



WELCURE REMEDIES



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WELCURE REMEDIES

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WELCURE REMEDIES

General Introduction of Welcure Group

- ❖ *Welcure group is established in year 2010 in leadership of Sh. Sanjay Ahuja (MD Of the Company)*
- ▣ **WELCURE REMDIES** was situated at Vill. Moginand, Nahan road, Kala-Amb, Distt-Sirmour-173030 (H.P.) India - in the State of Himachal Pradesh and is about 80 Kms from Chandigarh. Firm has Loan license with their sister concern “**Integrated Laboratories Pvt. Ltd.**” in the same premises for the manufacturing activity of small volume parenteral, external and ophthalmic products.
- ▣ The factory is situated in Govt. approved Industrial area of district Sirmour (Himachal Pradesh). It can also be reached by Air & the nearest airport is Chandigarh at about 80.Kms from the plant.



WELCURE REMEDIES



WELCURE REMEDIES is doing contract manufacturing for many companies which includes following :-

- ❖ **Third Party Manufacturing – Mankind and other companies too.**
- ❖ **Self Marked Products in Pharma Franchisee.**

WELCURE REMEDIES



- **GENERAL BLOCK**
 - **Dry Powder Injection**
 - **Liquid Injection**
 - **Eye Drops (Ophthalmic preparations)**
 - **Ear /Nasal Drops**

- **CEPHALOSPORIN BLOCK**
 - **Dry Syrup**
 - **Tablets**
 - **Dry Injection**



STERILE POWDER FOR INJECTABLES (CEPHALOSPORINS)

Cefepime with Sulbactam injection 750mg, 1.5gm
Cefetime Injection 1000mg
Cefepime with Tazobactam for Injection 1125mg,281.25mg
Cefoperazone Injection 1000mg ,3000mg,
Cefoperazone with Sulbactam for injection 500mg,750mg,1 gm,
1.5gm,2gm,3gm,4.5gm,3750mg
Cefoperazone with Tazobactam for injection 1.125gm,4.5gm
Cefotaxime for injection 250mg, 500mg, 1gm,2gm,3gm
Ceftazidime injection 250mg, 1gm
Ceftazidime with sulbactam for injection 1.5 gm
Ceftazidime with Tazobactam for injection 1.125gm
Ceftiofur Sodium Injection USP 500mg





STERILE POWDER FOR INJECTABLES (CEPHALOSPORINS)

Ceftiofur & Tazobactam For Injection 1125mg
Ceftizoxime & Tazobactam For Injection 3375mg
Ceftizoxime Sodium Injection 1500mg, 3000mg
Ceftriaxone for injection 125mg, 250mg, 500mg, 1000mg,2000mg,3000mg,4000mg
Ceftriaxone with Sulbactam for injection 375mg, 750mg, 1.5gm, 3gm,4.5gm
Ceftriaxone with Tazobactam for injection 281.25mg,562.5mg, 1000mg,1125mg, 2250mg ,
140.625mg,3375mg,4500mg
Cefuroxime for injection 250mg, 750mg, 1.5gm
Cefuroxime with Sulbactam for injection 1.125gm, 2.250gm





STERILE POWDER FOR INJECTABLES (GENERAL)

Amoxicillin & Cloxacillin Injection 500mg,1000mg,2000mg,3000mg,4000mg,4500mg
Amoxicillin & Potassium Clavulanate Injection 300mg,600mg,1200mg,3600mg
Amoxicillin & Sulbactam Injection 3000mg,4000mg,4500mg
Ampicillin Injection 500mg,1000mg
Ampicillin & Cloxacillin Injection 4000mg
Ampicillin & Tazobactam Injection 2250mg
Aztreonam for injection 1000mg
Anidulafungin for Injection 50mg, 100mg
Artesunate Injection 60mg, 120mg
Azithromycin Injection 500mg
Aztreonam For Injection 1000mg
Caspofungin acetate for injection 50mg, 70mg
Colistimethate for injection 1MIU, 2 MIU, 3MIU, 4.5MIU
Chloramphenicol Sodium Succinate Injection IP 1000mg
Clarithromycin Infusion BP 500mg
Doxycycline for Injection
Ertapenem For Injection 100mg
Ganciclovir For Injection 500mg
Esomeprazole for Injection 40mg





