## ANLAGE 8
(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt)

**Anschrift der Betriebsstätte des Herstellers**

Merz Pharma GmbH & Co. KGaA,
Ludwigstraße 22, 64354 Reinheim,

**Erlaubnis:**

DE_HE_01_MIA_2017_1011

**Liste der Produkte, auf die sich die Herstellungserlaubnis erstreckt**
*(in Übereinstimmung mit Artikel 41 der Richtlinie 2001/83/EG bzw. Artikel 44 der Richtlinie 2001/82/EG sofern angegeben)*

## ANNEX 8
(Products authorised to be manufactured/imported)

**Address of manufacturing site**

Merz Pharma GmbH & Co. KGaA,
Ludwigstraße 22, 64354 Reinheim

**Authorisation:**

DE_HE_01_MIA_2017_1011

**Products authorised to be manufactured**

*(in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended)*

**Bezeichnung der Humanarzneimittel (Darreichungsform) in der Herstellungserlaubnis**

**Name of Human Medicinal Products (dosage form) according to manufacturing authorisation**

| Lfd.-Nr. | Arzneimittelname | Darreichungsform | Herstellungsumfang unter Bezugnahme auf die lfd. Nr. aus Anlage 1 (Teil 1) in der Erlaubnis (Humanarzneimittel) |
|---|---|---|---|
| 1. | Medizinisches Erkältungs Bad | Badezusatz, flüssig | 1.2.1.5, 1.2.2, 1.5.1.5, 1.5.2 |
| 2. | Pantostin | Lösung | 1.2.1.5, 1.2.2, 1.5.1.5, 1.5.2 |
| 3. | tetesept Bademedizin Haut Regulativ Ölbad | Badezusatz, flüssig | 1.2.1.5, 1.2.2, 1.5.1.5, 1.5.2 |
| 4. | tetesept Erkältungs Bad | Badezusatz, flüssig | 1.2.1.5, 1.2.2, 1.5.1.5, 1.5.2 |
| 5. | tetesept Kinderbad Erkältungs Bad | Badezusatz, flüssig | 1.2.1.5, 1.2.2, 1.5.1.5, 1.5.2 |
| 6. | Axura 5 mg Pumpenhub (EU, CH) | Lösung | 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| | Akatinol 5 mg Pumpenhub (AR, CO) | Lösung | 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| | Memantine Merz 5 mg Pumpenhub | Lösung | 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| | Ebixa 5 mg Pumpenhub | Lösung | 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| 7. | Phytobronchin Sirup | Saft | 1.5.1.6, 1.5.2 |
| 8. | Phytohustil Hustenreizstiller | Lösung | 1.5.1.6, 1.5.2 |
| 9. | Prospan Hustensaft | Sirup | 1.5.1.6, 1.5.2 |
| 10. | Contractubex<br>AE, AM, AR, AT, AZ, BA, BG, BH, BO, BY, CH, CN, CL, CO, CR, CU, CY, CZ, DO, EC, EE, EG, GE, GT, HK, HN, HR, HU,IN, IR, JO, KG, KR, KW, KZ, LB, LT, LU, LV, ME, MK, MT, MN, MX, NI, OM, PA, PE, PH, PL, PY, RO, RS, RU, SA, SD, SK, SV, TM, TR, TT, UA, UY, ZU, VN, YE | Gel | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 11. | Delta Hädensa | Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 12. | Desitin Salbe | Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 13. | Essex Basissalbe | Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 14. | Essex Basiscreme | Creme | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 15. | Hädensa | Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 16. | Imex | Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 17. | Mederma Advanced Scar Gel (Export) US | Gel | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 18. | Mederma PM (Export) US | Gel | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 19. | Mederma Skin Care for Scars SPF 30 US (Ex- | Creme | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |



