

## AMWIN'S THIRD PARTY MANUFACTURING UNIT PROFILE

Manufacturing unit is sprawled over an area of about 500000 sq. ft. It is an independent State-of-the-art-manufacturing unit which has huge capacity to manufacture 40 million tablets & 8 million capsules per day one of the highest manufacturing capacity in any single unit in the country. Keeping up with the good manufacturing practices, Beta & Non Beta Lactum products are being manufactured in separate buildings

It has the largest manufacturing capacity in the country of manufacturing 40 Million Tablets, 8 Million Capsules, 0.3 Million Liquid, 0.3 Million Dry Syrup, 2.5 million Soft Gelatin, Injection: 0.8 Million Liquids Ampoules & Vials, 0.5 Million Dry Powder, 0.3 Million Eye/Ear Drops, 0.1 Million FFS Injections. Our Market Share in Pharmaceuticals Formulation has been increasing at a very fast Pace.

***Believes in Continuous developments and improvement for Redesigning the Global Healthcare by way of giving Quality, Innovative and Outstanding products to the World. Continuous efforts are there for Research and Development (R&D) programs for betterment. It has a habit of improving its Day-To-Day Results.***

## **ACCREDITATIONS**

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### **WHO-GMP**

By World Health Organisation, Regional Office for South East Asia, New Delhi-110002, Central Drugs Standard Control Organisation, North Zone India and Directorate General of Medical Health Services, Uttranchal

### **ISO 9001:2000**

By United Registrar of Systems Ltd. (URS) and Somerset UK B27 3AH with accreditation mark of UKAS

### **ISO 14001:2004**

By QMS Certification Pvt. Ltd., Bow 2006,Launceston,7250, Tasmania, Australia

### **Registered as Member of UNOPS ( United Nations Of Projects Services )**

By QMS Certification Pvt. Ltd., Bow 2006,Launceston,7250, Tasmania, Australia

### **Registered as Member of UNOPS ( United Nations Of Projects Services )**

UNOPS is an organization which provides project management, Procurement and other support services to United Nations agencies, international financial institutions, governments and non-governmental organizations. UNOPS services conform to the highest standards of transparency, efficiency and cost-effectiveness. UNOPS always ensures that project ownership rests with its clients. Established as part of the United Nations Development Programme in 1974, UNOPS became an independent, self-financing organization in 1995.

### **UKMHRA**

Company's Injectable Unit has been set up as per norms of U.K. Medicines & Health Regulatory

### **WHO-GMP**

By World Health Organisation, Regional Office for South East Asia, New Delhi-110002, Central Drugs Standard Control Organisation, North Zone India and Directorate General of Medical Health Services, Uttranchal

### **ISO-9001: 2000**

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### **ISO 14001:2004 Version A**

By QMS Certification Pvt. Ltd., Bow 2006,Launceston,7250, Tasmania, Australia

## PRODUCTS RANGE

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Unit is a life Healthcare science Company; manufactures wide range of pharmaceuticals formulations like Tablets, Capsules, Soft Gelatin Capsules, Liquid Orals, Dry Syrups, Injectables (Dry/Liquid), Small Volume Parenterals, Eye / Ear Drops in FFS Pack, Pre-Filled Syringes etc.

The company is into contract manufacturing for more than 200 leading National & Multinational Pharmaceuticals Companies, on third party /loan license & P to P basis. At present IT manufactures more than 13000 products with about 3500 different formulations.

Unit manufactures medicines covering almost all ailments, like; Anti-malarial, Analgesics, Anti-diabetics, Gastro-intestinals, Anti-allergic, Cough & cold preparations, Food Preparations, HIV Drugs, Antibiotics, Sedatives, Tranquilizers, Anti-amoebics, Anti-diarrheal, Vitamins, Corticosteroids, Anti-ulcerants and other Life saving medicines.

In a short span of time, it has become the Icon of India's Healthcare Industry and a Quality Pharma Manufacturer of the Country; with Global Vision. The presence of the products manufactured is so significant that there must be hardly any pharmacy in the country, where some products manufactured by unit are not available.

### All most all the Ailments are covered by the products manufactured by the Company

Anti-malarial	Anti-amoebics
Analgesics	Anti-diarrhea
Anti-diabetics	Pain Killers
Gastro-intestinals	Vitamins
Anti-allergic	Corticosteroids
Cough & cold preparations	Sedatives
Food Preparations	Anti-Ulcerants
Life saving medicines	Antibiotics,
Tranquilizers	Antipyretics
Anti-bacterial	And Others
Anti-Aids (HIV+)	

## LIST OF DOSSIER

1.	Active Salt	Country	Composition
2.	Atorvastatin-20mg	Libya	Each uncoated tablet contains: Atorvastatin Calcium eq. to Atorvastatin Calcium 20mg
3.	Albendazole-400mg	Ukraine	Each uncoated chewable tablet contains: Albendazole BP 400mg Colour: Sunset Yellow FCF
4.	Amlodipine Besilate-5mg	Venezuela	Each uncoated tablet contains: Amlodipine Besilate BP eq. to Amlodipine 5mg
5.	Azithromycin- 250 mg	Ukraine	Each film coated tablet contents: Azithromycin USP eq. to Anhy. Azithromycin 250mg Colour: Yellow Oxide of Iron & Titanium Dioxide BP
6.	Azithromycin-500 mg	Ukraine	Each film coated tablet contains: Azithromycin USP eq. to Anhy. Azithromycin 500mg Colour: Yellow oxide of Iron & Titanium Dioxide BP
7.	Azithromycin-1000 mg	Ukraine	Each film coated tablet contains: Azithromycin USP eq. to Anhy. Azithromycin 1000mg Colour: Yellow Oxide of Iron & Titanium Dioxide BP
8.	Amoxicillin & Potassium Clavulanate-625mg	Ukraine	Each film coated tablet contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 500mg Potassium Clavulanate BP eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
9.	Amoxicillin & Potassium Clavulanate-375mg	Ukraine	Each film coated tablet contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 250mg Potassium Clavulanate BP eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
10.	Amoxicillin & Potassium Clavulanate-DS	Ukraine	Each 5ml of the reconstituted suspension contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 200mg Potassium Clavulanate BP eq. to Clavulanic Acid 28.5mg
11.	Amoxicillin & Potassium Clavulanate-375mg	Nigeria	Each film coated tablet contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 250mg Potassium Clavulanate BP eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
12.	Amoxicillin & Potassium Clavulanate-625mg	Nigeria	Each film coated tablet contains: Amoxicillin Trihydrate BP Eq. To Amoxicillin 500mg Potassium Clavulanate BP eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
13.	Amoxicillin & Potassium Clavulanate-1gm	Nigeria	Each film coated tablet contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 875mg Potassium Clavulanate BP eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
14.	Amoxicillin & Potassium Clavulanate-228.5mg	Nigeria	Each 5ml of the reconstituted suspension contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 200mg Potassium Clavulanate BP eq. to Clavulanic Acid 28.5mg
15.	Amoxicillin Caps.-250mg	Philippines	Each hard gelatin capsule contains: Amoxicillin Trihydrate BP eq. to Amoxicillin 250mg
16.	Amoxicillin Caps.-500mg	Philippines	Each hard gelatin capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 500mg
17.	Aspirin-100mg	Turkmenistan	Each film coated tablet contains: Aspirin BP 100mg Colour: Titanium Dioxide BP