STERILE POWDER FOR INJECTABLES (GENERAL)

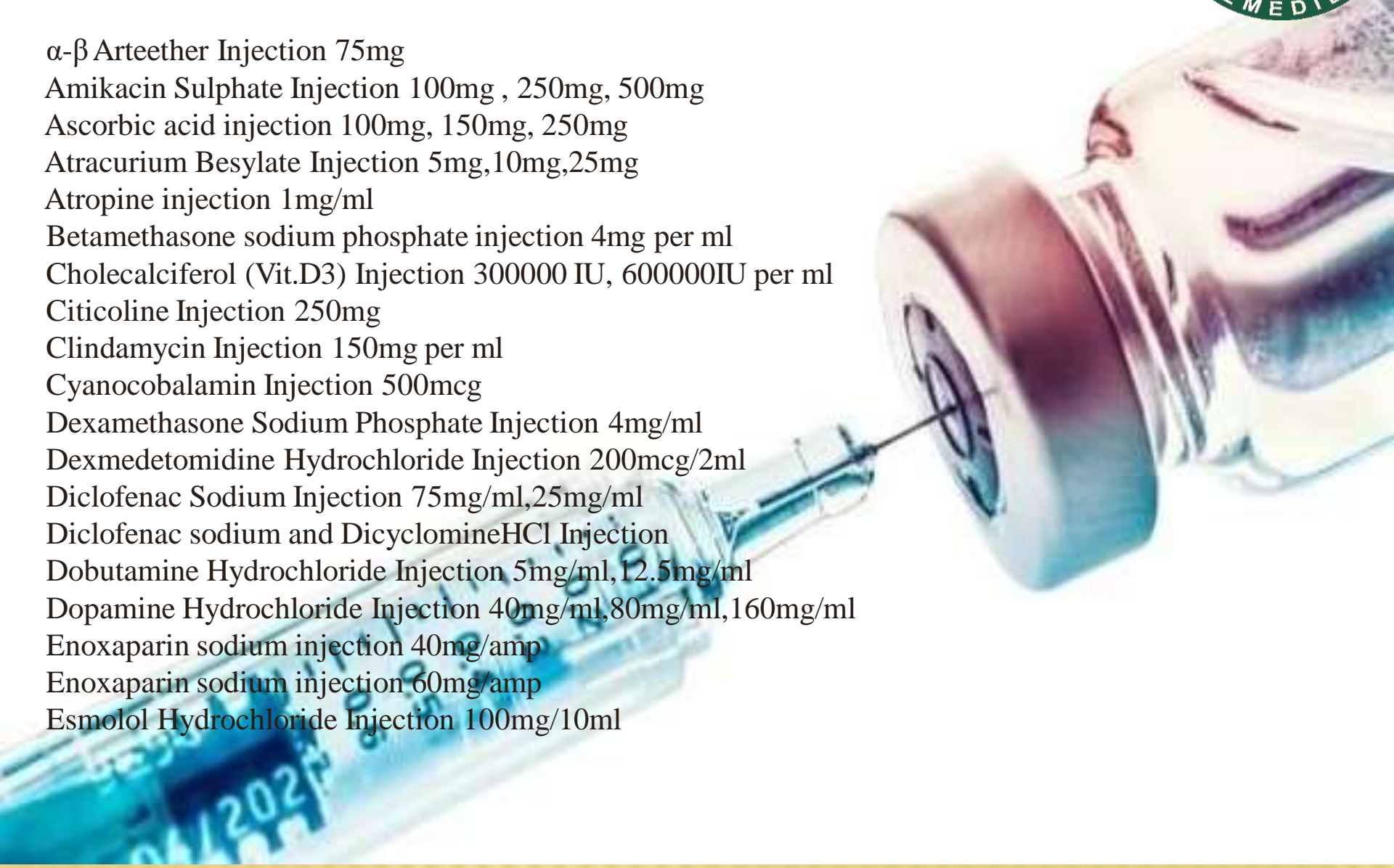
Glutathione for injection 600mg
Hydrocortisone sodium succinate injection 100mg
Impinem with Cliastatin Injection 1000mg
Kanamycin Injection IP 500mg,750mg,1000mg,2000mg
Lansoprazole For Injection 30mg
Methylprednisolone sodium succinate Injection 40mg, 125mg, 500mg, 1000mg
Micafungin Sodium For Injection 50mg
Omeprazole Sodium Injection 40mg per vial
Pantoprazole For Injection 40mg
Piperacillin & Tazobactam For Injection 1125mg,2250mg,4000mg,4500mg
Polymyxin B for Injection
Prednisolone Sodium Phosphate injection 10mg/ml, 20mg/ml
Propofol Emulsion for Injection 10mg/ml
Rabeprazole injection 20mg
Teicoplanin for Injection 200mg, 400mg
Tigecycline for Injection 50mg
Vancomycin for Injection 500mg, 1000mg
Voriconazole for Injection 200mg
Meropenam Injection 125mg,250mg,500mg,1000mg





