



SPAL

SP ACCURE LABS

*Touching Lives Globally®*

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EQUIPPED TO SAVE  
INVALUABLE LIFE

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## SP Accure Labs Pvt Ltd

### At a Glance

SP Accure Labs Pvt. Ltd. (SPAL) is a fully integrated quality led pharmaceutical company, making high quality medicines accessible to patients worldwide with core competencies in Oncology. Our Journey started in 2010 with a commitment to create a better quality of life by being at the forefront of Research, Manufacturing and Marketing high quality specialty formulations. We are geared to support the community of Oncologists with our novel drugs, diverse portfolio, state-of-the-art facility, team of dedicated professionals, and our worldwide network and presence. Thus, we are fully prepared to offer the best options to Oncologists and their patients.

## The Reference of Oncology Generics



### Our Strengths

1. Strong Biologics & Cytotoxic infrastructure to address Oncology market around the Globe
2. Robust portfolio of targeted therapies, cytotoxics, anti-hormonals and supportive care
3. Capability to swiftly register & launch new products globally
4. Dedicated Oncology team
5. Established capabilities in chemistry and biology enabling strong Intellectual Property positions
6. Low cost development and manufacturing operations

As we embark on our journey, at SP Accure Labs Pvt. Ltd., we are all set to break new grounds, explore new frontiers and deliver wellness. We will keep growing, meeting challenges head on, harnessing and leading change, consolidating on our competencies, far in to the future.



Better  
**Health  
Worldwide**

**Vision**

We aspire to be a specialty pharmaceutical company where the quality is deliverable, formulations are innovative, and products are affordable, with a reach transcending all boundaries.