18.	Atorvastatin-10mg	Ukraine	Each film coated tablet contains: Atorvastatin Calcium eq. to Anhy. Atorvastatin 10mg Colour: Titanium Dioxide BP
19.	atorvastatin-10mg	Nigeria	Each film coated tablet contains: Atorvastatin Calcium eq. to Atorvastatin 10mg Ezetimibe 10mg Colour: Sunset Yellow FCF
20.	Atorvastatin-20mg	Ukraine	Each film coated tablet contains: Atorvastatin Calcium eq. to Anhy. Atorvastatin 20mg Colour: Titanium Dioxide BP
21.	Atorvastatin -40mg	Ukraine	Each film coated tablet contains: Atorvastatin Calcium eq. to Anhy. Atorvastatin 40mg Colour: Titanium Dioxide BP
22.	Amlodipine-5mg	Nigeria	Each uncoated tablet contains: Amlodipine Besilate BP eq. to Amlodipine 5mg Colour: Tartrazine
23.	Cefixime Trihydrate-100DT	Ukraine	Each uncoated dispersible tablet contains: Cefixime USP as Trihydrate eq. to Anhydrous Cefixime 100mg
24.	Captopril-50mg &100mg	Turkmenistan	Each film coated tablet contains: Captopril BP 50mg Colour: Brilliant Blue FCF & Each film coated tablet contains: Captopril BP 100mg Colour: Erythrosin
25.	Ciprofloxacin-100ml	Nepal	Each vial contains: Ciprofloxacin IP 100ml Benzyl Alcohol IP 2%v/v (As preservative) Water for Injection IP q.s
26.	Cholestyramine	Cambodia	Each sachet contains: Cholestyramine Resin (Anhy.) USP 4.0gm (Use for Oral Suspension)
27.	Cefdinir-100 mg	China	Each uncoated dispersible tablet contains: Cefdinir 100mg Colour: Yellow Oxide of Iron
28.	Cefixime Trihydrate-200mg	Ukraine	Each film coated tablet contains: Cefixime USP as Trihydrate eq. to Anhydrous Cefixime 200mg Colour: Titanium Dioxide BP
29.	Cetirizine Hcl-10mg	Nigeria	Each film coated tablet contains: Cetirizine HCL BP 10mg Colour: Titanium Dioxide IP
30.	ceftriaxone-inj.	Nigeria	Each vial contains: Ceftriaxone Sodium USP (Sterile) eq. to Anhy. Ceftriaxone 1000mg
31.	Erythromycin-250mg	Turkmenistan	Each film coated tablet contains: Erythromycin BP 250mg Colour: Erythrosin
32.	Glipizide-2.5mg	Philippines	Each uncoated tablet contains: Glipizide BP 2.5mg
33.	Glimepiride & Metformin-SR	Philippines	Each uncoated bilayered tablet contains: Glimepiride USP 1mg Metformin HCL BP 500mg (in sustained release form) Colour: Carmoisine
34.	Gliclazide	Philippines	Each uncoated tablet contains: Glibenclamide BP 80mg
35.	Glipizide-5mg	Philippines	Each uncoated tablet contains: Glipizide BP 5mg
36.	Glimepiride & Metformin	Philippines	Each uncoated bilayered tablet contains: Glimepiride USP 1mg Metformin HCL BP 500mg Colour: Sunset Yellow FCF
37.	Glipizide & Metformin	Philippines	Each uncoated tablet contains: Metformin HCL BP 500mg Glipizide BP 5mg
38.	Gliclazide & Metformin	Philippines	Each uncoated tablet contains: Gliclazide BP 80mg Metformin HCL BP 500mg

39.	Glibenclamide & metformin HCL	Philippines	Each uncoated tablet contains: Glibenclamide BP 5mg Metformin HCL BP 500mg
40.	Gliclazide-80 mg	Vietnam	Each uncoated tablet contains: Gliclazide BP 80mg
41.	Glimepiride & metformin HcL	Philippines	Each uncoated bilayered tablet contains: Glimepiride USP 2mg Metformin HCL BP 500mg
42.	Glimepiride	Philippines	Each uncoated tablet contains: Glimepiride USP 1mg Colour: Red Oxide of Iron
43.	Gemifloxacin-320mg	Philippines	Each film coated tablet contains: Gemifloxacin Mesylate eq. to Gemifloxacin 320mg Colour: Yellow Oxide of Iron & Titanium Dioxide IP
44.	Loratadine-10	Nigeria	Each uncoated tablet contains: Loratadine 10mg Colour: Erythrosine
45.	methylcobalamin-500mcg (Soft gel)	Philippines	Each soft gelatin capsule contains: Methylcobalamin 500mcg Excipients: q.s Approved colour used in gelatin shells.
46.	Meloxicam-inj.	Ukraine	Each ml contains: Meloxicam BP 10mg/ml Benzyl Alcohol IP*85 4.0%v/v(As preservative)
47.	Meropenem-500mg	Ukraine	Each vial contains: Meropenem 500mg Colour: Off White, Crystalline Powder
48.	Meropenem-1000mg	Ukraine	Each vial contains: Meropenem 500mg Colour: Off White, Crystalline powder
49.	Multivitamin	Ukraine	Each soft gelatin capsule contains: Chromium Picolinate USP eq. to Elemental Chrom. 65mcg Mecobalamin 1500mcg Alpha Lipoic Acid USP 200mg Pyridoxine HCL IP 1mg Benfotiamine 33.5mg Folic Acid IP 0.5mg
50.	Mebendazole-100mg	Turkmenistan	Each film coated tablet contains: Mebendazole USP 100mg
51.	Nitrofurantoin-50mg	Turkministan	Each film coated tablet contains: Nitrofurantoin BP 50mg
52.	Nystatin -500000 IU	Turkministan	Each vial contains: Nystatin BP 500000IU
53.	Nifedipine-10mg	Turkministan	Each film coated tablet contains: Nifedipine BP 10mg
54.	Omeprazole	Khazakhstan	Each hard gelatin capsule contains: Omeprazole USP 20mg (As enteric coated granules)
55.	Omeprazole-20mg	Ukraine	Each hard gelatin capsule contains: Omeprazole USP 20mg (As enteric coated granules)
56.	Ofloxacin-200mg	Nigeria	Each film coated tablet contains: Ofloxacin USP 200mg Colour: Titanium Dioxide IP
57.	pancreatin	Philippines	Each enteric coated tablet contains: Pancreatin USP Eq. to Lipase Activity 20,000 units Amylase Activity 62,250 units Protease Activity 93,750units Colour: Titanium Dioxide
58.	Paracetamol Inj.	Turkministan	Each ml contains: Paracetamol BP 150mg Benzyl Alcohol BP 2% v/v (As preservative) Water for Injection BP q.s
59.	Paracetamol-100ml	Nepal	Each vial contains: Paracetamol IP 100ml Benzyl Alcohol IP 2%v/v (As preserve.)Water for Injec. IP q.s
60.	Paracetamol, Caffeine, Chlorpheniramine Maleate, Phenylephrine Hydrochloride	Tajikistan	Each uncoated tablet contains: Paracetamol BP 500mg Caffeine BP 30mg Chlorpheamine Maleate BP 2mg Phenylephrine HCL BP 5mg