REGIERUNGSPRÄSIDIUM DARMSTADT 45

| ANLAGE 8<br>(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt) | | ANNEX 8<br>(Products authorised to be manufactured/imported) | |
|---|---|---|---|
| | port) US | | |
| 20. | Mederma Skin Care for Kids (Export)<br>US | Gel | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 21. | Mederma Strechmarks (Export)<br>US | Creme | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 22. | Rheumon Creme | Creme | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 23. | tetesept Erkältungs Balsam | Creme | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 24. | Thermo-Rheumon Creme | Creme | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 25. | tetesept Husten Tropfen Bronchial-activ | Fluidextrakt | 1.2.2, 1.5.1.6, 1.5.2, |
| 26. | tetesept Husten Saft alkohol- und zuckerfrei | Sirup | 1.4.1.1, 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| 27. | tetesept Husten Saft | Sirup | 1.4.1.1, 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| 28. | tetesept Magen-Darm Tropfen | Flüssigkeit | 1.2.2, 1.5.1.6, 1.5.2 |
| 29. | Erkältungs Kapseln (DE) | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 30. | Pantogar (Export)<br>AE, BH, BO, BR, CH, CR, CU, CY, DO, EC, EG, GE, GT, HK, HN, ID, IN, JO, KR, KW, LB, LT, LV, MT, MX, PA, PE, PY, RS, SG, SV, TT, UA, UY, UZ, YE | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| | Pantovigar AZ, BY, RU, KZ, TM | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 31. | Pantogar (Österreich) AT | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 32. | Pantovigar (DE)<br>LU | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 33. | tetesept Johanniskraut Kapseln 500 mg | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 34. | Mariendistel Kapseln | Weichkapseln | 1.2.2, 1.5.1.2, 1.5.2 |
| 35. | Prosta Şabal-Kürbis-Kapseln | Weichkapseln | 1.2.2, 1.5.1.2, 1.5.2 |
| 36. | tetesept Eukalyptusöl Kapseln | Weichkapseln | 1.2.2, 1.5.1.2, 1.5.2 |
| 37. | Hepa-Merz Granulat 3000<br>AR, AT, AZ, BG, BO, BY ,CO, CR, CU, DO, GE, GT, HK, HO, HR, HU, ID, JO, KW, KZ, LT, LU, LV, MN, MK, NI, PA, PE, PH, PL, PY, RO, RS, RU, SA, SV, TH, TM, TR, TW, VN, UA,UR, UZ, YE | Granulat | 1.2.2, 1.5.1.8, 1.5.2 |
| | Hepa-Merz Granulat (Export)<br>BO, CR, HO, MX, PA, SV | Granulat | 1.2.2, 1.5.1.8, 1.5.2 |
| 38. | Hepa-Merz Granulat 6000 | Granulat | 1.2.2, 1.5.1.8, 1.5.2 |
| 39. | Axura 10 mg Filmtabletten (EU, CH) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Abixa 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Akatinol Memantine 10 mg Filmtabletten<br>(AR, BO, CO, CR, CU, DO, EC/PE, GE, GT, HO, MX, NI, PA, PY, RU, SV, UY) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Ebixa 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 10 mg Filmtabletten (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Ebix 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 40. | Axura 20 mg Filmtabletten (EU, CH) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Abixa 20 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Akatinol Memantine 20 mg Filmtabletten (AR, CO, CR, CU, DO, EC, GT, HO, MX, NI, PA, PE, PY, RU, SV) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Ebixa 20 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 20 mg Filmtabletten (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |

