg
31. **PARACETAMOL TABLETS Ph.Eur 500mg**
Paracetamol 500mg kring tablet Ph.Eur
Each uncoated tablet contains Paracetamol Ph.Eur 500mg
32. **Acetaminophen Tablets USP 500 mg**
Each film coated tablets contains Acetaminophen USP 500 mg
33. **PARACETAMOL TABLETS BP**
Paracetamol mdq 500mg tablets
Each uncoated tablet contains Paracetamol BP 500mg
34. **Boots Pharmaceuticals PARACETAMOL 500 mg tabletten**
Each uncoated tablet contains Paracetamol Ph.Eur 500mg
35. **Paracetamol Teva tablets 1000mg**
Each uncoated tablet contains Paracetamol Ph.Eur 1000mg
36. **Ibuprofen Tablets USP 600mg**
Each film coated tablet contains Ibuprofen USP 600mg
37. **Ibuprofen Tablets USP 800 mg**
Each film coated tablet contains Ibuprofen USP 800 mg

B. Vengal Rao
26/11/19

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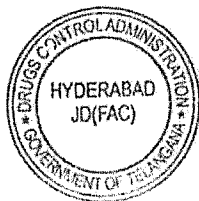
38. **Metformin Hydrochloride Tablets USP 500mg**
Each film coated tablet contains Metformin Hydrochloride USP 500mg
39. **Metformin Hydrochloride Tablets USP 850 mg**
Each film coated tablet contains Metformin Hydrochloride USP 850mg
40. **Paracetamol OVAAL 500 mg, Ph.Eur**
Each uncoated tablet contains Paracetamol Ph.Eur 500mg
41. **Metformin HCL Teva 500 mg Film coated tablet**
Metformin Hydrochloride Tablets 500 mg
Each film coated tablet contains Metformin Hydrochloride BP 500 mg
42. **Metformin Tablets BP**
Metformin Hydrochloride Tablets 500 mg, & 850 mg PCH
Each film coated tablet contains Metformin Hydrochloride BP 500 mg, & 850 mg
Approved colour: Titanium Dioxide BP
43. **Methocarbamol USP**
Compresso MCB 90
Directly compressible granules containing Methocarbamol USP 90-%
44. **Metformin Tablets BP 500 mg**
Metformin Dura 500 mg Filmtabletten
Each film coated tablet contain Metformin Hydrochloride Ph.Eur 500 mg
45. **Metformin Tablets BP 500 mg**
Metformin Mylan 500 mg
Each tablet contain Metformin Hydrochloride BP 500 mg
46. **Metformin Tablets BP 500 mg**
Each coated tablet contain Metformin Hydrochloride Ph.Eur 500 mg
47. **Metformin Tablets BP 500 mg**
MetformineMylan Generics
Each tablet contains Metformin Hydrochloride BP 500 mg
48. **Metformin Tablets BP 500 mg**
MetformineMylanPharma 500 mg
Each film coated tablet contain Metformin Hydrochloride Ph.Eur 500 mg

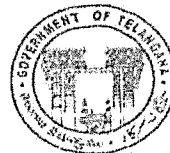


B. V. S. R. Reddy
26/11/19

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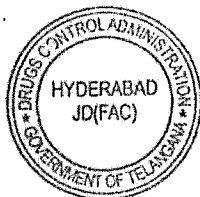
49. Metformin Tablets BP 500 mg
Mylan Metformin
Each film coated tablet contain Metformin Hydrochloride Ph.Eur 500 mg
50. Metformin Tablets BP 500 mg
Mylmet 500 mg Filmtabletta
Each tablet contain Metformin Hydrochloride BP 500 mg
51. Metformin Tablets BP 500 mg
MetformineMylan 500 mg
Each film coated tablet contains Metformin Hydrochloride Ph.Eur 500 mg
52. Metformin Tablets BP 850 mg
MetformineMylanPharma 850 mg
Each film coated tablet contain Metformin Hydrochloride Ph.Eur 850 mg
53. Metformin Tablets BP 850 mg
Metformin Dura 850 mg Filmtabletten
Each film coated tablet contains Metformin Hydrochloride Ph.Eur 850 mg
54. Metformin Tablets BP 850 mg
Metformin Mylan 850 mg
Each film coated tablet contains Metformin Hydrochloride Ph.Eur 850 mg
55. Metformin Tablets BP 850 mg
Mylmet 850 mg Filmtabletta
Each tablet contain Metformin Hydrochloride BP 850 mg
56. Metformin ARCANA 850 mg Filmtabletten
Metformin Tablets BP 850 mg
Each tablet contains Metformin Hydrochloride BP 850 mg
57. Metformin Tablets BP 850 mg
MetforminaMylan 850 mg
Each tablet contains Metformin Hydrochloride BP 850 mg
58. Metformin Tablets BP 850 mg
MetforminaMylan Generics
Each tablet contains Metformin Hydrochloride BP 850 mg
59. Paracetamol Sandoz 500 mg Compresse
Each uncoated tablet contains Paracetamol Ph.Eur 500 mg