61.	ranitidine-300mg	Nigeria	Each film coated tablet contains: Ranitidine 300mg Colour: Sunset Yellow FCF & Titanium Dioxide IP
62.	Rabeprazole & Domperidone	Ukraine	Each hard gelatin capsule contains: Rabeprazole Sodium 20mg (as enteric coated) Colour: Red Oxide of Iron Domperidone Maleate BP eq. to Domperidone 30 mg (10mg as immediate release and 20mg) As sustained release) Colour: Quinoline Yellow WS
63.	Sildenafil Citrate-100mg	Tajikistan	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil Citrate 100mg Color: Titanium Dioxide BP & Ponceau 4R
64.	Tramadol HCl & Paracetamol	Ukraine	Each film coated tablet contains: Tramadol HCL BP 30mg Paracetamol BP 500mg Colour: Yellow Oxide of Iron
65.	Metformin Hydrochloride	Philippines	Each uncoated tablet contains: Metformin Hydrochloride. BP 500mg
66.	Azithromycin	Nigeria	Each film coated tablet contains: Azithromycin USP eq. to Anhydr. Azithromycin 500mg Colour: Brilliant Blue FCF & Titanium Dioxide BP
67.	Albendazole oral suspension	Ukraine	Each 5 ml suspension contains : Albendazole USP 200 mg In flavored Syrup base q.s.
68.	Cefixime Dispersible Tablets 200 mg	Ukraine	Each uncoated dispersible tablet contains: Cefixime Trihydrate USP equivalent to Anhydrous Cefixime 200mg
69.	Albendazole	Ukraine	Each uncoated chewable tablet contains: Albendazole USP 400 mg Colour: Sunset Yellow FCF
70.	Paracetamol injection	Vietnam	Each 100ml contains: Paracetamol Infusion USP 1.0%w/v
71.	Amoxicillin + Clavulanic Acid	Venezuela	Each film coated tablet contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 500 mg Potassium Clavulante BP (Diluted Potassium Clavulanate BP) eq. to Clavulanic Acid 125 mg Colour : Titanium Dioxide BP
72.	Atorvastatin + Fenofibrate	Venezuela	Each uncoated tablet contains: Atorvastatin Calcium eq. to Atorvastatin 10 mg Fenofibrate BP 160 mg
73.	Ibuprofen	Venezuela	Each film coated tablet contains: Ibuprofen BP 400 mg Colour: Erythrosine
74.	Gliclazide & Metformin	Venezuela	Each uncoated tablet contains: Gliclazide BP 80mg Metformin Hydrochloride BP 500mg
75.	Prolonged release Diclofenac Tablets	Venezuela	Each film coated (Prolonged release) tablet contains: Diclofenac Sodium BP 100 mg Colour: Titanium Dioxide BP
76.	Amlodipine & Lisinopril Tablets	Nigeria	Each uncoated tablet contains: Amlodipine Besilate BP Eq. to Amlodipine 5 mg Lisinopril USP Eq. to anhydrous Lisinopril 5 mg Color: Tartrazine
77.	Lisinopril Tablets 5 mg	Nigeria	Each uncoated tablet contains: Lisinopril USP Eq. to anhydrous Lisinopril 5 mg Color: Erythrosine
78.	Lisinopril Tablets 10 mg	Nigeria	Each uncoated tablet contains: Lisinopril USP Eq. to anhydrous Lisinopril 10 mg Color: Brilliant blue FCF
79.	Amlodipine Tablet 5 mg	Nigeria	Each uncoated tablet contains: Amlodipine Besilate BP Eq. to Amlodipine 5 mg
80.	Amlodipine Tablet 10 mg	Nigeria	Each uncoated tablet contains: Amlodipine Besilate BP Eq. to Amlodipine 10 mg
81.	Cefadroxil 500mg	Ukraine	Each uncoated tablet contains: Cefadroxil USP Eq. to Anhydrous Cefadroxil 500 mg

82.	Paracetamol-100ml	Vietnam	Each vial contains: Paracetamol IP 100ml Benzyl Alcohol IP 2%v/v (As preserve.)Water for Injec. IP q.s
83.	Aceclofenac, Paracetamol & Tizanidine Tablets	Venezuela	Each uncoated tablet contains: Aceclofenac BP 100mg Paracetamol BP 500mg Tizanidine Hydrochloride USP Eq. to Tizanidine 2mg Colour: Ponceau 4R
84.	Paracetamol + Caffeine (Anhydrous) + Chlorpheniramine Maleate Tabs	Venezuela	Each uncoated tablet contains : Paracetamol BP 500 mg Caffeine BP (Anhydrous) 30 mg Chlorpheniramine Maleate BP 2 mg
85.	Amoxicillin 500mg + Lactic Acid Bacillus 60 Million Spores	Venezuela	Each uncoated tablet contains : Amoxicillin Trihydrate BP Eq. to Amoxicillin 500 mg Lactic Acid Bacillus 60 Million Spores
86.	Ketorolac Tab	Venezuela	Ketorolac tromethamine USP 10mg
87.	Glimepiride Tablets	Venezuela	Each uncoated tablet contains: Glimepiride USP 2mg
88.	Gatifloxacin 400 mg tablet	Ukraine	Each film coated contains: Gatifloxacin sesquihydrate Eq. to Gatifloxacin 400 mg Color: uinoline Yellow
89.	Rabeprazole-20 mg	Sri-lanka	Each enteric coated tablet contains: Rabeprazole Sodium 20 mg Color: Red oxide of iron & Titanium dioxide
90.	Metformin-850	Chile	Each uncoated tablet contains: Metformin Hydrochloride USP 850 mg
91.	Glibenclamide	Chile	Each uncoated tablet contains: Glibenclamide BP 5 mg
92.	Ibuprofen-400	Chile	Each film coated tablet contains: Ibuprofen BP 400 mg
93.	Enalapril-10	Chile	Each film coated tablet contains: Enalapril maleate USP 10 mg
94.	Paracetamol-500	Chile	Each uncoated tablet contains: Paracetamol USP 500 mg
95.	Atenolol-50 mg	Chile	Each uncoated tablet contains: Atenolol USP 50 mg
96.	Aspirin 100 mg tablet	Chile	Each uncoated tablet contains : Acetyl Salicylic Acid BP 100 mg
97.	Diclofenac Sodium 50 mg	Chile	Each film coated tablet contains: Diclofenac Sodium USP 50 mg
98.	Nicotinic Acid ER	Venezuela	ach Extended Release Tablet Contains: Niacinamide BP 250mg
99.	Nicotinic Acid ER	Venezuela	Each Extended Release Tablet Contains: Niacinamide BP 500mg
100.	Nicotinic Acid ER	Venezuela	Each Extended Release Tablet Contains: Niacinamide BP 750mg
101.	Amoxicillin 500mg + Lactic Acid Bacillus 60 Million Spores	Venezuela	Each uncoated tablet contains : Amoxicillin Trihydrate BP Eq. to Amoxicillin 500 mg Lactic Acid Bacillus 60 Million Spores
102.	Atorvastatin 20 mg + Amlodipine 5 mg	Venezuela	Each uncoated tablet contains: Atorvastatin Calcium eq. to Atorvastatin 20 mg Amlodipine Besilate BP eq. to Amlodipine 5 mg
103.	Alpha Lipoic Acid 600 mg	Belarus	Each film coated sustained release tablet contains: Alpha Lipoic Acid USP 600 mg
104.	Nutrimax capsule	Venezuela	Multivitamin
105.	Mefenamic Acid 500 mg	Venezuela	Each uncoated tablet contains: Mefenamic Acid BP 500 mg
106.	Zinc sulphate	Belarus	Each film coated tablet contains: Zinc sulphate 124 mg



