JUBILANT PHARMA

# SOLID DOSAGE FORMULATIONS

Jubilant Generics, is one of the business arms of Jubilant Pharma Group, catering to Dosage Formulations (DF) & Active Pharmaceutical Ingredients (API) business segment across developed & emerging markets.

The primary focus of the Jubilant Generics is development, manufacture and sale of proprietary Dosage Formulations & APIs for Cardiovascular system, Central Nervous system, Metabolism, Anti-infective and Anti-allergy therapy areas.

Jubilant Generic's business is **backward integrated with API business** and therefore well placed to strive for Cost leadership and high Customer satisfaction.

## KEY HIGHLIGHTS

### Manufacturing strengths

We have two manufacturing facilities catering to our Dosage Formulations business

1. Roorkee, Uttarakhand, India

   The manufacturing plant is approved by US FDA, Japanese PMDA, UKMHRA, Brazil ANVISA and by many other leading regulatory agencies of the world

2. Salisbury, Maryland, USA

   The manufacturing plant is approved by US FDA

### Research & Development

We have state of the art in-house R&D facility to develop diversified Dosage Formulations ranging from oral solids, liquids, Injectables to ophthalmics and semi-solids.

Apart from regular "me too" vanilla Gx, we also develop technology platform based Novel Drug Delivery System products such as taste masking, flash tablets, oral dispersible forms, chewable tablets and modified release forms.

### Strong regulatory team

We have a strong regulatory team as part of R&D who have successfully filed

- 85 filed ANDAs in US
- 40 dossiers in Europe
- 22 filings in Canada
- Over 650 filings in ROW countries across the world

### Bio-Equivalence Centre

We have state of the art in-house FDA audited Bio-Equivalence Centre for carrying BE studies on Proprietary Dosage formulations developed by us.

### Business Reach

We are present across developed & emerging markets of the world. Currently more than 50 proprietary products are commercialized by us in several developed and emerging markets including United States, Canada, Europe and Japan.

**United States:** We are leaders in Methylprednisolone, Prochlorperazine and Terazosin caps and amongst leading players in Meclizine, Lamotrigine, Cyclobenzaprine, HCTZ, Donepezil and Prednisone.

**Europe:** Our strength lies in formulation development, regulatory services and licensing of marketing authorizations in addition to supplies of Dosage Formulations to leading generic companies in Europe.

**Japan:** We are one of the largest exporters of Oral Solid Formulations to Japan and have multiple business alliances with leading local and global players.

**Emerging Markets:** We have a strong foothold in fast growing emerging markets supported with rapidly expanding Product Portfolio & Strategic business alliances with leading local players across APAC, LATAM, AFRICA & CIS markets.