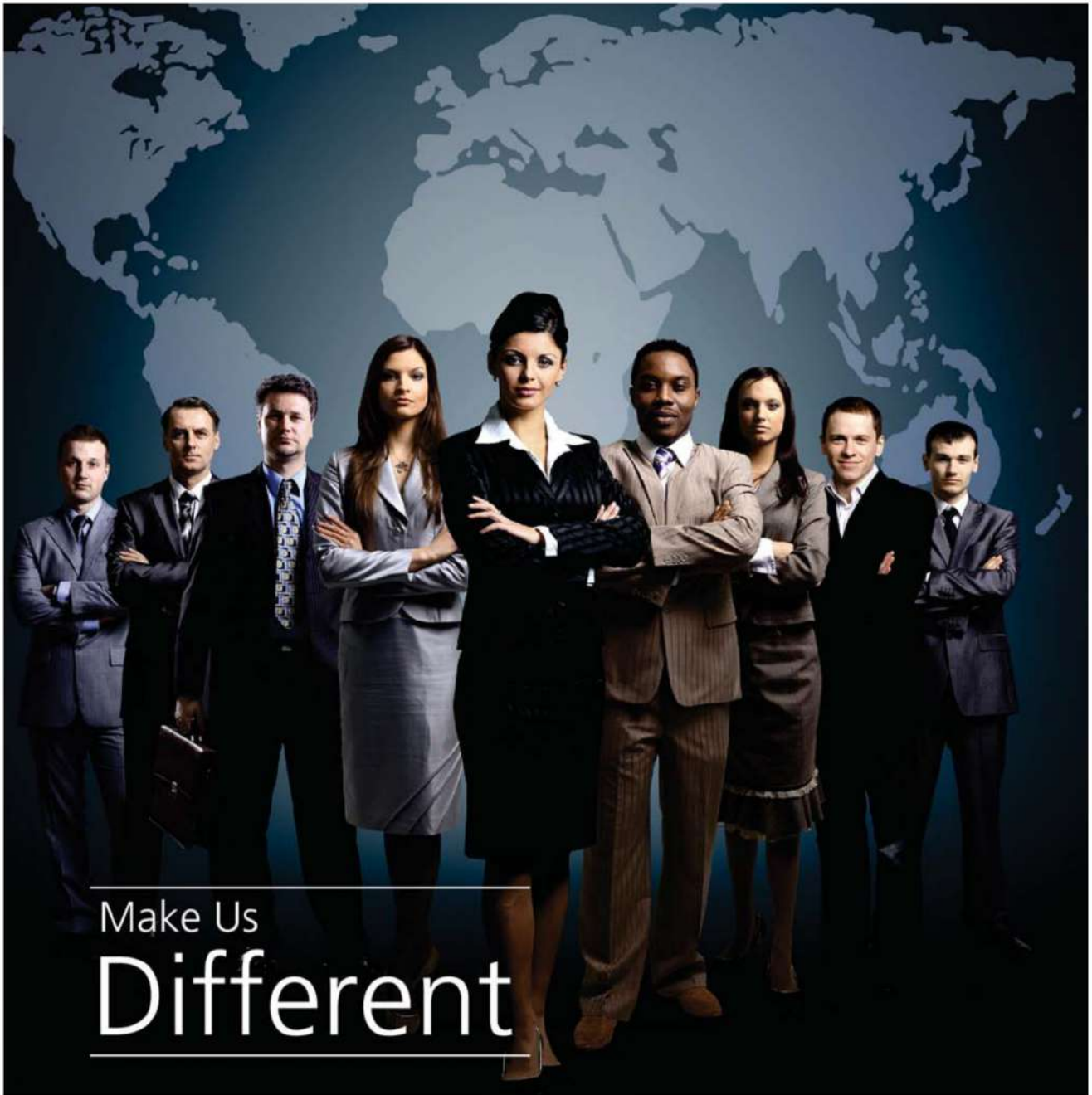
**Mission**

We strive to be a world class specialty pharmaceutical organization at the forefront of Research, Manufacturing and Marketing of high quality formulations, committed to create better quality of life. We believe quality creates trust. We also believe beyond that quality creates difference.

**Values**

The **Core Values** that  
Define our **Foundation**

1. Commitment
2. Integrity
3. Performance focus
4. Customer Responsiveness
5. Entrepreneurial drive
6. Team Work
7. Respect for Individuals
8. Social Responsibility



## Make Us Different

### Our People

If we are proud to an extent with our activities and quality, it is our associates making all the difference. Our team consists of highly qualified profiles in the pharmaceutical industry. Their professional approach is matched by their personal commitment. The products and services they deliver and the respect of the medical community they have earned vouch for their dedication to improved cancer care.

Thanks to the commitment of our associates that SP Accure Labs Pvt. Ltd will account to the company's standing as one of the most trusted names in Oncology.

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## Ensuring Your Heath

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## Corporate Social Responsibility

At SP Accure Labs, we help people lead healthier lives. We recognize the importance and impact our Oncology products can have on people's lives. We intend to create a healthy and happy society by improving the quality of life and longevity of individuals. In line with our vision, we seek to increase access to medicines and raise disease awareness in society.

Our initiatives are primarily focused on creating awareness on cancer, life style diseases and caring for the underprivileged. Our cancer detection camps and goodwill gestures at orphanages & pediatric cancer ward are amongst the few initiatives underway.





Quest for more  
**Efficacious**  
and affordable  
**Therapy**

## Quality Policy

Our continuous upgradation in technologies and quality management systems guarantees that our product meets most stringent international standards of quality, safety and efficacy.

To ensure Quality, Safety & Efficacy of the products, SP Accure Labs is committed towards manufacturing and marketing of pharmaceutical products that meet the customer and regulatory requirements, for which we follow:

- Integrated Approach towards Quality Control, Quality Assurance, Manufacturing & Regulatory Affairs.
- Robust Quality Management Systems (QMS) with core standard operating procedures.
- State-of-the-art analytical instrumentation, Quality Control and Quality Assurance systems at each level to ensure best quality products.
- Compliance with global quality standards of cGMP.

## Regulatory Affairs

- Dedicated regulatory affairs team for each region to keep track of ever changing legislations.
- Do It Right First Time (DRIFT) approach of our regulatory affairs plays crucial role in meeting the regulatory demands of various regions and maximizing the cost-effective use of resources.
- Our regulatory affairs department is capable of all types of regulatory submissions (ANDA/CTD/eCTD) from semi regulated to high-regulated markets ensuring fast turnaround in business.