| ANLAGE 8<br>(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt) | | ANNEX 8<br>(Products authorised to be manufactured/imported) | |
|---|---|---|---|
| 41. | **Treatment Initiation Pack** | | |
| | Axura 5 mg Filmtabletten (EU, CH) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Axura 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Axura 15 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Axura 20 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | **Treatment Initiation Pack** | | |
| | Akatinol Memantine 5 mg Filmtabletten (MX, RU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Akatinol Memantine 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Akatinol Memantine 15 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Akatinol Memantine 20 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | **Treatment Initiation Pack** | | |
| | Ebixa 5 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Ebixa 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Ebixa 15 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Ebixa 20 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | **Treatment Initiation Pack** | | |
| | Memantine Merz 5 mg Filmtabletten (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 10 mg Filmtabletten (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 15 mg Filmtabletten (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 20 mg Filmtabletten (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 42. | PK-Merz Filmtabletten 100 mg (DE)<br>AR, AT, BG, BO, BY, CH, CR, CU, CZ, DO, EC, EG, GE, GT, HK, HN, HR, HU, ID, IL, NI, JO, KR, LB, LT, LU, LV, KZ, ME, MK, MT, MX, MY, PA, PE, PH, PK, PL, PY, RS, RU, SA, SK, SV, TR, TW, UA, UY, UZ, YE | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Amantix Filmtabletten (PL, CO) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Hofcomant (AT) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | PK-Merz-Schoeller (AT) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 43. | PK-Merz Filmtabletten 150 mg | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 44. | Galle Dragee mit Artischocke | überzogene Tabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 45. | Merz Spezial Dragees (Russland)<br>CH, AZ, BY, MN, RU, TM, UA, ZU, KZ | überzogene Tabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 46. | Baldrian tetesept | überzogene Tabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 47. | Baldrian plus | überzogene Tabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 48. | Bocouture 50U<br>AT, BE, CH, CZ, DE, EL, ES, FI, FR, IT, MT, NL, PL, PT, SE, SK, UK | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 49. | Bocouture 100U<br>AT, BE, CZ, DE, ES, FI, FR, IT, NL, PL, SE, SK, UK | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 50. | Hepa-Merz Infusionslösungs Konzentrat<br>AR, AT, AZ, BALTIKUM, BG, BO, BY, CN, CO, CR, CU, CY, DO, EC, EE, GE, GR, GT, HK, HN, HR, HU, ID, JO, KW, KZ, LT, LV LU, MK, MX, NI, PH, PL, PY, RO, RS, RU, SA, SV, TH, TM, TR, UA, UZ, VN, YE | Infusionslösungs Konzentrat | 1.1.3, 1.5.2 |



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| ANLAGE 8<br>(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt) | | ANNEX 8<br>(Products authorised to be manufactured/imported) | |
|---|---|---|---|
| 51. | PK-Merz Infusion (DE)<br>AR, AT, BG, BO, BY, CH, CO, CR, CZ, EC, EE, EG, GE, GT, HN, HU, IL, JO, KR, KZ, LV, LT, LU, ME, MK, MT, MX, PA, PO, RS, RU, SK, TR, UA, UY, UZ | Infusionslösung | 1.1.3, 1.5.2 |
| | Amantix Infusionslösung (PL) | Infusionslösung | 1.1.3, 1.5.2 |
| | Hofcomant Infusion (AT) | Infusionslösung | 1.1.3, 1.5.2 |
| | PK-Merz-Schoeller Infusion (AT) | Infusionslösung | 1.1.3, 1.5.2 |
| 52. | Xeomin 50U<br>AE, AT, AU, BG, CH, CL, CO, CY, CZ, DE, DK, EE, EL, ES, FI, FR, GE, GT, HK, HR, HU, ID, IE, IL, IN, IR, IS, IT, KZ, LB, LI, LT, LU, LV, MY, NO, PL, RU, SE, SI, SK, TH, TW, UA, UK, US, UZ, VN | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | XEOMIN 50U<br>CA | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | Xeomeen 50U<br>BE, MX | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 53. | Xeomin 100U<br>AE, AR, AT, AU, BG, BR, CH, CL, CO, CR, CU, CY, CZ, DE, DK, EE, EL, ES, FI, FR, GE, GT, HK, HR, HU, ID, IE, IL, IN, IR, IS, IT, KR, KZ, LB, LI, LT, LU, LV, MT, MY, NL, NO, NZ, PL, PT, RO, RU, SE, SG, SK, SI, TH, TW, UA, UK, US, UY, UZ, VN, | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | XEOMIN 100U<br>CA | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | XEOMIN Cosmetic 100U<br>CA | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | XEOMEEN VIAL<br>(MX) | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | Xeomeen 100U<br>MX | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 54. | Xeomin 200U<br>AT, BE, CZ, DE, EE, ES, FI, FR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK, US | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| | Xeomeen 200U<br>BE | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 55. | Delta Hädensa | Suppositorien | 1.2.2, 1.5.2 |
| 56. | Hädensa | Suppositorien | 1.2.2, 1.5.2 |
| 57. | Patentex Oval<br>AT, BY, EE, LT, LV, HU, PL, RU | Ovula | 1.2.2, 1.5.2 |
| 58. | Solvex 4 mg | Filmtabletten | 1.2.2, 1.5.2 |
| 59. | Dismenol N (DE) | Filmtabletten | 1.2.2, 1.5.2 |
| 60. | Dismenol Ibuprofen 200 mg Filmtabletten (AT) | Filmtabletten | 1.2.2, 1.5.2 |
| 61. | Dismenol Ibuprofen 400 mg Filmtabletten (AT) | Filmtabletten | 1.2.2, 1.5.2 |
| 62. | Lipocol-Merz Kautabletten | Kautabletten | 1.2.2, 1.5.2 |