107.	Amlodipine Tablet 5 mg	Ukraine	Each uncoated tablet contains: Amlodipine Besilate BP Eq. to Amlodipine 5 mg
108.	Amlodipine Tablet 10 mg	Ukraine	Each uncoated tablet contains: Amlodipine Besilate BP Eq. to Amlodipine 10 mg
109.	Glibenclamide & metformin HCL Tablet	Venezuela	Each uncoated tablet contains: Glibenclamide BP 2.5mg Metformin HCL BP 500mg
110.	Nifedipine SR 30 mg tablet	Nigeria	Each extended release tablet contains: Nifedipine BP 30 mg
111.	Clopidogrel Tablet 75 mg	Guatemala	Each film coated tablet contains: Clopidogrel Bisulphate USP Eq. to Clopidogrel 75 mg Colorant: Red oxide of Iron & Titanium dioxide B.P
112.	Ibuprofen-600	Chile	Each film coated tablet contains: Ibuprofen BP 600 mg
113.	Glibenclamide & metformin HCL Tablet	Guatemala	Each uncoated tablet contains: Glibenclamide BP 5mg Metformin HCL USP 500mg
114.	Cefpodoxime Proxetil 100 mg Tablet	Vietnam	Each uncoated dispersible tablet contains: Cefpodoxime Proxetil USP Eq. to Cefpodoxime 100 mg Color: Sunset Yellow FCF
115.	Cefpodoxime Proxetil 100 mg Tablet	Cambodia	Each uncoated dispersible tablet contains: Cefpodoxime Proxetil USP Eq. to Cefpodoxime 100 mg Color: Sunset Yellow FCF
116.	Cefpodoxime Proxetil 200 mg Tablet	Vietnam	Each film coated tablet contains: Cefpodoxime Proxetil USP Eq. to Cefpodoxime 200 mg Color: Quinoline Yellow WS, Ponceau 4R & Titanium Dioxide BP
117.	Cefpodoxime Proxetil 200 mg Tablet	Cambodia	Each film coated tablet contains: Cefpodoxime Proxetil USP Eq. to Cefpodoxime 200 mg Color: Quinoline Yellow WS, Ponceau 4R & Titanium Dioxide BP
118.	Levofloxacin 250 mg	Ukraine	Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin 250 mg Color: Red oxide of iron & Titanium dioxide BP
119.	Levofloxacin 500 mg	Ukraine	Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin 500 mg Color: Red oxide of iron & Titanium dioxide BP
120.	Ibucure suspension	Ukraine	Each 5 ml contains Ibuprofen BP 100 mg Paracetamol BP 162.5 mg Color: Sunset Yellow FCF
121.	Losartan-25 mg tablet	Nigeria	Each film coated tablet contains: Losartan Potassium Tablet USP 25 mg Color: Quinoline Yellow WS
122.	Losartan-50 mg tablet	Nigeria	Each film coated tablet contains: Losartan Potassium Tablet USP 50 mg
123.	Gatifloxacin 400 mg tablet	Ukraine	Each film coated tablet contains: Gatifloxacin Sesquihydrate Eq. to Gatifloxacin 400mg Colour: Quinoline Yellow WS & Titanium Dioxide BP
124.	Glimepiride 4 mg Tablets	Guatemala	Each uncoated tablet contains: Glimepiride USP 4 mg
125.	Montelukast 4 mg Tablet	Guatemala	Each Uncoated tablet contains: Montelukast Sodium equivalent to Montelukast 4 mg Excipients q.s.
126.	Aceclofenac BP 100mg Tablet	Guatemala	Each Film coated tablet contains: Aceclofenac BP 100mg Colour: Titanium Dioxide BP
127.	Lisinopril Tablets 10 mg	Russia	Each uncoated tablet contains: Lisinopril USP Eq. to anhydrous Lisinopril 10 mg Color: Brilliant blue FCF
128.	Lisinopril Tablets 5 mg	Russia	Each uncoated tablet contains: Lisinopril USP Eq. to anhydrous Lisinopril 5 mg Color: Erythrosine

129.	Metformin Hydrochloride 500 mg tablet	Russia	Each uncoated tablet contains: Metformin Hydrochloride USP 500mg
130.	Pioglitazone 15 mg tablet	Guatemala	Each uncoated tablet contains:- Pioglitazone Hydrochloride Eqvt. to Pioglitazone 15 mg.
131.	Pioglitazone 15 mg tablet	Philippines	Each uncoated tablet contains:- Pioglitazone Hydrochloride Eqvt. to Pioglitazone 15 mg.
132.	Pioglitazone 30 mg tablet	Philippines	Each uncoated tablet contains:- Pioglitazone Hydrochloride Eqvt. to Pioglitazone 30 mg.
133.	Gliclazide Modified Release tablet 30 mg	Vietnam	Each modified release tablet contains: Gliclazide BP 30 mg
134.	Albendazole + Ivermectin Suspension	Nigeria	Each 10 ml suspension contains: Albendazole BP 200 mg Ivermectin BP 1.5 mg
135.	Albendazole + Ivermectin Tablet	Nigeria	Each uncoated tablet contains: Albendazole BP 400 mg Ivermectin BP 6 mg
136.	Ambroxol+ Phenyl propanalamine HCL+ Guifenasin +Menthol	Belarus	Each ml contains: Ambroxol Hydrochloride BP 15 mg Propanalamine HCL USP 12.5 mg Guifenasin USP 50 mg Menthol BP 1 mg
137.	Ambroxol + Acetyl Cystine Capsule	Belarus	Each Hard Gelatin Capsule contains: Ambroxol BP 15 mg Acetyl Cystine USP 200 mg
138.	Gliclazide BP 80 mg	Belarus	Each uncoated tablet contains: Gliclazide BP 80 mg
139.	Gliclazide MR BP 30 mg	Belarus	Each modified release tablet contains: Gliclazide BP 30 mg
140.	Ornidazole tab.	Ukraine	Each film coated tablet contains: Ornidazole 500 mg Color: Titanium dioxide BP
141.	Levofloxacin+ Ornidazole Tab.	Ukraine	Each film coated tablet contains: Levofloxacin Hemihydrate Eq. to Levofloxacin 250 mg Ornidazole 500 mg Color: Red oxide of iron+ Titanium dioxide BP
142.	Cefuroxime Axetil Tab.	Nigeria	Each film coated tablet contains: Cefuroxime Axetil USP Eq. to Cefuroxime 250 mg Color: Titanium dioxide BP
143.	Cefuroxime Axetil Tab.	Vietnam	Each film coated tablet contains: Cefuroxime Axetil USP Eq. to Cefuroxime 250 mg Color: Titanium dioxide BP
144.	Cefuroxime Axetil oral suspension	Nigeria	Each 5 ml of constituted suspension contains: Cefuroxime Axetil USP Eq. to Anhydrous Cefuroxime 125 mg Color: Sunset Yellow FCF
145.	Domperidone Tab.	Philippines	Each uncoated tablet contains: Domperidone Maleate BP Eq. to Domperidone 10 mg Color: Tartrazine
146.	Norfloxacin+Metronidazole Tab.	Philippines	Each film coated tablet contains: Norfloxacin BP 400 mg Metronidazole BP 500 mg Color: Titanium dioxide BP & Quinoline Yellow
147.	Moxifloxacin infusion	Myanmar	Each 100 ml contains: Moxifloxacin Hydrochloride BP Eq. to Moxifloxacin 400 mg Mannitol USP 5 gm Water for injection USP q.s
148.	Moxifloxacin infusion	Guatemala	Each 100 ml contains: Moxifloxacin Hydrochloride BP Eq. to Moxifloxacin 400 mg Mannitol USP 5 gm Water for injection USP q.s
149.	Losartan-50 mg tablet	Guatemala	Each film coated tablet contains: Losartan Potassium Tablet USP 50 mg