# Expect Excellence

## Manufacturing Prowess

Our production plant is strategically located in the biotech park at Hyderabad, India possessing a phenomenal infrastructure facility. The technology used in the plant is actually commendable and the research and development center has all the facilities that are required to come out with world class, safe and reliable pharmaceutical products. Our facility is built on platform to clear and get approvals from major regulatory agencies around the globe like USFDA, MHRA and any PICs agency. Our facility is totally a containment facility complying with cGMP guidelines which can manufacture the following:

- Cytotoxic & anti-hormonal manufacturing oral solid dosage (tablets & capsules)
- Sterile Products (liquid and lyophilized vials)

We have a separate R&D Block for new upcoming products and existing products development. At SPAL, we have expertise in all phases of product life cycle. We can assist our partners providing the following services:

- Dosage form development
- Analytical Services
- Manufacturing for clinical trial and commercial productions
- Documentation Services





# Driving Value through Collaboration

## Partnership for Synergies

We, at SP Accure Labs, possess the management resources to exploit and interpret the best international technology to specific markets and needs. We not only believe but value lifelong partnerships. It is the underlying philosophy of SP Accure Labs that all progressive business models are based on the foundation of relationships.

SP Accure will be leveraging its production and Research & development competency for supplying affordable quality pharmaceuticals across the globe. To make a holistic impact on the health of patients worldwide we work with partners across the healthcare value chain.

SP Accure Labs aims, in all its endeavours, to win customers through its quality pharmaceutical products and wish to join hands for the following:

### 1. Marketing and Distribution Alliance

- a. Collaborating with organizations with local expertise in marketing & logistics, to complement them with our Manufacturing & Technical capabilities resulting into synergistic relationship.
- b. Providing our business partners with the option of Co-Marketing.

### 2. Contract Manufacturing

- a. Harnessing our Manufacturing Facilities, approvable by renowned International Regulatory Authorities.
- b. Value Additions
  - i. Product modification/up-gradation
  - ii. Development of additional dosage forms
  - iii. Extension into other strengths
  - iv. Packaging modification
  - v. Custom designed packaging
  - vi. Dossier Standardization



### 3. Supply Arrangement

- a. Entering into Supply Agreements with the distinguished Marketing & Distribution companies
- b. Providing our Partners with the options of Finished product in the retail pack as per their requirement or in the bulk pack to be repackaged in their respective facilities based on their local requirements.

### 4. Technology Transfer

- a. Enabling rapid entry into the regulated markets by transferring Technology to our partners.

### 5. Licensing Out /In

- a. SP Accure Labs offers the possibility to sell future rights for commercialization of its products under development to those companies willing to collaborate in the specialty pharmaceuticals/ registration with us at the current stage of every project, allowing us to accelerate the development

- process or to reach major markets in the world.
- b. SP Accure Labs is looking for interesting opportunities that can be complementary to our own products in the field of oncology.

### 6. Contract Research and Development

- a. We command comprehensive Research and Development facility with expertise in Novel Drug Delivery Systems, to assist global pharmaceutical companies from conceptualization of product till the dossier development thereby offering the possibilities of:
  - i. Collaborative R & D.
  - ii. Developing patentable non infringing processes and Innovative Technologies.





# Discovering Hope Names

## Our Products

Our attempt is to create a rich pipeline of oncology products that assures consistency in quality, affordability, and availability to all sections of society. We believe that every human deserves a chance at life. Our Oncology pipeline holds great hope for the future.

We are preparing ourselves a range of Products going off patent in the next 7 years which are under various stages of development with DMF available through strategic tie-ups. We aspire that we will be trusted for our products & commitment and seek more partnerships.

## Our Oncology Pipeline Contains:

Cytotoxic Drugs

Targeted Therapies

Anti-Hormonal Therapies

Supportive Care



# CRAFTING OUR FOOTPRINTS

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## To Begin a Relationship

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**Office:** F-2, City Home residency, Road no. 3, Kamala Nagar, Dilshuknagar, Hyderabad, Telangana State, Pin:500060, India

**Factory:** Plot No. 12, Biotech Park Phase II, Lalgadi Malakpet, Shameerpet, Ranga Reddy District, Hyderabad, Telangana State

For more information:

Visit us: [www.spaccurelabs.com](http://www.spaccurelabs.com)

Call: +91 40 42604191

Email: [contact@spaccurelabs.com](mailto:contact@spaccurelabs.com)



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Touching Lives Globally™

## TO BEGIN A RELATIONSHIP

### **SP ACCURE LABS PVT. LTD.**

**Office:** 504, 5th Floor, Kubera Towers, Narayanaguda,  
Hyderabad-500029, Telangana, India.

**Factory:** Plot No.12, Biotech Park, Phase II, Lalgadi Malakpet (V), Shamirpet (M),  
Medchal - Malkajgiri District, Hyderabad, Telangana State - 500 101, INDIA.