LIQUID INJECTABLES (GENERAL)

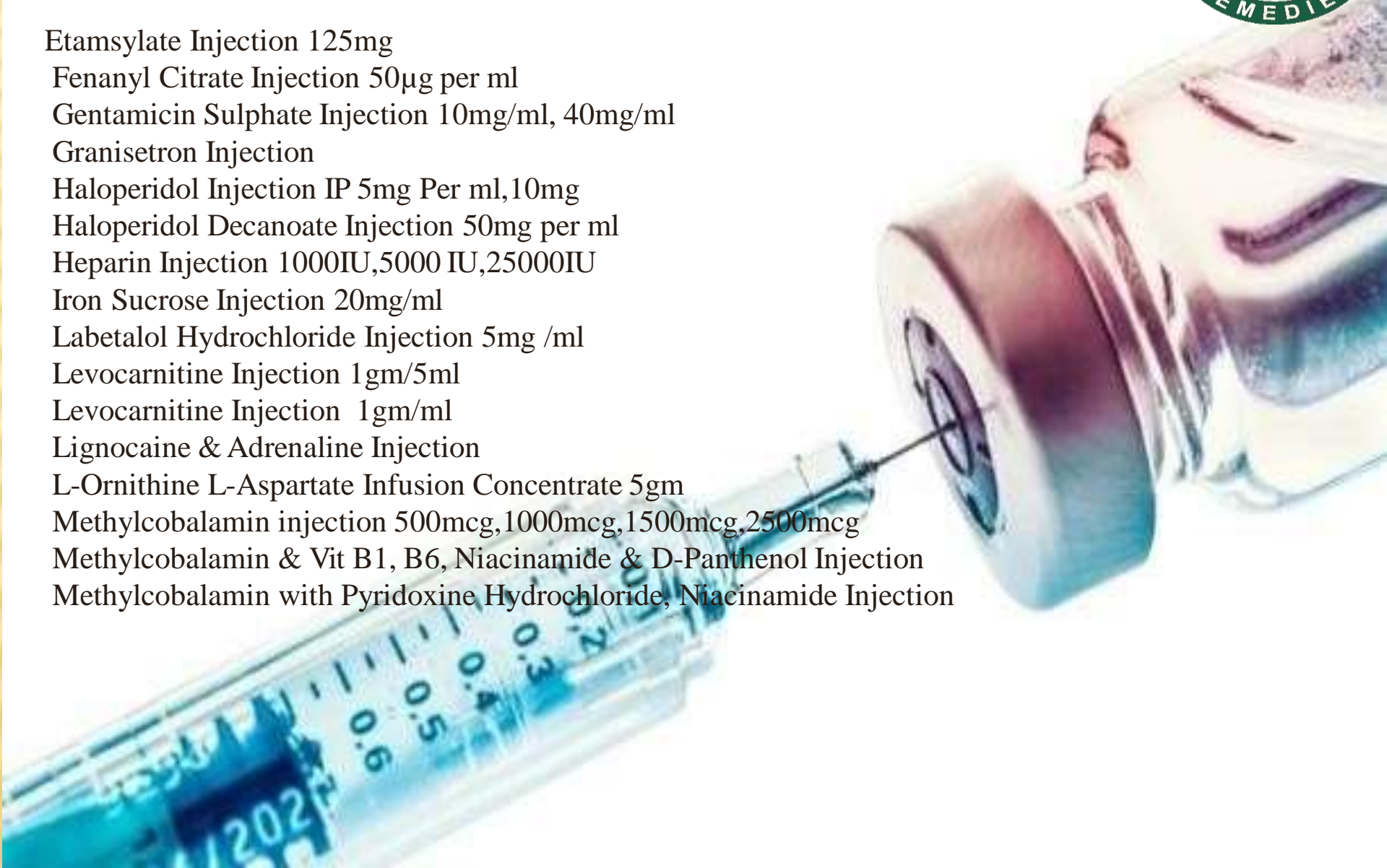
α - β Arteether Injection 75mg
Amikacin Sulphate Injection 100mg , 250mg, 500mg
Ascorbic acid injection 100mg, 150mg, 250mg
Atracurium Besylate Injection 5mg,10mg,25mg
Atropine injection 1mg/ml
Betamethasone sodium phosphate injection 4mg per ml
Cholecalciferol (Vit.D3) Injection 300000 IU, 600000IU per ml
Citicoline Injection 250mg
Clindamycin Injection 150mg per ml
Cyanocobalamin Injection 500mcg
Dexamethasone Sodium Phosphate Injection 4mg/ml
Dexmedetomidine Hydrochloride Injection 200mcg/2ml
Diclofenac Sodium Injection 75mg/ml,25mg/ml
Diclofenac sodium and DicyclomineHCl Injection
Dobutamine Hydrochloride Injection 5mg/ml,12.5mg/ml
Dopamine Hydrochloride Injection 40mg/ml,80mg/ml,160mg/ml
Enoxaparin sodium injection 40mg/amp
Enoxaparin sodium injection 60mg/amp
Esmolol Hydrochloride Injection 100mg/10ml