150.	Rabeprazole + Domperidone capsule	Kenya	Each hard gelatin capsule contains:- Rabeprazole Sodium: 20 mg (as enteric coated) Colour: Red Oxide of Iron Domperidone Maleate BP Eq. to Domperidone: 30 mg (10 mg as immediate release and 20 mg as sustained release) Colour: Quinoline Yellow WS
151.	CEFDINIR DISPERSIBLE TABLETS	Kenya	Each uncoated dispersible tablet contains: Cefdinir 100mg Colour: Yellow Oxide of Iron
152.	Amoxicillin & Clavulanate Potassium 625 mg. TABLET	Kenya	Each film coated tablet contains:- Amoxicillin & Clavulanate Potassium Tablets USP Eq. To Amoxicillin.....500mg (Including 5.0 % overages included) Potassium Clavulanate BP (As Dilute Potassium Clavulanate BP) Eq. To Clavulanic Acid.....125mg Colour: Titanium Dioxide BP
153.	Amoxicillin & Clavulanate Potassium 375 mg. TABLET	Kenya	Each film coated tablet contains:- Amoxicillin Trihydrate BP eq. to Amoxicillin 250mg Potassium Clavulanate BP (As diluted Potassium Clavulanate BP) eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
154.	Amoxicillin & Clavulanate Potassium 228.5 mg dry syp.	Kenya	Each 5 ml of reconstituted suspension contains:- Amoxicillin Trihydrate BP eq. to Amoxicillin 200mg Potassium Clavulanate BP (As diluted Potassium Clavulanate BP) eq. to Clavulanic Acid 28.5 mg
155.	(Amoxicillin + Clavulanic Acid Inj )	Kenya	Each vial contains: Amoxicillin Sodium BP (Sterile) eq. to Amoxicillin 1000mg Potassium Clavulanate BP (Sterile) eq. to Clavulanic Acid 200 mg
156.	Amoxicillin & Clavulanate Potassium 1g. TABLET	Kenya	Each film coated tablet contains:- Amoxicillin Trihydrate BP eq. to Amoxicillin 875mg Potassium Clavulanate BP (As diluted Potassium Clavulanate BP) eq. to Clavulanic Acid 125mg Colour: Titanium Dioxide BP
157.	Meropenem 500 mg Inj	Kenya	Each vial contains: Meropenem USP (Sterile) eq. to Meropenem 500 mg
158.	Meropenem 1gm Inj	Kenya	Each vial contains: Meropenem USP (Sterile) eq. to Meropenem 1000 mg
159.	Glimepiride 1 mg + Metformin 500 mg Tab.	Africa	Each uncoated bilayered tablet contains: Glimepiride USP 1 mg Metformin Hydrochloride USP 500 mg (In sustained release form) Color: Sunset Yellow FCF
160.	Glimepiride 2 mg + Metformin 500 mg Tab.	Africa	Each uncoated bilayered tablet contains: Glimepiride USP 2 mg Metformin Hydrochloride USP 500 mg (In sustained release form) Color: Carmoisine
161.	Nitazoxanide Tablets 500 mg	Ukraine	Each film coated tablet contains:- Nitazoxanide 500 mg Colour: Quinoline Yellow
162.	Moxifloxacin Tablets 400 mg	Ukraine	Each Film Coated Tablet Contains: Moxifloxacin Hydrochloride BP Eq. to Moxifloxacin 400mg Colour: Red Oxide of Iron & Titanium Dioxide BP
163.	Glibenclamide Tablets 3.5 mg	Ukraine	Each Uncoated Tablet Contains: Glibenclamide BP 3.5 mg
164.	Albendazole-Chewable Tablets 400mg	Ukraine	Each uncoated chewable tablet contains: Albendazole BP 400mg
165.	Rabeprazole-20	Vietnam	Each enteric coated tablet contains: Rabeprazole Sodium 20 mg Colours: Red oxide of iron & Titanium dioxide BP
166.	Rabeprazole + Domperidone	Vietnam	Each hard gelatin capsule contains: Rabeprazole Sodium 20 mg Colours: Red oxide of iron Domperidone Maleate BP Eq. to Domperidone 30 mg (10 mg immediate release and 20 mg sustained release) Color: Quinoline Yellow
167.	Clarithromycin-250	Ukraine	Each film coated tablet contains: Clarithromycin USP 250 mg Colors: Quinoline Yellow WS & Sunset Yellow FCF

168.	Clarithromycin-500	Ukraine	Each film coated tablet contains: Clarithromycin USP 500 mg Colors: Quinoline Yellow WS & Sunset Yellow FCF
169.	Risperidone BP 2 mg	Vietnam	Each Un-coated tablet contains: Risperidone BP 2 mg
170.	Risperidone BP 1 mg	Vietnam	Each Un-coated tablet contains: Risperidone BP 1 mg
171.	Venlafaxine 37.5 mg	Vietnam	Each Un-coated tablet contains: Venlafaxine Hydrochloride BP Eq. to Venlafaxine 37.5 mg
172.	Ofloxacin USP 200 mg	Myanmar	Each 100ml contains: Ofloxacin USP 200 mg Sodium Chloride BP 900 mg Water for injection BP q.s
173.	Levofloxacin 500 mg	Myanmar	Each 100ml contains: Levofloxacin Hemihydrate Eq. to Levofloxacin 500 mg Sodium Chloride BP 900 mg Water for injection BP q.s
174.	Ciprofloxacin USP 200 mg	Myanmar	Each 100ml contains: Ciprofloxacin USP 200 mg Sodium Chloride BP 900 mg Water for injection BP q.s
175.	Moxifloxacin 400mg	Myanmar	Each 100ml contains: Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 400mg Mannitol USP 5 gm Water for Injection USP q.s
176.	Meropenem For Injection USP 500 mg	Thailand	Each vial contains:- Meropenem USP (Sterile) Eq. to anhydrous Meropenem 500mg Sodium as Sodium Carbonate) 45.1mg
177.	Meropenem For Injection USP 1000 mg	Thailand	Each vial contains:- Meropenem USP (Sterile) Eq. to anhydrous Meropenem 1000mg Sodium as Sodium Carbonate) 90.2 mg
178.	Risperidone Tablets USP	Sri Lanka	Each uncoated tablet contains: Risperidone BP 1 mg
179.	Risperidone Tablets USP	Sri Lanka	Each uncoated tablet contains: Risperidone BP 2 mg
180.	Risperidone Tablets USP	Sri Lanka	Each uncoated tablet contains: Risperidone BP 3 mg
181.	Risperidone Tablets USP	Sri Lanka	Each uncoated tablet contains: Risperidone BP 4 mg
182.	Azithromycin Tablets 250 mg	Sri Lanka	Each Film Coated Tablet Contains: Azithromycin USP Eq. to Anhydrous Azithromycin 250 mg Colour: Yellow Oxide of Iron
183.	Azithromycin Tablets 500 mg	Sri Lanka	Each Film Coated Tablet Contains: Azithromycin USP Eq. to Anhydrous Azithromycin 500 mg Colour: Yellow Oxide of Iron
184.	Amoxicillin Capsules BP 250 mg	Sri Lanka	Each Hard Gelatin Capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 250 mg
185.	Amoxicillin Capsules BP 500 mg	Sri Lanka	Each Hard Gelatin Capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 500 mg
186.	Cephalexin Capsules USP 250 mg	Sri Lanka	Each Hard Gelatin Capsule contains: Cephalexin USP Eq. to Anhydrous Cephalexin 250 mg
187.	Cephalexin Capsules USP 500 mg	Sri Lanka	Each Hard Gelatin Capsule contains: Cephalexin USP Eq. to Anhydrous Cephalexin 500 mg
188.	Hydrocortisone Sodium Succinate inj. USP	Philippines	Each vial contains: Hydrocortisone Sodium Succinate USP (Sterile) Eq. to Hydrocortisone 100 mg
189.	Gatifloxacin Sesquihydrate Eq. to Anhydrous Gatifloxacin	Myanmar	Each 100 ml Contains: Gatifloxacin Sesquihydrate Eq. to Anhydrous Gatifloxacin : 200 mg Sodium Chloride BP : 900 mg Water for injection BP : q.s

