DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 9831/E(K)/TS/2017

Dated: 22.09.2017

To
M/s. Hetero Biopharma Limited,
Sy.No. 458 (Part), TSIIC Formulation SEZ
Polepally Village, Jadcherla Mandal
Mahaboobnagar District, Telangana State, India

Digitally signed by Margină Veaceslav
Date: 2019.03.05 11:31:58 EET
Reason: MoldSign Signature
Location: Moldova

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: 03.08.2017.
2. Joint Inspection Report dated: 14.09.2017.

@@@

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

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

DRUGS CONTROL ADMINISTRATION * HYDERABAD * GOVERNMENT OF TELANGANA

Yours faithfully

22/9/2017

M. AMRUTH RAO
Joint Director & Licensing Authority

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 9831/E(K)/TS/2017 Dated: .09.2017

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

1	**Rituximab** **100mg / 10ml,** **Concentrate for Solution for Injection in Single use vial** **r-DNA product** **For Intravenous Infusion use** DCI NO.: MF-76/2015 Dated: 25 Mar 2015 Composition: Each 10 ml vial contains: Rituximab (r-DNA Origin) (*Active ingredient*) 100 mg Sodium Chloride USP (*as tonicity agent*) 90 mg Tri Sodium Citrate Dihydrate USP (*as buffering agent*) 73.5 mg Polysorbate 80 USP (*as stabilizer*) 7.0 mg Water for Injection USP q.s. to 10 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 30 months from the date of manufacture. Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.
2	**Rituximab** **100mg / 10ml,** **Concentrate for Solution for Injection in Single use vial** **r-DNA product** **For Intravenous Infusion use** **MABALL 100** DCI NO.: MF-76/2015 Dated: 25 Mar 2015 Composition: Each 10 ml vial contains: Rituximab (r-DNA Origin) (*Active ingredient*) 100 mg Sodium Chloride USP (*as tonicity agent*) 90 mg Tri Sodium Citrate Dihydrate USP (*as buffering agent*) 73.5 mg Polysorbate 80 USP (*as stabilizer*) 7.0 mg Water for Injection USP q.s. to 10 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 30 months from the date of manufacture. Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

22/9/2017

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 9831/E(K)/TS/2017 Dated: .09.2017

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

3	**Rituximab** **100mg / 10ml,** **r-DNA product** **Concentrate for Solution for Injection in Single use vial** **For Intravenous Infusion use** **RILAST 100** DCI NO.: MF-76/2015 Dated: 25 Mar 2015 Composition: Each 10 ml vial contains: Rituximab (r-DNA Origin) 100 mg (*Active ingredient*) Sodium Chloride USP 90 mg (*as tonicity agent*) Tri Sodium Citrate Dihydrate USP 73.5 mg (*as buffering agent*) Polysorbate 80 USP 7.0 mg (*as stabilizer*) Water for Injection USP q.s. to 10 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 30 months from the date of manufacture. Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.
4	**Rituximab** **500mg / 50ml,** **r-DNA product** **Concentrate for Solution for Injection in Single use vial** **For Intravenous Infusion use** DCI NO.: MF-76/2015 Dated: 25 Mar 2015 Composition: Each 50 ml vial contains: Rituximab (r-DNA Origin) 500 mg (*Active ingredient*) Sodium Chloride USP 450 mg (*as tonicity agent*) Tri Sodium Citrate Dihydrate USP 367.5 mg (*as buffering agent*) Polysorbate 80 USP 35.0 mg (*as stabilizer*) Water for Injection USP q.s. to 50 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 30 months from the date of manufacture. Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

22/9/2017

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 9831/E(K)/TS/2017 Dated: .09.2017

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

5	**Rituximab** **500mg / 50ml,** **r-DNA product** **Concentrate for Solution for Injection in Single use vial** **For Intravenous Infusion use** **MABALL 500** DCI NO.: MF-76/2015 Dated: 25 Mar 2015 Composition: Each 50 ml vial contains: Rituximab (r-DNA Origin) 500 mg (*Active ingredient*) Sodium Chloride USP 450 mg (*as tonicity agent*) Tri Sodium Citrate Dihydrate USP 367.5 mg (*as buffering agent*) Polysorbate 80 USP 35.0 mg (*as stabilizer*) Water for Injection USP q.s. to 50 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 30 months from the date of manufacture. Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.
6	**Rituximab** **500mg / 50ml,** **r-DNA product** **Concentrate for Solution for Injection in Single use vial** **For Intravenous Infusion use** **RILAST 500** DCI NO.: MF-76/2015 Dated: 25 Mar 2015 Composition: Each 50 ml vial contains: Rituximab (r-DNA Origin) 500 mg (*Active ingredient*) Sodium Chloride USP 450 mg (*as tonicity agent*) Tri Sodium Citrate Dihydrate USP 367.5 mg (*as buffering agent*) Polysorbate 80 USP 35.0 mg (*as stabilizer*) Water for Injection USP q.s. to 50 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 30 months from the date of manufacture. Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