LIQUID INJECTABLES (GENERAL)



Etamsylate Injection 125mg
Fenanyl Citrate Injection 50µg per ml
Gentamicin Sulphate Injection 10mg/ml, 40mg/ml
Granisetron Injection
Haloperidol Injection IP 5mg Per ml,10mg
Haloperidol Decanoate Injection 50mg per ml
Heparin Injection 1000IU,5000 IU,25000IU
Iron Sucrose Injection 20mg/ml
Labetalol Hydrochloride Injection 5mg /ml
Levocarnitine Injection 1gm/5ml
Levocarnitine Injection 1gm/ml
Lignocaine & Adrenaline Injection
L-Ornithine L-Aspartate Infusion Concentrate 5gm
Methylcobalamin injection 500mcg,1000mcg,1500mcg,2500mcg
Methylcobalamin & Vit B1, B6, Niacinamide & D-Panthenol Injection
Methylcobalamin with Pyridoxine Hydrochloride, Niacinamide Injection





LIQUID INJECTABLES (GENERAL)

Methylcobalamin, Folic acid & Niacinamide injection

Methylcobalamin, Folic acid & Pyridoxine injection

Methylcobalamin, Pyridoxine Hydrochloride, Thiamine Hydrochloride & D-Panthenol Injection

Methylcobalamin, Pyridoxine Hydrochloride, Nicotinamide Injection

Midazolam Injection 1mg/ml, 5mg/ml

Minocycline For Injection USP 100mg

Nandrolone Decanoate Injection 25mg, 50mg, 100mg

Netilmicin Injection 25mg, 50mg, 100mg

Nitroglycerine Injection IP 5mg/ml, 5mg/5ml, 5mg/10ml

Ondansetron Injection 4mg

Pentazocine Injection 30mg

Piracetam Injection 200mg per ml

Piroxicam Injection 20mg

Promethazine HCL Injection 25mg

Terlipressin Acetate Injection 0.1mg

Tramadol Hydrochloride Injection 50mg

Tranexamic Acid Injection 100mg

Triamcinolone Acetonide Injection 40mg



TABLETS & CAPSULES



Cefadroxil Tablets -250 mg, 500mg,1 gm

Cefadroxil& Potassium Clavulanate dispersible Tablets 312.5mg, 625mg

Cefixime dispersible Tablets- 50mg, 100mg, 200mg

Cefixime Tablets -100mg, 200mg, 400mg

Cefixime and Ornidazole Tablets

Cefixime with Ofloxacin Tablets -200mg, 400mg

Cefixime with Ofloxacin dispersible Tablets -200mg, 400mg

Cefixime with Lactic Acid bacillus Tablets

Cefixime with Lactic Acid bacillus dispersible Tablets

Cefixime, Ofloxacin& Lactic Acid Bacillus Tablets

Cefixime with Potassium Clavulanate Tablets 325mg

Cefpodoxime Tablets - 100mg,200mg

Cefpodoxime Dispersible Tablets 50mg,100mg,200mg





TABLETS & CAPSULES

Cefpodoxime Proxetil Dispersible Tablets 200mg
Cefpodoxime with Ofloxacin Dispersible Tablets- 200mg
Cefpodoxime with Ofloxacin Tablets-100mg, 200mg, 300mg, 400mg
Cefpodoxime with Potassium Clavulanate Tablets- 162.5mg, 325mg