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## ANLAGE 8
(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt)

## ANNEX 8
(Products authorised to be manufactured/imported)

**Bezeichnung der Humanarzneimittel (Darreichungsform) in der Einfuhrerlaubnis**

**Name of Human Medicinal Products (dosage form) according to importers authorisation**

**Acino Pharma AG, Birsweg 2, 4253 Liesberg/Schweiz**

| Lfd. Nr. | Arzneimittelname | Darreichungsform | Herstellungsstufe im Exportland | Einfuhrumfang unter Bezugnahme auf die lfd. Nr. aus Anlage 1 (Teil 2) in der Erlaubnis (Humanarzneimittel) |
|---|---|---|---|---|
| 1. | Hepa-Merz Granulat (Bulk) | Granulat | Bulk | 2.2.2 |
| 2. | Pantogar (AT) (Bulk) | Hartkapseln | Bulk | 2.2.2 |
| 3. | Pantogar (Schweiz/International) (Bulk) | Hartkapseln | Bulk | 2.2.2 |
| 4. | Pantogar (Schweiz/International) | Hartkapseln | Bulk | 2.2.2 |
| 5. | Pantovigar (Bulk) | Hartkapseln | Bulk | 2.2.2 |

**aenova Swiss Caps AG, Husenstraße 35, 9533 Kirchberg/Schweiz**

| Lfd. Nr. | Arzneimittelname | Darreichungsform | Herstellungsstufe im Exportland | Einfuhrumfang unter Bezugnahme auf die lfd. Nr. aus Anlage 1 (Teil 2) in der Erlaubnis (Humanarzneimittel) |
|---|---|---|---|---|
| 1. | Prosta Sabal-Kürbis-Kapseln | Weichkapseln | Bulk | 2.2.2 |

**Alpinamed AG, Alte Landstraße 35, 9533 Kirchberg/Schweiz**

| Lfd. Nr. | Arzneimittelname | Darreichungsform | Herstellungsstufe im Exportland | Einfuhrumfang unter Bezugnahme auf die lfd. Nr. aus Anlage 1 (Teil 2) in der Erlaubnis (Humanarzneimittel) |
|---|---|---|---|---|
| 1. | tetesept Husten Tropfen Bronchial – activ (Spitzwegerich Flüssigextrakt – Bulk) | Flüssigextrakt | Bulk | 2.2.2 |



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## ANLAGE 8
(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt)