0.2%

190.	Atorvastatin Tablets 10 mg	Sri Lanka	Each Film Coated Tablet Contains: Atorvastatin Calcium Eq. to Atorvastatin 10 mg Colour: Titanium Dioxide BP
191.	Atorvastatin Tablets 20 mg	Sri Lanka	Each Film Coated Tablet Contains: Atorvastatin Calcium Eq. to Atorvastatin 20 mg Colour: Titanium Dioxide BP
192.	Sildenafil Citrate Tablets 50 mg	Sri Lanka	Each Film Coated Tablet Contains: Sildenafil Citrate Eq. to Sildenafil 50 mg Colour: Titanium Dioxide BP & Indigo Carmine
193.	Metformin HCl Tablets USP 850 mg	Sri Lanka	Each Uncoated Tablet Contains: Metformin Hydrochloride USP 850 mg
194.	Clonazepam Tablets 0.25 mg	Sri Lanka	Each Uncoated Mouth Dissolving Tablet Contains: Clonazepam USP 0.25 mg
195.	Clonazepam Tablets 0.5 mg	Sri Lanka	Each Uncoated Mouth Dissolving Tablet Contains: Clonazepam USP 0.5 mg
196.	Clonazepam Tablets 1 mg	Sri Lanka	Each Uncoated Mouth Dissolving Tablet Contains: Clonazepam USP 1 mg
197.	Clonazepam Tablets 2 mg	Sri Lanka	Each Uncoated Mouth Dissolving Tablet Contains: Clonazepam USP 2 mg
198.	Cefuroxime Axetil Tablets USP 500 mg	Sri Lanka	Each Film Coated Tablet Contains: Cefuroxime Axetil USP Eq. to Anhydrous Cefuroxime 500 mg Colour: Titanium Dioxide BP
199.	Cefuroxime Axetil Tablets USP 250 mg	Sri Lanka	Each Film Coated Tablet Contains: Cefuroxime Axetil USP Eq. to Anhydrous Cefuroxime 250 mg Colour: Titanium Dioxide BP
200.	Cefixime Dispersible Tablets 100 mg	Sri Lanka	Each Uncoated Dispersible Tablet Contains: Cefixime USP as Trihydrate Eq. to Anhydrous Cefixime 100 mg
201.	Cefixime Tablets USP 200 mg	Sri Lanka	Each Film Coated Tablet Contains: Cefixime USP as Trihydrate Eq. to Anhydrous Cefixime 200 mg Colour: Titanium Dioxide BP
202.	Folic Acid Tablets USP 5 mg	Sri Lanka	Each Uncoated Tablet Contains: Folic Acid USP 5 mg
203.	Albendazole Tablets	Sri Lanka	Each Uncoated Chewable Tablet Contains: Albendazole USP 400 mg Colour: Sunset Yellow FCF
204.	Cephalexin 250 USP (Universal)	Sri Lanka	Each hard gelatin capsule contains: Cephalexin USP Eq. to Anhydrous Cephalexin 250mg
205.	Cephalexin 500 USP (Universal)	Sri Lanka	Each hard gelatin capsule contains: Cephalexin USP Eq. to Anhydrous Cephalexin 500 mg
206.	Losartan Potassium USP 50 mg (Universal)	Sri Lanka	Each Film coated tablet contains: Losartan Potassium USP 50 mg Color: Quinoline Yellow & Brilliant Blue
207.	Losartan Potassium USP 25 mg (Universal)	Sri Lanka	Each Film coated tablet contains: Losartan Potassium USP 25 mg Color: Quinoline Yellow & Brilliant Blue
208.	Clopidogrel Bisulfate 75 (Universal)	Sri Lanka	Each film coated tablet contains: Clopidogrel Bisulfate Eq. to Clopidogrel 75 mg
209.	Amoxicillin Trihydrate BP 500 mg (Universal)	Sri Lanka	Each hard gelatin capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 500 mg
210.	Amoxicillin Trihydrate BP 250	Sri Lanka	Each hard gelatin capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 250

	mg (Universal)		mg
211.	Levocetirizine Dihydrochloride 5 mg (Universal)	Yemen	Each film coated tablet contains: Levocetirizine Dihydrochloride 5 mg
212.	Clopidogrel Bisulfate 150 (Universal)	Yemen	Each film coated tablet contains: Clopidogrel Bisulfate Eq. to Clopidogrel 150 mg
213.	Clopidogrel Bisulfate 75 (Universal)	Yemen	Each film coated tablet contains: Clopidogrel Bisulfate Eq. to Clopidogrel 75 mg
214.	Amlodipine + Atenolol (Universal)	Yemen	Each uncoated tablet contains: Amlodipine Besilate BP eq. to Amlodipine 5 mg Atenolol BP 50 mg Color: Sunset yellow
215.	Amoxicillin Trihydrate BP 500 mg (Universal)	Yemen	Each hard gelatin capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 500 mg
216.	Amoxicillin Trihydrate BP 250 mg (Universal)	Yemen	Each hard gelatin capsule contains: Amoxicillin Trihydrate BP Eq. to Amoxicillin 250 mg
217.	Ketorolac Tromethamine USP 10 mg	Vietnam	Each uncoated dispersible tablet contains: Ketorolac Tromethamine USP 10 mg
218.	Methylcobalamin 500 mcg	Vietnam	Each film coated tablet contains: Methylcobalamin 500 mcg
219.	Nitazoxanide Tablets 200 mg	Ukraine	Each film coated tablet contains:- Nitazoxanide 200 mg Colour: Quinoline Yellow

## **MANUFACTURING APPROVALS**

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### **WHO-GMP**

By World Health Organisation, Regional Office for South East Asia, New Delhi-110002, Central Drugs Standard Control Organisation, North Zone India and Directorate General of Medical Health Services, Uttranchal

### **ISO-9001: 2000**

By United Registrar of Systems Ltd. (URS) and Somerset UK B27 3AH with accreditation mark of UKAS

### **ISO 14001:2004**

By QMS Certification Pvt. Ltd., Bow 2006,Launceston,7250, Tasmania, Australia

### **MANUFACTURING RANGE - UNIT WISE PRODUCT RANGE**

<b>UNIT- I</b>	<b>UNIT- II</b>	<b>UNIT- III</b>
<b>Beta Lactum Section</b> Tablets Capsules Dry Syrups	<b>Liquid Orals</b>	<b>Dry Powder Injectable-</b> Vials / Bottles Cephalosporins Penicillins
<b>Non Beta Lactum Section</b> Tablets Capsules Dry Syrups Pouch Powders Soft Gelatin Capsule Amoxicillin + Calvulanic Acid Tablet		<b>Liquid Injectable-</b> Vials & Ampoules Pre Filled Syringes Medicinal Preparations Eye / Ear Drops  <b>Form, Fill &amp; Seal (FFS)-</b> Small Value Parentals (SVP)-up to 100 ml Large Value Parentals (LVP)- above 100 ml I.V. Fluids/Dextrose Eye / Ear Drops Water for Injectables Medicinal Preparations

## INSTALLED CAPACITY

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### Highly Sophisticated Manufacturing Facilities

1. Ultra-modern plant
2. Sophisticated Machinery
3. Captive Power Generation
4. Pollution control equipment
5. In house testing facilities
6. Instrumentation laboratory