**For more information:**

Visit us: [www.spaccurelabs.com](http://www.spaccurelabs.com)

Call: +91 08418663201

Email: [contact@spaccurelabs.com](mailto:contact@spaccurelabs.com)



**SP ACCURE LABS**  
Touching Lives Globally™

## The Reference of Oncology Generics

### INJECTABLES



### SOLID ORALS



## PRODUCT PORTFOLIO

## LIST OF INJECTABLE PRODUCTS

1. Amifostine for Injection 500 mg
2. Azacitidine for Injection 100 mg
3. Bendamustine for Injection 25 mg and 100 mg
4. Bleomycin for Injection 15 Units and 30 Units
5. Bortezomib for Injection 1 mg, 2 mg, 2.5 mg and 3.5 mg
6. Busulfan Injection 60 mg/10 mL
7. Carmustine for Injection 100 mg (Combipack)
8. Cabazitaxel Injection 60 mg/1.5 mL (Combipack)
9. Carfilzomib for Injection 60 mg
10. Carboplatin Injection 60 mg/5 mL, 150 mg/15 mL, 450 mg/45 mL and 600 mg/60 mL
11. Cisplatin Injection 10 mg/10 mL, 20 mg/20 mL, 50 mg/50 mL and 100 mg/100 mL
12. Cladribine Injection 10 mg/10 mL
13. Cytarabine Injection 100 mg/1 mL, 500 mg/5 mL, 1000 mg/10 mL and 2000 mg/20 mL
14. Cyclophosphamide for Injection 200 mg, 500 mg, 1 g and 2 g
15. Dacarbazine Injection 100 mg, 200 mg, 500 mg and 1000 mg
16. Daunorubicin for Injection 20 mg
17. Decitabine for Injection 50 mg
18. Docetaxel Injection 20 mg/0.5 mL, 80 mg/2 mL, 120 mg/3 mL (Combipack)
19. Docetaxel Injection 20 mg/1 mL, 80 mg/4 mL, 120 mg/6 mL
20. Doxorubicin HCl Injection 10 mg/5 mL, 50 mg/25 mL
21. Doxorubicin Polyglutyl Liposomal Injection 20 mg/10 mL, 50 mg/25 mL
22. Dactinomycin Injection 0.5 mg
23. Etoposide Injection 100mg/5mL, 250mg/12.5mL, 500mg/25mL and 1g/50mL
24. Epirubicin Injection 10 mg/5 mL, 50 mg/25 mL
25. Eribulin Mesylate Injection 0.88 mg/2 mL
26. Fludarabine Phosphate for Injection 50 mg
27. Fludarabine Phosphate Injection 50 mg/2 mL
28. Flouxuracil Injection 250 mg/5 mL, 500 mg/10 mL and 1000 mg/20 mL
29. Fulvestrant Injection 250 mg/5 mL
30. Gemcitabine for Injection 200mg, 1 g, 1.4 g, and 2 g
31. Ifosfamide for Injection 1000 mg and 2000 mg
32. Irinotecan Injection 40 mg/2 mL, 100 mg/5 mL, 300 mg/15 mL and 500 mg/30 mL
33. Irinotecan Injection 43 mg/10 mL
34. Idarubicin Injection 20 mg/20 mL
35. L-Asparaginase Injection 5000 IU and 10000 IU
36. Leuprolide Acetate Depot Injection 3.75 mg, 11.25 mg and 22.5 mg
37. Leucovorin Calcium Injection 15 mg and 50 mg
38. Levo-Leucovorin Calcium for Injection 50 mg
39. Melphalan for Injection 50 mg (Combipack)
40. Methotrexate Injection 15 mg/3 mL, 50 mg/2 mL, 100 mg/4 mL, 500 mg/20 mL and 1000 mg/40 mL
41. Mitomycin for Injection 2 mg, 5 mg, 10 mg and 40 mg
42. Mitoxantrone Injection 20mg/10mL, 25mg/12.5mL and 30mg/15mL
43. Octreotide for Depot Injection 10 mg, 20 mg and 30 mg
44. Oxaliplatin Injection 50 mg/10 mL, 100 mg/20 mL and 200 mg/40 mL
45. Pamidronate Disodium for Injection 30 mg, 60 mg and 90 mg
46. Pemetrexed for Injection 100 mg and 500 mg
47. Paclitaxel Injection 30 mg/5 mL, 100 mg/16.7 mL, 150 mg/25 mL, 260mg/43.3 mL and 300mg/50 mL
48. Paclitaxel Albumin Bound Nanoparticle for Injection 100 mg
49. Perkeator Injection 24 mg / 1.2 mL
50. Peg L - Asparaginase Injection 3750IU/5 mL
51. Topotecan Injection 1 mg/1 mL, 2.5 mg/2.5 mL and 4 mg/4 mL
49. Thiopeta for Injection 15 mg and 100 mg
50. Temozolimus Injection 25 mg
51. Trabectedin for Injection 0.25 mg and 1 mg
52. Trifluoretin for Depot Injection 3.75 mg, 11.25 mg and 22.5 mg
53. Treosulfan for Injection 5g/Vial
54. TPGS Docetaxel Solution for Injection 20mg/2 mL, 80mg/8 mL and 120mg/12 mL
55. Vincristine Sulfate Injection 1 mg/1 mL, 2 mg/2 mL and 5 mg/5 mL
56. Vinorelbine Injection 10 mg/10 mL
57. Vinorelbine for Injection 10mg
58. Vinorelbine Injection 10 mg/1 mL, 50 mg/5 mL
59. Zoledronic Acid for Injection 4 mg/5 mL, 5 mg/100 mL
60. Vincristine Sulfate Liposome Injection 5 mg/Vial
61. Daunorubicin and Cytarabine Liposome for Injection 44 mg and 100 mg