## ANNEX 8
(Products authorised to be manufactured/imported)

**Bezeichnung der Prüfpräparate für die Klinische Prüfung (Darreichungsform) in der Herstellungserlaubnis**

**Name of Human Investigational Medicinal Products for clinical trials (dosage form) according to manufacturing authorisation**

| Lfd.-Nr. | Arzneimittelname | Darreichungsform | Herstellungsumfang unter Bezugnahme auf die lfd. Nr. aus Anlage 2 (Teil 1) in der Erlaubnis (Prüfpräparate) |
|---|---|---|---|
| 1. | Memantine 10 mg /g Rezepturvariante | Lösung | 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| 2. | Memantine Placebo | Lösung | 1.2.1.6, 1.2.2, 1.5.1.6, 1.5.2 |
| 3. | Contractubex Placebo | Gel | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 4. | Contractubex Rezepturvariante | Gel | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 5. | Mederma | Creme, Gel, Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 6. | Mederma Placebo | Creme, Gel, Salbe | 1.2.1.11, 1.2.2, 1.5.1.11, 1.5.2 |
| 7. | Pantogar | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 8. | Pantogar Placebo | Hartkapseln | 1.2.2, 1.5.1.1, 1.5.2 |
| 9. | Amantadin Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 10. | Amantadin Filmtabletten Placebo | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 11. | Axura 10 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 10 mg (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 12. | Axura 5 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 13. | Axura 15 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 14. | Axura 20 mg Filmtabletten | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| | Memantine Merz 20 mg (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 15. | Axura Filmtabletten Placebo | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 16. | Memantine Merz 5 mg (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 17. | Memantine Merz 10 mg (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 18. | Memantine Merz 15 mg (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 19. | Memantine Merz 20 mg (EU) | Filmtabletten | 1.2.2, 1.5.1.13, 1.5.2 |
| 20. | Amantadinsulfat | Infusion | 1.2.2, 1.5.2 |
| 21. | Amantadinsulfat Placebo | Infusion | 1.2.2, 1.5.2 |
| 22. | Ornithinaspartat | Granulat | 1.2.2, 1.5.1.8, 1.5.2 |
| 23. | Ornithinaspartat Placebo | Granulat | 1.2.2, 1.5.1.8, 1.5.2 |
| 24. | Ornithinaspartat | Infusion | 1.2.2, 1.5.2 |
| 25. | Ornithinaspartat Placebo | Infusion | 1.2.2, 1.5.2 |
| 26. | Xeomin | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 27. | Xeomin Placebo | Pulver zur Herstellung einer Injektionslösung | 1.1.3, 1.5.2 |
| 28. | Pantovigar Placebo | Hartkapseln | 1.2.2, 1.5.2 |

## ANLAGE 8
(Liste der Produkte, auf die sich die Herstellungs-/Einfuhrerlaubnis erstreckt)

## ANNEX 8
(Products authorised to be manufactured/imported)

Regierungspräsidium Darmstadt
II 23.2 (Uhr) - 18 I 02 (1)- FA 63

Darmstadt, den 23.08.2017

Im Auftrag

Uhrmacher

Sonja Uhrmacher, Amtfrau
e-mail: sonja.uhrmacher@rpda.hessen.de
Telefon: + 49 (0) 6151 125264
Telefax: + 49 (0) 6151 125055

*This English translation is for reference only.*
*It is not part of the official certificate.*

*Date and signature of the authorised person of the Competent Authority*

*name and title* *seal of the certifying authority*
*e-mail* *sonja.uhrmacher@rpda.hessen.de*
*phone number:* *+ 49 (0) 6151 125264*
*fax number:* *+ 49 (0) 6151 125055*

I hereby certify that the foregoing photocopy is a true and complete photostat of the original thereof.