## DOSSIER READILY AVAILABLE

| | Molecule | Strength (mg) | Dosage Form | Reference Product | Originator | Therapeutic Class |
|---|---|---|---|---|---|---|
| CV | Acetazolamide | 125 /250 | FC Tablets | Diamox | Teva | Diuretic |
| CV | Amantadine | 100 | FC Tablets | Symmetrel | Endo | Anti-parkinsonism |
| CV | Amlodipine | 5/10 | FC Tablets | Norvasc | Pfizer | Anti-hypertensive |
| CV | Amlodipine Olmesartan + | 5 + 20 , 5 + 40 , 10 + 20 , 10 + 40 | FC Tablets | Azor | Daiichi Sankyo | Anti-hypertensive |
| CV | Bupropion SR | 100/150/200 | SR Tablets | Wellbutrin SR | GSK | Anti-depressant |
| CV | Bupropion SR | 150 | SR Tablets | Zyban | GSK | Smoking -Cessation |
| CV | Candesartan | 4/8/16/32 | FC Tablets | Atacand | Astra Zeneca | Anti-hypertensive |
| CV | Candesarntan + HCTZ | 16+12.5<br>32+ 12.5<br>32+25 | FC Tablets | Atacand-HCT | Astra Zenecea | Anti-hypertensive |
| CV | Felodipine ER tab | 2.5/5/10mg | ER Tablet | Plendil | Astra Zeneca | Anti-hypertensive |
| CV | Irbesartan | 75/150/300 | FC Tablets | Avapro | Sanofi Aventis | Anti-hypertensive |
| CV | Irbesartan + HCTZ | 150+12.5/300 + 12.5/300+25 | FC Tablets | Avalide | Sanofi Aventis | Anti-hypertensive |
| CV | Lisinopril | 0.25/5/10/20/40 | FC Tablets | Zestril | Merck | Anti-hypertensive |
| CV | Losartan | 25/50/100 | FC Tablets | Cozaar | Merck | Anti-hypertensive |
| CV | Losartan + HCTZ | 50+12.5 /100+25 | FC Tablets | Hyzaar | Merck | Anti-hypertensive |
| CV | Metoprolol Succinate | 25/50 /100 /200 | ER Tablet | Toprol XL | Astra Zeneca | Anti-Angina |
| CV | Niacin ER | 500/750/1000 | ER Tablet | Niaspan | AbbVie | Anti-hyperlipidemic |
| CV | Olmesartan | 10/20/40 | FC Tablets | Benicar | Daichii Sankyo | Anti-hypertensive |
| CV | Olmesartan + HCTZ | 20+12.5/20+25 | FC Tablets | Benicar - HCTZ | Daichii Sankyo | Anti-hypertensive |
| CV | Rosuvastatin | 5/10/20/40 | FC Tablets | Crestor | IPR | Anti-hyperlipidemic |
| CV | Simvastatin | 10/20/40 | FC Tablets | Zocor | Merck | Anti-hyperlipidemic |
| CV | Telmisartan | 20/40/80 | FC Tablets | Micardis | Boehringer Ingelheim | Anti- hypertensive |
| CV | Telmisartan + HCTZ | 40+12.5/ 80+ 12.5/80+ 25 | FC Tablets | Micardis HCTZ | Boehringer Ingelheim | Anti-hypertensive |
| CV | Valsartan | 40/80/160 | Capsules | Diovan | Novartis | Anti-hypertensive |
| CV | Valsartan | 40/80/160/320 | FC Tablets | Diovan | Novartis | Anti-hypertensive |
| CV | Valsartan + HCTZ | 160+12.5/320 + 12.5 /160+ 25/300+25 | FC Tablets | Diovan HCT | Novartis | Anti-hypertensive |
| CNS | Bupropion XL | 150/300 | ER Tablets | Wellbutrin XL | Valeant | Anti-depressant |
| CNS | Citalopram | 10/20/40 | FC Tablets | Celexa | Forest Labs | Anti-depressant |
| CNS | Clonidine | 0.1 | ER Tablet | Kapvay | Forest Labs | Anti-depressant |
| CNS | Donepezil | 5/10 | FC Tablets | Aricept | Pfizer | Anti-alzheimer |
| CNS | Donepezil ODT | 5/10 | Orally Disint.Tab | Aricept odt | Eisai inc | Anti-alzheimer |
| CNS | Escitalopram | 5/10/15/20 | FC Tablets | Lexapro | Forest Labs | Anti-depressant |
| CNS | Fluoxetine | 10/20 | FC Tablets | Prozac | Eli Lilly | Anti-depressant |
| CNS | Lamotrigine | 25/50/100/200 | FC Tablets | Lamictal | GSK | Anti-epileptic |
| CNS | Lamotrigine MR | 25/50/100/150/ 200/250/300 | ER Tablets | Lamictal xr | GSK | Anti-depressant |