Cefuroxime Axetil Tablets- 125mg, 250mg, 500mg
Cefuroxime with Potassium Clavulanate Tablets- 375mg, 625mg
Cephalexin Tablets- 250mg, 500mg
Faropanam sodium 200 mg, 300mg
Sultamicillin Tosilate Dihydrate Tablets 375mg
Cephalexin Capsules 250mg, 500mg





DRY SYRUPS

Cefadroxil 125mg & Potassium Clavulanate 31.25mg oral suspension

Cefadroxil 250mg & Potassium Clavulanate 125mg oral suspension

Cefadroxil oral suspension 125mg, 250mg

Cefixime and Lactic acid bacillus oral suspension

Cefixime and Ofloxacin oral suspension

Cefixime oral suspension 50mg, 100mg

Cefixime with Potassium Clavulanate oral suspension

Cefpodoxime oral suspension

Cefpodoxime with Potassium Clavulanate oral suspension

Cefuroxime Axetil for oral suspension

Cefuroxime Axetil with Potassium Clavulanate for oral suspension

Cephalexin oral suspension 125mg, 250mg

OPHTHALMIC PREPARATIONS



Carmellose Sodium Eye Drops BP

Chloramphenicol Eye Drop USP 0.5% w/v

Chloramphenicol Eye Drop USP 5% w/v

Ciprofloxacin Ophthalmic Solution USP 0.3% w/v

Fluometholone USP Eye drops 0.1%

Gentamicin Eye Drops USP 0.3% w/v

Ketorolac Eye drops 0.5% w/v

Ketorolac Tromethamine 0.05% & Ofloxacin 0.3% Eye Drops

Moxifloxacin Eye Drops USP 0.5% w/v

Moxifloxacin Hydrochloride & Bromfenac Sodium Eye Drops USP

Moxifloxacin Hydrochloride & Ketorolac Tromethamine Eye Drops

Ofloxacin with Dexamethasone Phosphate Eye Drops

Prednisolone acetate Ophthalmic Suspension USP 1% w/v

Tobramycin Ophthalmic Solution USP



AVAILABLE COPP



Cefixime Dispersible Tablets IP 200mg
Cefixime Oral Suspension 50mg/5ml
Cynocobalamin Injection IP 500mcg/ml
Ceftriaxone Injection IP 1000 mg/Vial
Cefixime Dispersible Tablets 200mg
Cefixime Oral Suspension USP 50mg/5ml
Ceftriaxone Injection USP 1000 mg/Vial
Cynocobalamin Injection 500mcg/ml
Cefixime Tablets 400mg
Meropenem Injection USP 1000 mg/ Vial
Ceftriaxone Injection USP 500 mg/Vial
Ondansetron Injection USP 4mg/2ml
Gentamicin Sulphate Injection USP 40mg/ml
Dexamethasone Sodium Phosphate Injection USP 4mg/ml
Enoxaparin Sodium Injection IP 40mg/AMP
Enoxaparin Sodium Injection IP 60mg/AMP
Pantoprazole For injection 40mg (Lyophilized)
Hydrocortisone Sodium Succinate for Injection USP 100mg/Vial
Methyl Prednisolone Sodium Succinate for injection USP 40mg/Vial
Vancomycin for Injection USP 500mg /vial
Voriconazole for Injection 200 mg/vial (10mg/ml)
Doxycycline for Injection USP 100mg/ Vial

