



### About Us

Valence Labs is a research-driven pharmaceutical API company dedicated to working at the forefront of chemical and pharmaceutical innovation. Established in 2021, Valence has strived to become a leading global manufacturer of high-quality APIs with an unwavering commitment to product quality.

The company embarked on a greenfield project for APIs and advanced intermediates manufacturing within a sprawling 21-acre site at Punjab, India. Moving forth on this journey, our steadfast efforts are determined to emerge as a preferred and reliable partner for pharmaceutical companies worldwide facilitating the development of life-changing medications.

## **Manufacturing Facility**

Our modern GMP-compliant manufacturing facility covers 7000 square meters footprint and four floors with separate areas for intermediate and API production. Empowering innovation with cutting-edge technology, the facility is meticulously designed to ensure the highest standards of manufacturing and meet the regulatory standards of the US, Japan, and the EU.

We've invested in the latest equipment to facilitate precision and efficiency in API production. Our manufacturing lines are equipped with advanced process controls ensuring consistency and quality in every batch.

- Facility designed for multiple product manufacturing
- Class 100,000 (ISO 8) cleanroom modules with 0.3 micron terminal HEPA filters
- Contained Powder Transfer Systems for all powder transfers
- Separate entries for man and material
- Airlocks at all entry areas
- Online metal detection system for final product
- DCS system for critical process controls
- 100% power backup
- Exclusion of penicillins, cephalosporin, steroids, cytotoxics, and agrochemicals' products development or production at the site.





### **Science and Technology**

At Valence, we have a fully integrated Active Pharmaceutical Ingredient (API) R&D centre suitable for performing reactions over broad pressuretemperature ranges. It is supported by a robust "Analytical Research and Development" division, equipped with advanced and latest instruments.

Developing products through cutting-edge technologies, green chemistry, and cost-effective processes, the centre ensures continual improvements following "Product Life Cycle Management."

### Core Chemistry Competencies

- Grignard's reaction
- Friedel-Crafts acylation
- Enzymatic Reduction
- Chlorination
- Chiral Chemistry
- Organometallic Chemistry
- Coupling Reactions

A dedicated team of scientists develops non-infringing processes from gram scale to kilogram scale synthesis. "Manufacturing Science and Technology" division ensures efficient technology absorption and transfer through competent Chemical Engineers and experienced Chemists.

# Quality

At Valence, we believe in 'Quality by Design', which is embibed in every product we manufacture. With a stringent quality management system in place, product quality and patient safety is ensured.

Valence has state-of-art Quality Control function which is equipped with all latest chromatographic and non chromatographic instruments, complying to 21 CFR Part 11 requirement.



### **Product List**

APIs			10.1	
Product	CAS No	Therapeutic Category	Pharmacopoeia	Status
Phenylephrine Hydrochloride(Oral and Injectable)	61-76-7	Decongestant	IP/USP/EP	Commercialised(CEP Filed)
Dexketoprofen Trometamol(Oral and Injectable)	156604-79-4	Anti-Inflammatory	In-House	Commercialised(DMF Available)
Dapagliflozin Propanediol	960404-48-2	Antidiabetic	USP/In-House	Commercialised(DMF Available)
Dapagliflozin Amorphous	461432-26-8	Antidiabetic	In-House	Commercialised
Ursodeoxycholic Acid	128-13-2	Cholelithiasis Agent	IP/USP/EP/JP	Commercialised(DMF in Q3 FY25)
Citicoline Sodium(Oral and Injectable)	33818-15-4	Psychostimulant	IP/USP	Commercialised
Fexofenadine Hydrochloride	153439-40-8	Antihistaminic	IP/USP/EP/JP	Under Validation(CEP Filing in Q4 FY25)
Nicotine	54-11-5	Stimulant	EP/USP	Validation in Q4 FY25
Tolvaptan	150683-30-0	Diuretic	IP/In-House	Validation in Q4 FY25
Ticagrelor	274693-27-5	Antiplatelet		In Pipeline
Bempedoic Acid	738606-46-7	Lipid Lowering Agent		In Pipeline
Bilastine	202189-78-4	Antihistaminic		In Pipeline
Vonoprazan Fumarate	881681-01-2	Antiulcerative		In Pipeline
Lercanidipine	100427-26-7	Antihypertensive		In Pipeline
Intermediates				
Product	CAS No	End API	Intermediate Code	Status
Methyl 2-(4-(4-(hydroxydiphenylmethyl)piperidin- 1-yl)butanoyl)phenyl)-2-methylpropanoate	154477-55-1	Fexofenadine Hydrochloride	Fex X/ D10	Commercialised
Phenylephrine Base	59-42-7	Phenylephrine Hydrochloride		Commercialised
L-proline benzyl ester hydrochloride	16652-71-4	Lisinopril		Commercialised
3-Hydroxyacetophenone	121-71-1	Phenylephrine Hydrochloride		Under Commercialisation
2-[benzyl(methyl)amino]-1-(3-hydroxyphenyl) ethan-1-one hydrochloride	71786-67-9	Phenylephrine Hydrochloride		Under Commercialisation
2,4-Difluoro-(1H-1,2,4-triazolyl)acetophenone	86404-63-9	Fluconazole	DFTA	Commercialisation in Q4 FY25
Phenylacetone	103-79-7	Lisdexamfetamine		Commercialisation in Q4 FY25
7-Ethyltryptophol	41340-36-7	Etodolac		In Pipeline
Ethyl 7-chloro-2,2-dimethylheptanoate	2570179- 39-2	Bempedoic Acid		In Pipeline
Diethyl 2,2,14,14-tetramethyl-8- oxopentadecanedioate	738606-43-4	Bempedoic Acid		In Pipeline
2,2,14,14-tetramethyl-8-oxopentadecanedioic acid	413624-71-2	Bempedoic Acid		In Pipeline
2-methyl-4-(2-methyl-benzoylamino)-benzoic acid	317374-08-6	Tolvaptan		In Pipeline
7-Chloro-1,2,3,4-tetrahydro-5H-1-benzazepin- 5-one	160129-45-3	Tolvaptan		In Pipeline

Note: These products are not available for sale in countries where the patents are applicable or still valid

#### **Contact Information**

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