## DOSSIER READILY AVAILABLE

| | Molecule | Strength (mg) | Dosage Form | Reference Product | Originator | Therapeutic Class |
|---|---|---|---|---|---|---|
| CNS | Levetiracetam | 250/500/750/1000 | FC Tablets | Keppra | UCB | Anti-epileptic |
| | Levetiracetam | 500 mg/5ml | Injectable | Keppra | UCB | Anti-epileptic |
| | Lurasidone | 20 /40 /60/ 80/ 120 | FC Tablets | Latuda | Sunovion | Anti-psychotic |
| | Memantine | 5/10 | FC Tablets | Namenda | Forest Labs | Anti-Alzheimer |
| | Olanzapine IR | 2.5/5/7.5/10/15/20 | FC Tablets | Zyprexa | Eli Lily | Anti-psychotic |
| | Olanzapine OD | 5/10/15/20 | Orally Disint.Tab | Zyprexa | Eli Lily | Anti-psychotic |
| | Oxcarbazepine | 150/300/600 | FC Tablets | Trileptal | Novartis | Anti-epileptic |
| | Paroxetine | 10/20/30/40 | FC Tablets | Paxil | Apotex | Anti-depressant |
| | Pregabalin | 25/50/75/100/150/ 200/225/300 | Capsule | Lyrica | Pfizer | Management of Neuropathic pain |
| | Quetiapine fumarate | 25/100/200/300 | FC Tablets | Seroquel | Astra Zeneca | Anti-psychotic |
| | Quetiapine SR | 50/150/200/300/400 | ER Tablet | Seroquel XR | Astra Zeneca | Anti-psychotic |
| | Risperidone | 0.25/0.5/1/2/3/4 | FC Tablets | Risperdal | Janssen | Anti-psychotic |
| | Risperidone OD | 0.5/1/2/3/4 | Orally Disint.Tab | Risperdal | Janssen | Anti-psychotic |
| | Rizatriptan | 5/10 | FC Tablets | Maxalt | Merck | Anti-migraine |
| | Rizatriptan OD | 5/10 | Orally Disint.Tab | Maxalt Mlt | Merck | Anti-migraine |
| | Ropinirole | 0.25/0.5/1/2/5 | FC Tablets | Requip | GSK | Anti-parkinsonism |
| | Zolmitriptan | 2.5 /5 | FC Tablets | Zomig | Astra Zeneca | Anti-migraine |
| | Zolmitriptan OD | 2.5 /5 | OD Tablets | Zomig ZMT | Astra Zeneca | Anti-migraine |
| | Ziprasidone | 20/40/60/80 | Capsules | Geodon | Pfizer | Anti-psychotic |
| | Zopiclone | 3.75/7.5 | FC Tablets | Zimovane | Sanofi | Hypnotic & Sedative |
| AI | Azithromycin dihydrate | 250/500 | FC Tablets | Zithromax | Pfizer | Anti-bacterial |
| | Itraconazole | 100 | Capsules | Sporanox | Janssen Pharma | Anti-fungal |
| | Levofloxacin | 250/500 | FC Tablets | Levoquin | Janssen | Anti-bacterial |
| | Valacyclovir | 500/1000 | FC Tablets | Valtrex | GSK | Anti-viral |
| GI | Esomeprazole GR | 20/40 | GR Tablets | Nexium | Astra Zeneca | Anti-ulcerant |
| | Pantoprazole GR | 20/40 | GR Tablets | Protonix | Pfizer | Anti-ulcerant |
| | Rabeprazole DR | 20 | DR Tablets | Aciphex | Eisai Inc | Anti-ulcerant |
| Others | Alendronate | 5/10/35/70 | FC Tablets | Fosamax | Merck | Anti-osteoporotic |
| | Celecoxib | 50 /100 /200 /400 | Capsules | Celebrex | GD Searle | NSAID |
| | Cetirizine | 5/10 | FC Tablets | Zyrtec | UCB | Anti-allergic |
| | Cetirizine Chew | 5/10 | Chewable Tablets | Zyrtec | UCB | Anti-allergic |
| | Cinacalcet | 30/60/90 | FC Tablets | Sensipar | Amgen | Drug for hyperparathyroidism |
| | Darifenacin | 7.5/15 | ER Tablets | Enablex | Warner Chilcott | Anti-spasmodic |
| | Indomethacin | 25/50 | Capsules | Gx - RLD (US) | Sandoz | NSAID |
| | Indomethacin ER | 75 | ER Capsules | Gx - RLD (US) | Mylan | NSAID |
| | Montelukast | 5/10 | FC Tablets | Singulair | Merck | Anti-asthmatic |
| | Montelukast Chew | 4/5 | Chewable Tablets | Singulair | Merck | Anti-asthmatic |
| | Olopatadine | 0.10% | Ophthalmic Solution | Patanol | Alcon | Anti histaminic |
| | Repaglinide | 0.5/1/2 | FC Tablets | Paradin | Novo - Nordisk | Anti-diabetic |

## DOSSIER READILY AVAILABLE

| | Molecule | Strength (mg) | Dosage Form | Reference Product | Originator | Therapeutic Class |
|---|---|---|---|---|---|---|
| Others | Risedronate sodium | 5/30/35/75/150 | FC Tablets | Actenol | P & G | Anti-osteoporotic |
| | Sildenafil | 20 | FC Tablets | Revatio | Pfizer | Drug for PAH |
| | Sildenafil Citrate | 25/50/100 | FC Tablets | Viagra | Pfizer | Drug for Erectile Dysfunction |
| | Solifenacin | 5/10 | FC Tablets | Vesicare | Astellas | Anti-spasmodic |
| | Spironolactone | 25/50/100 | FC Tablets | Aldactone | GD Searle | Diuretic |
| | Tizanidine | 2/4/6 | Capsule | Zanaflex | Acorda | Muscle relaxant |
| | Tadalafil | 2.5/ 5/ 10/ 20 | FC Tablets | Cialis | Eli lilly | Drug for ED |
| | Tadalafil | 20 | FC Tablets | Adcirca | Eli lilly | Drug for PAH |

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Jubilant Pharma is a Partner of Choice for R&D, manufacture and supply of Generics - Dosage Formulations and APIs, Specialty Pharmaceuticals - Radiopharmaceuticals, Allergy Therapy Products and Contract Manufacturing of Sterile Injectables. We have Business partnerships in over 65 countries.

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