### MANUFACTURING INFRASTRUCTURE

*Manufacturing Area is divided into ground floor, First Floor for Beta Lactam and Ground floor, first floor & second floor in Non-Betalactam*

#### Beta-Lactam

Section	Size in sq. meter
Tablets	252.04 m <sup>2</sup>
Capsules	108.84 m <sup>2</sup>
Dry Syrups	98.48 m <sup>2</sup>
Store (R.M.)	195.60 m <sup>2</sup>
Packaging Area	144.25 m <sup>2</sup>
Utility Block	178.00 m <sup>2</sup>
Service Floor	506.00 m <sup>2</sup> /em>
Corridor, Change-Room & Others	132.49 m <sup>2</sup>

#### Non Beta-Lactam

Floor / Description	Size in sq. meter
G.F: Production & Store	4122.00 m <sup>2</sup>
F.F. Pkg. & Store	3840.00 m <sup>2</sup>
Dry Syrups	S.F. Pkg. & Store
S.F. QC & QA	523.00 m <sup>2</sup>
Service Floor I	1141.00 m <sup>2</sup>
Service Floor II	617.00 m <sup>2</sup>
Soft Gelatin area	589 m <sup>2</sup>

#### General



Floor / Description	Size in sq. meter
S.F.Office & Administration	672.00 m <sup>2</sup>
Utilities & Misc.	300.00 m <sup>2</sup>
Canteen	188.00 m <sup>2</sup>
Rest House	252.00 m <sup>2</sup>

### **Building construction and its finish:**

The construction of the building ensures the protection from contamination, permits efficient cleaning, avoids accumulation of dust and dirt and prevents entry of insects, birds, rodents' etc. Flooring is done by Kota stone. The edge lines between floors and walls are made of smooth covings. Adequate slopes are provided towards drainage system. The walls & ceilings are plastered with cement and its finishing is with appropriate paint, so as to avoid dust and facilitate cleaning. Toilets do not communicate directly either with production or with storage area. The light fixtures, which are present, are suspended over the working area and they can be easily cleaned. There are minimum projections, shelves, cupboard, fixtures and fittings in manufacturing area, so as to avoid dust and facilitates cleaning. Cabin is provided for each and every machine to avoid contamination and mix-up and to maintain potential pressure in granulation, compression & quarantine area. Adequate space is provided for work in process. Flow of work is orderly and positioning of equipment and machine is logical so as to minimize the risk of contamination. Doors and windows are made of aluminum frames using pre-laminated boards and glasses or boards/ painted steel structure. All the doors have got hydraulic door closures to shut the doors immediately. Glass fixed in windows are smooth and free from uneven surfaces. Drains in the building are of adequate size and have trapped gullies. Where drains are connected directly to a sewer, there are air-break provided at the point to prevent back siphon.

### **Products and Production Capacities**

Pharmaceuticals Formulation	Installed Production Capacity per Annum (millions)
Tablets ( Lactum & Non Lactum )	12000
Capsules ( Lactum & Non Lactum)	2400
Dry Syrup(Cephalosporins & Ampicillins)	90
Liquid Orals (Syrups & Suspension )	45
Injectables ( Dry Powders )	120
Injectables ( Liquids-Ampoules & Vials )	210
Form Fill & Seal (FFS) Eye / Ear Drops	60
Form Fill & Seal (FFS) Pharmaceutical Injections & Water for Injection	12
Soft Gelatin capsules Vitamins & Other preparations	600
Ointments	60

## **PLANTS OVERVIEW**

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## **INFRASTRUCTURE / FACILITIES**

Sprawled over an area of about 500000 sq. ft., unit's independent State-of-the-art-manufacturing units have modern & sophisticated manufacturing facilities of international standards which include ultra-modern plant, machineries & equipments, in house testing facilities - instrumentation and microbiology laboratory.

It is India's largest single manufacturing unit having enormous capacity to manufacture 40 million tablets, 8 million Hard Gelatin capsules, 2.5 million soft Gelatin capsules, 0.5 million Dry Syrup, 0.5 million Liquid Orals, 0.5 million FFS Eye/Ear drops, 0.8 million Liquid Injections (amp/vials), .05 million Small Volume Parenterals.

Keeping up with the good manufacturing practices, Beta & Non Beta Lactum products are being manufactured in separate buildings. In Beta Lactum section there are isolated facilities for Cefalosporins & Penicillins.

It possess the highest number of manufacturing & packing machines in the country in any single unit including 42 pkg. lines, 5 Alu-Alu, 2 AF150, RMGs, 4 Fluid Bed Processors, Auto coaters, 2 FFS, 6 tunnels, Most Sophisticated Lab, 15 HPLCs, 2 FTIRs, GC, TOC, DG Sets 5000 KVA, Scada, Hot & Cold loop Water system, 180 AHUs., R&D and Microbiology.



### **Brief description of critical areas:**

**R.M. Store: The store is divided into different areas as follows**

1. Receiving Bay: This area is meant for unloading & preliminary inspection of the incoming material.
2. Sampling Unit & Dispensing Unit: These areas are developed for sampling for incoming raw material & for dispensing of raw material to the production areas. Each area has reverse laminar air flow having 5 micron filter at delivery point and a prefilter of 10 micron at the entry from where fresh air is drawn.
3. Under test raw material store: Developed to retain the received raw material till its analysis from Q.C. Department.
4. Approved R.M. Store: The area is meant for storage of approved R.M. after analysis by Q.C. It has one air conditioned sub store for storage of thermoliable items.
5. Rejected R.M. Store: A separate area for the raw material found rejected by Q.C. as per the laid down specification is developed for storage and further preceding there after.

#### **Carton /Lable Store:**

The area is meant for the storage of packing material only. This has been provided with racks for proper storage. The labels storage area is provided with separate lock & key arrangements.

#### **Finished Goods Store:**

Sufficient area for storage of finished goods has been provided. Air conditioned area is also there for storing goods under controlled environment.

#### **Production Area:**

It consists of Tablets, Capsule, Dry Powder, Liquid Orals & Packaging areas. Manufacturing area are provided with separate AHU's to minimize the chances of contamination. Dehumidifiers are also provided wherever required.

Packing area is divided into strip, blister and loose packing areas. Separate AHU's are provided for each strip/blister Machine to maintain temperature & humidity for the product & to reduce the chances of contamination.

Finished goods quarantine is also provided from where material is transferred to finished goods after approval by Q.A.

#### **Q.C. Department:**

It is the heart of the whole plant. It is divided into different sections as:

1. Chemical Section
2. Instrument Section
3. Microbiological Section
4. A library & chemist room for recording the data

**Utility Block:**

**The block comprises of following:**

<b>U-I</b>	<b>U-II</b>	<b>U-III</b>
D.G. sets	Purified water generation plant	Air compressors with drier
Boiler		
Workshop Area		
Control Panels		

## **R & D and F & D**

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### **Brief description of major equipment used in production and quality control laboratories**

#### **Equipments (Production):**

Standard quality equipments are used in production area with all contact parts made of stainless steel 316, stainless steel 304 or Teflon. Other parts are made of S.S. or M.S. All the equipments are duly painted. Oil seals bearings etc. are arranged in such a manner to avoid of contamination of lubricants. Lids, closures and /or rubber packing are provided to avoid any contamination. All machines are of GMP model. All equipments are so designed that they can be easily cleaned. Generally automated machine are used to avoid human contamination

#### **Equipments (Quality Control Laboratories )**

Good quality instruments are provided in the quality control laboratory. All equipments are well calibrated and are of standard make only and conforms to be IP/USP standards.