AVAILABLE COPP



Glutathione for Injection 600mg/Vial
Enoxaparin Sodium Injection USP 40mg/0.4ml
Enoxaparin Sodium Injection USP 60mg/0.6ml
Cefixime Oral Suspension USP 100mg/5ml
Tigecycline for Injection USP 50mg/ Vial
Diclofenac Sodium Injection 25mg/ml
Heparin Injection USP 1000IU/ml
Heparin Injection USP 5000IU/ml
Colistimethate for Injection USP 1 MIU
Colistimethate for Injection USP 2 MIU
Colistimethate for Injection USP 3 MIU
Triamcinolone Acetonide Injection 40mg/ml
Vitamin B1,B6,B12, Niacinamide & Panthenol Injection
Polymyxin-B for Injection USP 5000 IU / Vial
Ceftriaxone and Tazobactam for Injection 1125mg
Esomeprazole for Injection 40mg/Vial
Rabeprazole Injection 20mg /Vial
Imipenem with Cilastatin for Injection USP 1000 mg
Piperacillin & Tazobactam USP 4500mg /Vial
Iron Sucrose Injection USP 20mg/ml
Clindamycin injection USP 150mg/ml
Methyl Prednisolone Sodium Succinate 500mg USP

WELCURE REMEDIES



PLANT APPROVALS

**MANUFACTURING LICENSE
Form 28, Valid up to 25.03.2025**

**MANUFACTURING LICENSE
Form 25, Valid up to 26.01.2027**

**WHO GMP CERTIFICATION,
Valid up to 22.11.2023**

HEALTH & FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This one page certificate conforms to the format recommended by the **World Health Organization** [General Instructions and Explanatory Notes attached].

Certificate No. DCA/SLN/DML/125/10- 23 03

On the basis of the inspection carried out on 18th and 11th November 2020, It is certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table I:

1. Name and Address of Site: M/s Welcure Remedies,
Nahan Road, Village Magisand,
Kala-Anb, District Sirmaur-173030
Himachal Pradesh (INDIA).

2. Manufacturer's License No: Form 28- S-MI/10/110 valid upto 25.03.2025.

3. Table-I:

Dosage Form(s)	Category(ies)	Activity(ies)
Sterile Powder for Injectable, Tablets and Dry Syrup.	Cephalosporin	Production, Packing & Quality Control
Small Volume Parenterals (Liquid Injections).	General	Production, Packing & Quality Control

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

This certificate now remains valid until 22.11.2023. 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: Assistant Drugs Controller,
-cum-Drugs Licensing Authority,
CMO Office Complex, Nahan,
District Sirmaur-HP 173001(INDIA).

Name & Function of Responsible person: (SUNNY KAUSHAL)
Assistant Drugs Controller
-cum-Drugs Licensing Authority
Nahan, District Sirmaur-HP 173001(INDIA)
01702-222543, adr@sirmaur@gmail.com

Telephone/Fax No:

Date: 23.11.2020

Signature: (SUNNY KAUSHAL) 23/11/2020
Stamp: Assistant Drugs Controller
-Cum-Drugs Licensing Authority
District Sirmaur, Hq, Nahan, H.P.
173001(INDIA)

