FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-**14 Mar 2022**

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/106587/2022/11/39601**

On the basis of the inspection carried out on **26/10/2021,27.10.2021** ,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 : **ATLANTIC BIOMEDICAL PVT. LTD**
   Address : **SAWARSAI.S.NO.43/2B & 3B,44/3B & 4B, TALUKA-PEN,DIST- RAIGAD. RAIGAD 402107 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD762 In Form 25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Heamodialysis Solutions / powder (Non Sterile)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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 13 Mar 2025 . 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: +91-22-26592363/64
Fax: +91-22-26591959
1LTA07810658720220314
ATLANTIC BIOMEDICAL PVT. LTD - NEW-WHO-GMP/CERT/KD/106587/2022/11/39601

Name of the Authorised person : **D. R. GAHANE**
Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**14 Mar 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/106587/2022/11 /39601 **VALID UP TO :13 Mar 2025**

Name of Manufacturing Firm : ATLANTIC BIOMEDICAL PVT. LTD
SAWARSAI.S.NO.43/2B & 3B,44/3B & 4B,
TALUKA-PEN,DIST- RAIGAD. RAIGAD 402107
MAHARASHTRA STATE, INDIA

Drug License No : KD762 In Form 25

Sr.No.	Name of the Product	Composition
1	Concentrated Haemodialysis Solution B.P (Non Sterile)	Each 1000 ml contains Potassium Chloride (for Part -I) IP 6.00 gm Magnesium Chloride (for Part -I) IP 3.70 gm Calcium Chloride (for Part -I) IP 8.10 gm Sodium Chloride (for Part -I) IP 178.50 gm Acetic Acid(Glacial) (for Part -I) IP 9.46 gm Sodium Bicarbonate (For Part -II) IP 59.20 gm Sodium Chloride(for Part-II) IP 23.50 gm Purified water to make 1000ml IP - qs Part I to be used with Part II Part II to be supplied in powder form in polythene bags & corrugated box to be used with Part I Colour:-
2	Concentrated Haemodialysis Solution BP	Each 1000 ml contains Potassium Chloride (For Part -I) IP 5.22 gm Magnesium Chloride (For Part -I) IP 3.56 gm Calcium Chloride (For Part -I) IP 9.00 gm Sodium Chloride(For Part -I) IP 210.68 gm Acetic Acid(Glacial) (For Part -I) BP 6.31 gm Dextrose Monohydrate (For Part -I) IP 38.50 gm Sodium Bicarbonate (For Part -II) IP 84.00 gm Purified water to make 1000ml IP qs Part I to be used with Part II Part II to be supplied in powder form in polythene bags & corrugated box to be used with Part I Colour:-
3	Concentrated Haemodialysis Solution BP(Non Sterile)	Equivalent per litre of the diluted solution part I afetr diluting with 32.775 volumes of purified water and 1.225 volumes of recinstituted part II provides mmol/ltrs Each 1000 ml contains Potassium Chloride (For Part -I) BP 5.22 gm Magnesium Chloride (For Part -I) BP 3.56 gm Calcium Chloride (For Part -I) BP 9.00 gm Sodium Chloride(For Part -I) BP 210.68 gm Acetic Acid(Glacial) (For Part -I) BP 6.31 gm Dextrose Monohydrate (For Part -I) BP 38.50 gm Sodium Bicarbonate (For Part -II) BP 84.00 gm Purified water to make 1000ml BP qs
4	Dry Citracon Haemodialysis Concentrated Powder	Each 1000 ml contains Potassium Chloride (Part I) IP 6.00 gm Magnesium Chloride (Part I) IP 3.70 gm Calcium Chloride (Part I) IP 8.10 gm Sodium Chloride (Part I) IP 178.5 gm Sodium Acetate (Part I) IP 1.00 gm Citric Acid (Part I) IP 5.7 gm Sodium Bicarbonate (Part II) IP 59.20 gm Sodium chloride (Part II) IP 23.50 gm Part-I to be diluted with purified water to make 4ltr/40ltr and used with part-II Part-II to be diluted with purified water to make 8ltr/80ltr and used with part-I to be supplied in powder form in plythene bag and corrugated box

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

		Colour:-
5	Haemodialysis Concentrate Solution (Non Sterile) with low calcium	Each 1000ml contains potassium Chloride(Part-I) BP 5.22 gm Magnesium Chloride(part-I) BP 3.56 gm Calcium Chloride (Part-I) BP 7.72 gm Sodium Chloride (Part-I) BP 210.68 gm Acetic Acid (Glacial)(Part-I) BP 6.31 gm Dextrose monohydrate (Part-I) BP 38.50 gm Purified water Part I to make 1000ml BP - qs Sodium Bicarbonate (Part-II) BP 84.00 gm Part I to be used with Part II Part I to be Supplied in 10 ltr canister Part II to be supplied in powder Form in aluminium pouch, final package is in corrugated box
6	Renaclean (Cold Sterliant) Dialyser Reprocessing Concentrate / haemodialysis machine disinfectant based on Peracetic acid & Hydrogen Peroxide	Each 100 ml contains Hydrogen peroxide IHS 21.00 gm Peracetic Acid IHS 4.00 gm purified water IP qs Colour:-
7	Renasteril (Hot Disinfectant) Citric,Malic & lactic Acid Based Hot disinfectant for Haemodialysis Machine	Each 100 ml contains Citric acid IP 21 gm Malic acid IHS qs Lactic Acid IHS qs Colour:-

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