The sophisticated equipments like ultraviolet and visible spectrophotometer ,FTIR spectrophotometer, and HPLC with latest computer programme are installed in separate AC room.

Other instruments are there, for accurate analysis of products like digital analytical balance (with printer), polarimeter, potentiometric titrator, karl Fischer apparatus, dissolution test apparatus, ultrasonic bath, humidity chamber etc.

Microbiology lab is good, well equipped and good designed to perform related tests. It have preparation room, sterile area with air lock, pass box adjoining to autoclave with oven, BOD incubator and laminar air flow.

Microbiology lab has separate AHU. Sterile room, laminar air flow and autoclave has been validated at scheduled timings.

#### **Description of planned preventive maintenance programs for equipment and of the recording system.**

Plant and maintenance head is responsible for maintenance and servicing. A written schedule for preventive maintenance programmes for manufacturing area equipments is made.

Frequency of preventive maintenance depends on the frequency of use & type of equipment for individual equipment.

Preventive maintenance is carried out as per written SOPs for preventive maintenance for each machine.

Each person has been trained and have knowledge of what affects the quality of products.

Preventive maintenance for Quality Control equipment is done at the time of their calibration.

#### **Recording System**

Preventive Maintenance register contains separate account for each and every equipment in which the proceeding done by maintenance department either on account of preventive maintenance or on account of any kind of breakdown is recorded.

Qualification and calibration, including the recording systems and arrangements for computerized systems validation. Validation is a necessary requirement of the Current Good Manufacturing Practice Regulations and therefore, is applicable to the manufacture of Pharmaceutical Products. For the same we believe in using validated systems and procedures employed in manufacturing and testing of pharmaceutical products.

**The validation Plan includes:**

1. The equipment, system, method and process, which shall be validated.
2. The formats required for validation i.e. for D.Q., I.Q., O.Q., P.Q., Process Validation, cleaning Validation and Analytical Validation.
3. When and why revalidation will be performed.
4. The guidelines for each type of validation i.e. process, equipment, cleaning and analytical validation.

**QUALIFICATION OF EQUIPMENT:**

**All the equipment prior to their installation are checked for the qualification for their Design, Installation, Operation and Performance.**

1. **Design Qualification : (DQ)**  
The design of equipment suits to the requirements of The company.
2. **Installation Qualification :(IQ)**  
Proper environment, suitable utilities, place and Other requirements to be fulfilled prior to its installation.
3. **Operation Qualification : (OQ)**  
When the equipment will be in operation. It will fulfill the requirement.
4. **Performance Qualification (PQ)**  
Will the equipment perform as per the requirement.

**Prospective Process Validation:**

Validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may affect the product's characteristics.

**Retrospective Process Validation :**

Validation of a process for a product already in distribution based upon accumulated production, testing and control data.

**Analytical Method Validation :**

Analytical method has been validated before taking it in use.

**Cleaning Validation :**

Cleaning procedure of critical equipments has been validated to ensure the performance of method use. Additional tests as rinse water analysis and swab test is also being done regularly.

**Validation team governs all the activities of validations Which consists of :**

1. Director
2. Q. A. Manager
3. Q. C. Manager
4. Production Head
5. Analytical Chemist
6. Executive, Regulatory Affairs
7. Engineering Head

**Functions of validation team :**

1. Creates, updates, and reviews/ approves individual project validation plans and validation deliverables
2. Ensures validation compliance with the company validation master plan.
3. Coordinates, implements, verifies elements of the VMP
4. Consults on, evaluates and approves changes
5. Reviews and approves IQ/OQ/PQ procedures and plans
6. Reviews test results and makes recommendations regarding release
7. Assess risks and develops contingency plan

## **CONTRACT TESTING FACILITIES**

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### **QC Laboratories are equipped with 21 CFR compliant equipments.**

- Following Major QC Equipments are available for performing Analytical Testing:
  - Automatic High Performance Liquid Chromatograph -2010 CHT
  - Automatic High Performance Liquid Chromatograph - 2010 AHT
  - Automatic High Performance Liquid Chromatograph -2010 AHT with PDA Detector
  - Automatic High Performance Liquid Chromatograph -2010 AHT with RI Detector
  - UV Visible Spectrophotometer
  - Gas Liquid Chromatograph Head Space (Auto sampler 16 Head) (GC- Head space)
  - Total Organic Carbon Detection Apparatus (TOC) (Auto sampler with 8 Head Sampling Unit)
  - Fourier Transform Infra Red Spectrophotometer (FTIR)
  - Karl Fischer Water Determination Apparatus
  - Automatic Potentiometric Titrator
  - Refractometer
  - Liquid Particle Counting (LPC) System

and other major and minor analytical instruments.



## **STABILITY TESTING FACILITIES**

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It offers stability testing services to evaluate Drug Product and Drug Substance Stability in accordance with ICH Q1A guidelines.

To support these activities, It offers full Analytical Method Development and Qualification, Validated Stability Chambers at all storage conditions, and a Laboratory Information Management System (LIMS) for complete sample and Document Management.

### **Stability Capabilities:**

- ICH Compliant Protocols
- Centralized LIMS for Sample Tracking
- Analytical Method Development
- Long-term Stability Studies
- Accelerated Stability Studies

### **Stability Testing Methods:**

- Potency
- pH and Appearance
- HPLC
- UV
- Sterility
- Endotoxin

### **Storage Conditions:**

- 5°C ± 3°C
- 25°C ± 2°C with 60% RH ± 5% RH
- 30°C ± 2°C with 65% RH ± 5% RH
- 40°C ± 2°C with 75% RH ± 5% RH

## **ANALYTICAL TESTING & DEVELOPMENT**

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It provides analytical support to comply with all GMP & Regulatory requirements.

New analytical methods development and transfer to the customer's site

### **Method Validation**

- Pre validation study
- Preparation of validation protocol
- Conducting Validation Study as per Protocol
- Validation Report
  
- Conducted as per ICH guidelines Q2B

### **Parameters for method validation:**

- Specificity
- Linearity
- Accuracy
- Precision
- Limit of detection
- Limit of Quantification
- Robustness
- Ruggedness
  
- Solution stability.

Pharmacopeial methods verification

Analytical method validations using diversified instrumentation and traditional wet chemistry techniques based on ICH requirements

Pharmaceutical services with reference to Pharmacopeias for Raw Materials, Intermediates and Finished Products for release testing.

Stability studies at various temperature stations according to ICH guidelines.

Isolation and characterization of impurities, report generation and qualification, and inclusion into specifications

Dosage forms: dissolution, tablet hardness, thickness, disintegration and friability, and uniformity of content

Testing of drug substances and drug products for light sensitivity, including and excluding packaging material.

Reference material and standards: controlling and supplying reference materials including securing reference standard, testing and certification and then shipping to facilities requiring reference materials

Design, implement and validate cleaning procedures for processes that are compliant with current regulations

Primary container/packaging compatibility studies for various dosage forms, packaging development for drug substance and drug product

## **MICROBIOLOGY**

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It is competent in performing advanced tests and analysis for pathogen testing (Aerobic Plate Count and Anaerobic Plate Count), routine quality control, minimum inhibitory concentration and water activity.

### **Quality Control Laboratories are equipped to perform following testings:**

- Sterility
- Bacterial Endotoxin (BET) Test
- Microbial Limit Test
- Passive Air Sampling (Settle Plate).
- Active Air Sampling
- Air Borne Non Viable Particle count
- Microbiological Swab of walls, Floors and Machine
- Personal Monitoring of all persons involved in Production Activity.
- Water Testing

## PHOTO GALLERY

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### PLANT 1









## PLANT 2







## PLANT 3