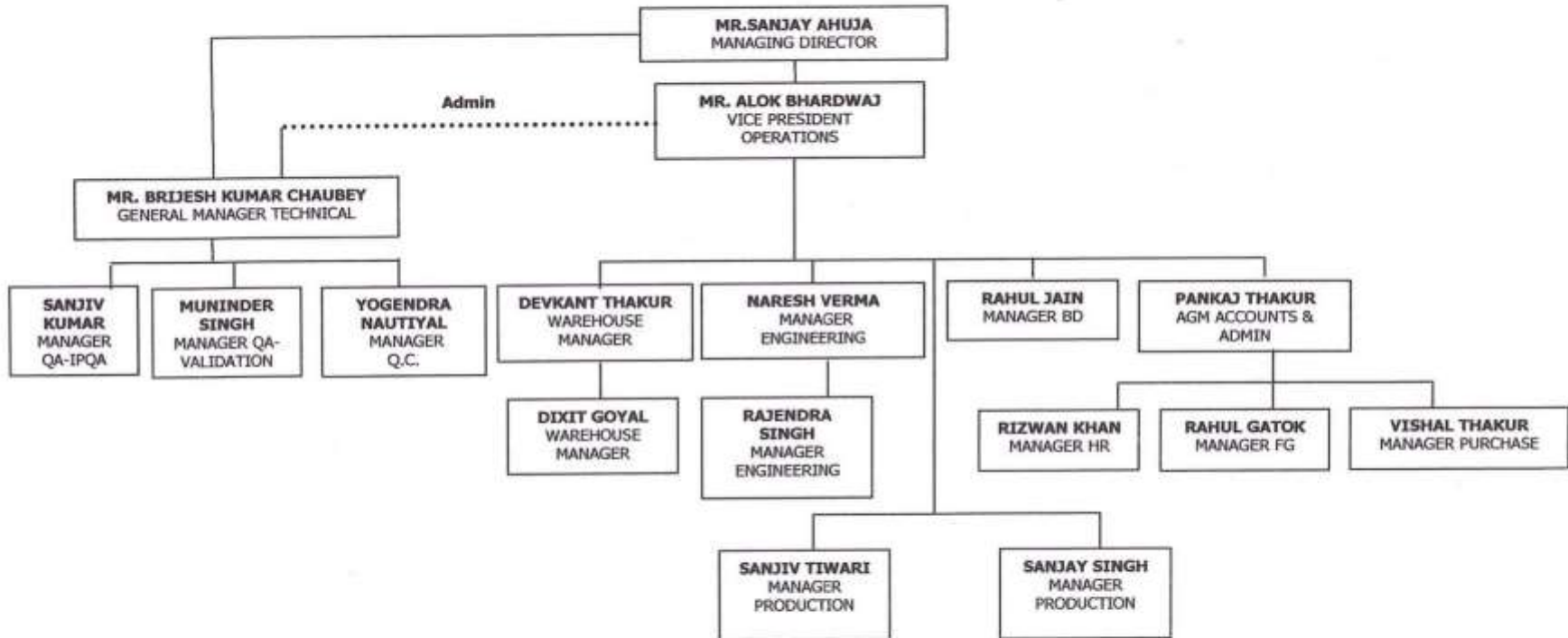
Sirmaur
23 NOV 2020

WELCURE REMEDIES



WELCURE REMEDIES
 Nahar Road, Village : Moginand , Kala-Amb
 District : Sirmour-173030 (H.P.)

ORGANOGRAM PLANT



Prepared By: *[Signature]*
 Name: ANSHIKA SAKLANI
 Date: 24/06/2022

Checked By: *[Signature]*
 Name: SANJIV KUMAR
 Date: 24/06/2022

Approved By: *[Signature]*
 Name: BRIJESH KUMAR CHAUBEY
 Date: 24/06/2022



WELCURE REMEDIES

FACILITY TOUR OF DRY INJECTION (GENERAL SECTION)



WELCURE REMEDIES

WAREHOUSE

- **All the input materials shall be received in the ware house.**
- **Sampling and storage of the material is done in ware house.**
- **Storage of the materials shall be done on racks and material movement is done as per requirement through material trolley.**
- **Status labeling of the material is done on all the stages of quarantine, under test, sampled, approved and rejected.**
- **Separate sampling booths are provided for sampling and dispensing.**
- **Intact containers of the approved materials are transferred to approved material store after QC release.**
- **Storage area for Raw / Packing / Finished goods maintained separately.**



WELCURE REMEDIES

SALIENT FEATURES OF PLANT

- Floor of the plant is made up in core area with epoxy.
- Wall to floor and wall to roof coving is done in the plant.
- All the change rooms are facilitated with proper gowning / De-gowning procedure.
- Sanitary type of drain traps are used in the facility.
- Fire extinguishers and smoke detectors are provided at the critical locations.
- Panel doors and panel windows are provided for smooth and cleanable surface in entire plant.
- GMP doors and Aluminum fittings are use in entire plant,