Frankfurt am Main, this 20th of August, 2018

Dr. Philipp Häuser
Notary

Die Echtheit vorstehender Unterschrift des Notars Dr. Philipp Häuser
und die Echtheit des Siegels/Stempels wird hiermit bestätigt.
Zugleich wird bescheinigt, dass der Vorgenannte zur Vornahme der Amtshandlung befugt war.

Frankfurt am Main, den 22.08.18
Der Präsident des Landgerichts
Im Auftrag

Folter

*Regional Council Darmstadt*

CERTIFICATE NUMBER: ***DE_HE_01_GMP_2017_1027***

# 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
Art. 15 of Directive 2001/20/EC

The competent authority of Germany confirms the following:
The manufacturer: ***Merz Pharma GmbH & Co. KGaA***
Site address: ***Ludwigstrasse 22, Reinheim, Hessen, 64354, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_HE_01_MIA_2017_1011*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
***§ 13 Abs. 1 Arzneimittelgesetz (manufacture) and § 72 Arzneimittelgesetz (import)***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-05-10*** , 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.*

## Part 2

| |
|---|
| Human Medicinal Products<br>Human Investigational Medicinal Products |

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.1** | **Sterile products** |
| | *1.1.3 Batch certification* |
| **1.2** | **Non-sterile products** |
| | *1.2.1 Non-sterile products (processing operations for the following dosage forms)*<br>1.2.1.5 Liquids for external use<br>1.2.1.6 Liquids for internal use<br>1.2.1.11 Semi-solids |
| | *1.2.2 Batch certification* |
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.1 Manufacture of*<br>1.4.1.1 Herbal products |
| **1.5** | **Packaging** |
| | *1.5.1 Primary Packing*<br>1.5.1.1 Capsules, hard shell<br>1.5.1.2 Capsules, soft shell<br>1.5.1.5 Liquids for external use<br>1.5.1.6 Liquids for internal use<br>1.5.1.8 Other solid dosage forms<br>1.5.1.11 Semi-solids<br>1.5.1.13 Tablets |
| | *1.5.2 Secondary packing* |
| **1.6** | **Quality control testing** |
| | *1.6.2 Microbiological: non-sterility*<br>*1.6.3 Chemical/Physical* |

| 2 IMPORTATION OF MEDICINAL PRODUCTS | |
|---|---|
| **2.1** | **Quality control testing of imported medicinal products** |
| | *2.1.2 Microbiological: non-sterility*<br>*2.1.3 Chemical/Physical* |

| 2.2 | **Batch certification of imported medicinal products** |
|---|---|
| | *2.2.2 Non-sterile products* |

Clarifying remarks (for public users)

***to point 1.1.3, 1.2.2, 1.5.2 and 2.2.2: see current annex 8 to point 1.4.1.1: only within the allowed manufacturing operations according to 1.2 and 1.5 to point 1.5.1.8: granules***

***2017-08-29***

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

---

***Confidential***
***Regional Council Darmstadt***
Tel: ***Confidential***
Fax: ***Confidential***

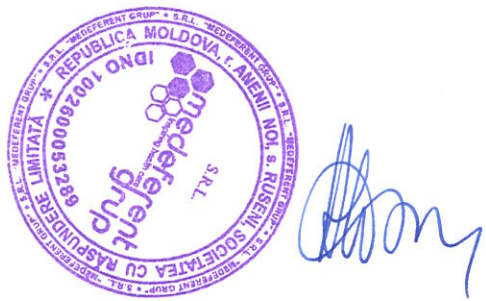
ANMDM - Nomenclatorul medicamentelor pentru uz uman