B. Venkatesh
26/11/19



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

60. **Acetaminophen 500 mg & Methocarbamol 400 mg Tablets**
Each film coated tablet contains Acetaminophen USP 500 mg & Methocarbamol USP 400 mg
61. **Acetaminophen 500mg and Diphenhydramine HCl 25mg Rapid Release Gelcaps**
Each Rapid Release Gelcap contains Acetaminophen USP 500mg and Diphenhydramine HCl USP 25mg
62. **Naproxen Sodium Tablets USP 220mg**
Each film coated tablet contains Naproxen Sodium USP 220mg
63. **Panadol FD Granulate (Paracetamol DC Granules)**
Each gram of granules contains Paracetamol Ph.Eur 742.3 mg
64. **METFORMIN HYDROCHLORIDE DC GRANULES COMPRESSO MF86.66**
Each gram of granules contains Metformin Hydrochloride Ph.Eur 866.6mg
65. **METFORMIN HYDROCHLORIDE DC GRANULES COMPRESSO MF86.66**
Each gram of granules contains Metformin Hydrochloride USP 866.6mg
66. **Compresso PAP 90 CPG**
(Directly compressible granules containing Paracetamol Ph.Eur 90.0% w/w)
Each gram of granules containing Paracetamol Ph.Eur 900mg
67. **Compresso PAP 90 CPG**
(Directly compressible granules containing Acetaminophen USP 90.0%)
Each gram of granules containing Acetaminophen USP 900mg
68. **Metformin Hydrochloride 500 mg Film-Coated Tablets BP**
Each Film-Coated Tablet Contains Metformin Hydrochloride Ph.Eur. 500 mg
Coating Material Details: Titanium dioxide
69. **Metformin Hydrochloride 850 mg Film-Coated Tablets BP**
Each Film-Coated Tablet Contains Metformin Hydrochloride Ph.Eur. 850 mg
Coating Material Details: Titanium dioxide



B. Venkatesh
26/11/19

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70. **Metformin Tablets BP 500 mg**
Metformin Mylan 500 mg Film coated tablets
Each film coated tablet contains Metformin Hydrochloride Ph.Eur 500 mg
71. **Metformin Tablets BP 850 mg**
Metformin Mylan 850 mg Film coated tablets
Each film coated tablet contains Metformin Hydrochloride Ph.Eur 850 mg
72. **Metformin Hydrochloride Extended Release Tablets USP 500 mg**
Each Extended Release Tablet contains Metformin Hydrochloride Tablets USP 500 mg
73. **Cetirizine Hydrochloride Tablets USP 10mg**
Each film coated tablet contains Cetirizine Hydrochloride Tablets USP 10mg
74. **Methocarbamol Tablets USP 500mg**
Each film coated tablet contains Methocarbamol USP 500mg

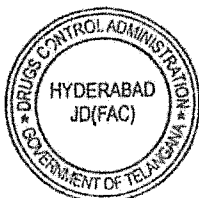
Manufacturer : M/s. GRANULES INDIA LIMITED, Sy.No.160/A, 161/E, 162, & 174/A,
Gagillapur Village, Dundigal-Gandimaisamma Mandal, Medchal-
Malkajgiri District – 500043, Telangana, INDIA.

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

Drug Licence No. : 37/RR/AP/2003/F/R, dated 17.07.2003, in FORM-25.

It is certified that the above products had been authorized to be placed on the market for use in
the Country and exporting countries.

The Unit M/s. GRANULES INDIA LIMITED, Sy.No.160/A, 161/E, 162, & 174/A,
Gagillapur Village, Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District – 500043,
Telangana, INDIA, was inspected jointly by Mrs. L. Suganthi, Drugs Inspector, CDSCO, Zonal office,
Hyderabad., and Dr. K.Prabhakar, Drugs Inspector, Quthbullapur (Mfg.) Zone, Drugs Control
Administration, Telangana, Hyderabad on 03.07.2019 & 04.07.2019.

*B. V. S. R.*
26/11/19

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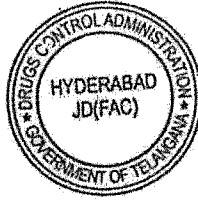
DRUGS CONTROL ADMINISTRATION
Government of Telangana



Dated: -11-2019

The manufacturer conforms to requirements for **GOOD MANUFACTURING PRACTICES** in the manufacturer and Quality Control (As recommended by the **WORLD HEALTH ORGANIZATION** in respect of the products mentioned above (Seventy Four in numbers) **FOR EXPORT** in the international market.

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



B. Venkateshwarlu
26/11/19
Dr. B. VENKATESHWARLU
JOINT DIRECTOR(FAC)
LICENSING & CONTROLLING AUTHORITY

To
M/s. GRANULES INDIA LIMITED,
Sy.No.160/A, 161/E, 162, & 174/A,
Gagillapur Village, Dundigal-Gandimaisamma Mandal,
Medchal-Malkajgiri District – 500043,
Telangana, INDIA.