## LIST OF SOLID ORAL PRODUCTS

1. Anastrozole Tablets 1 mg
2. Axitinib Tablets 1 mg and 5 mg\*
3. Abiraterone Acetate Tablets 250 mg and 500 mg
4. Afatinib Tablets 20 mg, 30 mg and 40 mg\*
5. Alectinib Capsules 150 mg\*
6. Azacitidine Tablets 200 mg and 300 mg
7. Apalutamide Tablets 75 mg, 100 mg, and 150 mg\*
8. Bicalutamide Tablets 50 mg and 150 mg
9. Busulfan Tablets 2 mg
10. Capecitabine Tablets 150 mg and 500 mg
11. Chlorambucil Tablets 2 mg and 5 mg
12. Cyclophosphamide Tablets 50 mg
13. Celestinib Capsules 150 mg\*
14. Cabozantinib Tablets 20 mg, 40 mg and 60 mg\*
15. Crizotinib Capsules 200 mg and 250 mg\*
16. Dabrafenib capsules 50 mg and 75 mg\*
17. Dasatinib Tablets 20 mg, 50 mg, 70 mg and 100 mg
18. Erlotinib Tablets 25 mg, 100 mg and 150 mg
19. Exemestane Tablets 25 mg
20. Enzalutamide Tablets 160 mg
21. Etoposide Capsules 50 mg and 100 mg
22. Enzalutamide HG Capsules 40 mg and 80 mg
23. Fludarabine Phosphate Tablets 10 mg
24. Flutamide Capsules 125 mg
25. Flutamide Tablets 250 mg
26. Gefitinib Tablets 250 mg
27. Hydroxyurea Capsules 500 mg
28. Imatinib Capsules 100 mg
29. Imatinib Tablets 100 mg and 400 mg
30. Ibrutinib Capsules 140 mg\*
31. Lapatinib Tablets 250 mg
32. Lenvatinib Capsules 4 mg and 10 mg\*
33. Levalodine Capsules 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 25 mg
34. Letrozole Tablets 2.5 mg
35. Melphalan Tablets 2 mg and 5 mg
36. Methotrexate Tablets 2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg
37. Nilotinib Capsules 150 mg and 200 mg\*
38. Olaparib Tablets 100 mg and 150 mg\*
39. Olaparib Capsules 50 mg\*
40. Osimertinib Tablets 40 mg and 80 mg\*
41. Pazopanib Tablets 200 mg and 400 mg
42. Pegorafenib Tablets 40 mg\*
43. Rucaparib Tablets 200 mg, 250 mg and 300 mg\*
44. Sorafenib Tablets 200 mg
45. Sunitinib Capsules 12.5 mg, 25 mg, 37.5 mg and 50 mg
46. Tamoxifen Tablets 10 mg and 20 mg
47. Temozolomide Capsules 5mg, 20mg, 100mg, 140mg, 180mg & 250mg

\* Products can be Offered for Countries where Patent is not Applicable



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