WELCURE REMEDIES

PRODUCTION

- **Manufacturing & Packaging of the Dry Injection is on Ground floor.**
- **Separate Filling and sealing area are provided in the section.**
- **Separate personnel and material airlocks are provided in the entire section.**
- **All the area's are designed as per class c. Filling & Sealing are carried out in class B/A.**
- **All the area's are catered by individual AHU's of suitable capacity.**
- **Corridor in the facility are designed at differential pressure of 24 Pascal's and Core Area are designed at differential pressure of 36 Pascal's .**
- **Full Line from Tunnel to Sealing are NKP make.**
- **Filling line is 8 head Filling with single hopper and sealing machine with 4 head.**

PACKING AREA

- **Ground floor of the facility is designed for primary and secondary packing of Dry injection.**



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PLANT TOUR OF QUALITY CONTROL LABORATORY



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QUALITY CONTROL:

Quality control Laboratory is available at First Floor of the plant.

Testing shall be performed on the input materials, intermediates and finished goods.

- **Quality control is divided in to the following sections :-**
- **Instrumentation Analysis Section**
- **Wet/ Chemical Analysis Section**
- **Microbiology Section**
- **Packing Materials Section**
- **Stability Section**



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QUALITY CONTROL

- **04 HPLC systems are available for analysis of various samples.**
- **HPLC systems are make of Shimanzu & Waters are equipped with UV detector.**
- **01 GC available with make of Perkin Elmer.**
- **01 TOC available with make of Shimanzu.**
- **01 Liquid Particle Counter available with make of Pamas.**
- **All other instruments like IR, analytical balances, dissolution apparatus, UV spectrophotometer, Karl Fischer and down the line other instruments are also available in laboratory.**



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QUALITY CONTROL

- **02 Stability chambers of 1000 liters capacity are available for accelerated and real time stability studies.**
- **Follow the Stability Condition of Zone IVB as mentioned below:-**
- **Long term condition at Temperature $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ Relative Humidity.**
- **Accelerated condition at Temperature $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ Relative Humidity.**



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QUALITY CONTROL

- **Microbiological analysis, Dedicated area is available for Sterility & BET testing.**
- **Sufficient change room provided in the Micro Section.**
- **Dedicated autoclave is available for sterilization in media preparation & Media discardation.**
- **Incubators of the suitable capacities are available for incubation of samples at variable temperatures.**



WELCURE REMEDIES

General Introduction

of

Quality Policy

and

Quality systems



WELCURE REMEDIES

Quality Policy

The management and staff of Welcure Remedies is committed towards manufacturing and marketing of pharmaceutical products following an integrated quality system, meeting the customer and regulatory requirements ensuring the quality, safety and efficacy of the product. Striving for excellence through continuous up gradation of resources and facilities to meet the ever-changing demands with respect to technologies and systems, aiming at continuous quality improvement and customer satisfaction, giving due to consideration for the protection of the environment. Providing training, safe working environment and opportunities for all the employees to grow along with the organization and striving for the better cause of the society.



WELCURE REMEDIES

WE HAVE THE FOLLOWING QUALITY SYSTEMS

- **SMF**
- **VMP**
- **Document Control**
- **Change control Procedure**
- **Deviation/NCR**
- **OOS/ Incidents**
- **Self Inspection**
- **Vendor Qualification**
- **Complaints handling**
- **Product recall**
- **Batch release**
- **Training programme**
- **Quality Risk Management**
- **CAPA**
- **Specifications**
- **Validations & Qualifications**
- **Calibrations**
- **Preventive maintenance**
- **APQR**

WELCURE REMEDIES



SAFETY SYSTEMS



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WE HAVE THE FOLLOWING SAFETY SYSTEMS :-

- Fire extinguisher
- Fire hydrant system
- Smoke detectors
- Emergency lights
- PPE'S in all Area
- Eye Wash and shower
- Emergency exits
- Trained First aiders
- First Aid Kits
- Trained Rescue Security force