22/9/2017

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 9831/E(K)/TS/2017 Dated: .09.2017

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

7	**Bevacizumab** **400mg / 16ml,** **Concentrate for Solution for Injection in Single use vial** — **r-DNA product** **For Intravenous Infusion use** **BEVAAS 400** DCI NO.: MF-63/2016 Dated: 13 May 2016 Composition: Each 16ml vial contains: Bevacizumab (r-DNA Origin) — 400 mg (*Active ingredient*) α, α- Trehalose Dihydrate USP — 960 mg (*as tonicity agent*) Monobasic Sodium Phosphate (Monohydrate) USP — 92.8 mg (*as buffering agent*) Dibasic Sodium phosphate (Anhydrous) USP — 19.2 mg (*as buffering agent*) Polysorbate 20 USP — 6.4 mg (*as stabilizer*) Water for Injection USP — q.s. to 16 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 2 years from the date of manufacture Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.
8	**Bevacizumab** **400mg / 16ml,** **Concentrate for Solution for Injection in Single use vial** — **r-DNA product** **For Intravenous Infusion use** **CIZUMAB 400** DCI NO.: MF-63/2016 Dated: 13 May 2016 Composition: Each 16ml vial contains: Bevacizumab (r-DNA Origin) — 400 mg (*Active ingredient*) α, α- Trehalose Dihydrate USP — 960 mg (*as tonicity agent*) Monobasic Sodium Phosphate (Monohydrate) USP — 92.8 mg (*as buffering agent*) Dibasic Sodium phosphate (Anhydrous) USP — 19.2 mg (*as buffering agent*) Polysorbate 20 USP — 6.4 mg (*as stabilizer*) Water for Injection USP — q.s. to 16 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 2 years from the date of manufacture Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

22/9/2017

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 9831/E(K)/TS/2017 Dated: .09.2017

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

9	**Bevacizumab** **400mg / 16ml,** **Concentrate for Solution for Injection in Single use vial** **r-DNA product** **For Intravenous Infusion use** DCI NO.: MF-63/2016 Dated: 13 May 2016 Composition: Each 16ml vial contains: Bevacizumab (r-DNA Origin) 400 mg (*Active ingredient*) α, α- Trehalose Dihydrate USP 960 mg (*as tonicity agent*) Monobasic Sodium Phosphate (Monohydrate) USP 92.8 mg (*as buffering agent*) Dibasic Sodium phosphate (Anhydrous) USP 19.2 mg (*as buffering agent*) Polysorbate 20 USP 6.4 mg (*as stabilizer*) Water for Injection USP q.s. to 16 ml Storage: +2°C to +8°C. Do not freeze or shake. Protect from light. Expiry: 2 years from the date of manufacture Container-closure: In USP Type-I clear glass vial with elastomeric butyl rubber stopper and flip-off seal.

Manufacturer : **M/s. Hetero Biopharma Limited,**
Sy.No. 458 (Part), 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. : **01/MN/AP/rDNA/2014/G, dated: 22.04.2014 in Form - 28 D.**

The firm **M/s. Hetero Biopharma Limited**, Sy.No. 458 (Part), TSIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, India was jointly inspected by Mr. P. Santhosh, Drugs Inspector & C. Vivekananda Reddy, Drugs Inspector, Drugs Control Administration, Telangana, Hyderabad on 14.09.2017.

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

22/9/2017

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

L.Dis.No. 9831/E(K)/TS/2017 - Grant of WHO GMP Certificate:

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 **(Nine)** for Export in the international market.

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

DRUGS CONTROL ADMINISTRATION ★ HYDERABAD ★ GOVERNMENT OF TELANGANA

22/9/18

M. AMRUTH RAO
Joint Director & Licensing Authority

To

M/s. HETERO BIOPHARMA LIMITED
Sy.No. 458 (Part), TSIIC Formulation SEZ,
Polepally Village, Jadcherla Mandal,
Mahaboobnagar District, Telangana State, India