# Lista medicamentelor din NOMENCLATOR

Actualizat în 12.03.2019

Căutare | Anulare filtru | Legendă | Descarcă Varianta Excel

| | Denumire comercială | DCI | Forma farmaceutică | Cod ATC | Cod CIM | Firma / țara deținătoare APP |
|---|---|---|---|---|---|---|
| Detalii | HEPA - MERZ GRANULAT | COMBINATII | GRAN. PT. SOL. ORALA | A05BAN4 | W01530001 | PHARMA MERZ - GERMANIA |
| Detalii | HEPA - MERZ GRANULAT | COMBINATII | GRAN. PT. SOL. ORALA | A05BAN4 | W01530002 | PHARMA MERZ - GERMANIA |
| Detalii | HEPA - MERZ GRANULAT | COMBINATII | GRAN. PT. SOL. ORALA | A05BAN4 | W01530003 | PHARMA MERZ - GERMANIA |



## FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

## CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

This certificate conforms to the format recommended by the World Health Organisation
(General instructions and explanatory notes attached)

**No. of certificate** : **COPP/CERT/KD/78010/2018/11/25284/131831** Valid Upto :01 Aug 2021

**Exporting Country** : INDIA

**Importing Country** : **SRI LANKA**

1. Name and dosage form of product : **LABETALOL HYDROCHLORIDE INJECTION USP 5MG/ML**

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each ml contains:

| |
|---|
| Labetalol Hydrochloride USP 5 mg |

For complete qualitative composition including excipients [4]

1.2 Is this product licensed to be placed on the market for use in the exporting country ?[5] Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country ? Yes ☒ No ☐ Unknown ☐

2A.1 Number of product license:[7] **KD74 In Form 28** and date of issue **04 Mar 2017**

2A.2 Product License holder (Name and address)
**CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA**

2A.3 Status of product-license Holder [8]
A ☒ B ☐ C ☐

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:[9]

2A.4 Is summary basis of Approval appended ?[10]
Yes ☐ No ☒

2A.5 Is the attached, officially approved product information complete and consonant with the license ?[11]
Yes ☐ No ☐ Not Provided ☒

2A.6 Applicant for certificate if different from License holder [12]
**Not Applicable**

2B.1 Applicant for certificate (name and address)

2B.2 Status of applicant :
A ☐ B ☐ C ☐

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ Refused

2B.4 Remarks [13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
if no or not applicable proceed to question 4. Yes ☒ No ☐ Not Applicable[14] ☐

3.1 Periodicity of routine inspections(years) **Once a year**

3.2 Has the manufacture of this type of dosage form been inspected ? Yes ☒ No ☐

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?[15]
Yes ☒ No ☐ Not Applicable [14] ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?[16]
Yes ☒ No ☐

If no, explain :

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax. +91-22-26591959
4RIC183/801020181012059

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai
Maharashtra State, India
Date:12 Oct 2018

12 OCT 2018

**GENERAL INSTRUCTION :**

Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the scheme.The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand written.Additional sheets should be appended, as necessary, to accommodate remarks and explanations .

**EXPLANATORY NOTES :**

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country .It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNS) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-Licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product Licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the Licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market :
   (a) manufactures the dosages form
   (b) packages and / or labels a dosage form manufactured by an independent company : or
   (c) is involved in none of the above .
9. This information can be provided only with the consent of the product - Licence holder or, in the case of non-registered products, the applicant . Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.It should be noted that information concerning the site of production is part of the product Licence. If the production site is changed the Licence must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product Licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
    (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export:
    (b) the product has been reformulated with a view to improving its stability under tropical conditions:
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient
    (e) any other reason, please specify.
14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and Inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to the certificate are those included in the thirty- second report of the Expert Committee on specifications for Pharmaceutical Preparations (WHO Technical Report Series, No.823 , 1992 , Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series , No . 822, 1992, Annex 1).
16. The Section is to be completed when the product - licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product . In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

*The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.*

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :

13 AUG 2018

NOTARY
Name: H. Shukla
Area: Mumbai
Reg. No. 121/84
GOV. OF MAHARASHTRA

# CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
*(General instructions and explanatory notes attached).*
Certificate No.: **NEW-WHO-GMP/CERT/KD/72365/2018/11/24339**

On the basis of the inspection carried out on **07/06/18 , 08/07/18 and 18/07/2018** ,we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.**
   Address : **N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD80 in Form 25, KD74 in Form 28, KD/3 in Form 28B**

Table 1

| Sr.No. | Dosage Form(s) | Categor(ies) | Activity(ies) |
|---|---|---|---|
| 1 | External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray) | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 2 | Eye / Ear Drops | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 3 | Eye Drops / Ophthalmic Preparations | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 4 | Inhalation | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 5 | Liquid Injection ( SVP ) | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 6 | Liquid Orals | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 1 2 | | | |

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 01 Aug 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai - 400 051.
Maharashtra,INDIA
Tel: +91-22-2659 3634
Fax: +91-22-2659 1950

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:09 Aug 2018

09 AUG 2018

A copy of this document / CERTIFICATE has been received with the Chamber
PRATIK RALE
EXECUTIVE
Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No.....Date
69558

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified, record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

| Pharmaceutical Product (s)1 | Category (ies) | Activity (ies) |
|---|---|---|
| Dosage form (s) | | |
| Tablets | Cytotoxic | Packaging |
| | Hormone | Production, Packaging, Quality control. |
| Injectables | Penicillin | Repackaging & Labelling. |
| | Cefalosporin | Aseptic preparation, Packaging, Labelling. |

Example - 2.

| Pharmaceutical Product | |
|---|---|
| Starting material (s)2 | |
| Paracetamol | |

Use, whenever r otherwise national nonproprietary n

5. The certificate comes invalid if the activities and/o er considered to be in compliance wit

6. The requireme of drugs referred to in the certificate uls: a compendium of guidelines an inspection, Volume 2, 1999. World H

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to CIRON DRUGS & PHARMACEUTICALS PVT. LTD
has been signed by PRATIK RALE
with the seal / stamp of EXEC. BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 18-Sep-2018 at NEW DELHI, INDIA
MHMC0029960818

BOMBAY CHAMBER OF COMMERCE & INDUSTRY ★1836★
MAHARASHTRA STATE

S.R.L. medeferent grup 1002600053289

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 13 AUG 2018

# CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
*(General instructions and explanatory notes attached).*
Certificate No.: **NEW-WHO-GMP/CERT/KD/72365/2018/11/24339**

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1. Name of the Firm : **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.**
   Address : **N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD80 In Form 25, KD74 In Form 28, KD/3 In Form 28B**

Table 1

| Sr.No. | Dosage Form(s) | Categor(ies) | Activity(ies) |
|---|---|---|---|
| 7 | Lyophilised / Powder injectable | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 1 2 | | | |

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 01 Aug 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 05
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:09 Aug 2018

09 AUG 2018

Explanatory note

1. This certif … hended in point 1 …

2. The certifi … eable … certificate.

3. Where the regulato… …ues a licence for the si… …ified record "not applicable" in cases where there is no legal frame…

4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

| Pharmaceutical Product (s)1 | Category (ies) | Activity (ies) |
|---|---|---|
| Dosage form (s) | | |
| Tablets | Cytotoxic | Packaging |
| | Hormone | Production, Packaging, Quality control. |
| Injectables | Penicillin | Repackaging & Labelling. |
| | Cefalosporin | Aseptic preparation, Packaging, Labelling. |

Example - 2.

| Pharmaceutical Product (s)1 | Category (ies) | Activity ( ies ) |
|---|---|---|
| Starting material (s)2 | | |
| Paracetamol | Analgesic | Synthesis, Purification, Packing, Labelling. |

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

ATTESTED TRUE COPY
C. H. SHUKLA,
NOTARY GREATER MUMBAI
Jagdamba Bhavan, Ground Floor,
Ganpatrao Kadam Marg, Lower Parel,
MUMBAI 400 013.
28 AUG 2018
28 AUG 2018