



JUPITER GROUP

Jupiter Bioscience Ltd
ジュピターバイオサイエンス

&

Sven Genetech Ltd
シュベン ジェネテック

&

Jupiter Bioscience Inc.,
米国ジュピター

Corporate Office: Hyderabad, India.



JUPITER GROUP

Operates three manufacturing facilities インド国内3ヶ所での製造

- Unit I (Bidar) Unit II (Cheriyal) Unit III (Kazipally)
Acquired from Aurobindo Pharma
- Complying with Good Manufacturing Practices (GMP) GMP基準
- Unit IV - (Sven Genetech, Cherlapally) 第4プラント シュベンジェネテック
- Unit V - Coming up in USA in Maryland for Custom Peptides, Clinical Peptides & Generic Peptides 米国ジュピター(メリーランド)における、ペプチドの受託製造、臨床試験、ジェネリックペプチド薬の製造



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- New Initiatives 新規課題



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Introduction of the Company 会社の略歴

1985

The Late Mr. K.S. Sarma, a respected figure in the Indian Pharmaceutical / Specialty Chemicals Industry founded Jupiter Orga Pvt. Ltd 創業者のサルマ氏がインドにおける医薬業界の将来性に期待して、ジュピター有機化学工業を設立

1987

Commercial Production of API (Single Product) APIの製造開始

1992

Backward integration of key raw material 原料ビジネスの事業化の推進

1995

Initial Public Offering 上場

1998

Protecting Reagents アミノ酸保護基ビジネスに参入

2000

Sven Genetech Ltd, Protected Amino Acids シュベン社にて保護アミノ酸の製造開始



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2001

Coupling Reagents ペプチド縮合試薬の製造開始

2002

Derivatives of Protected Amino Acids アミノ酸誘導体に参入

2004

Unnatural Amino Acids, Fragments of Peptides 非天然型アミノ酸、ペプチドフラグメントに参入

2005

Solution Phase Peptide Synthesis (18 Amino Acid Chain Length) 液相にて18残基の合成に成功

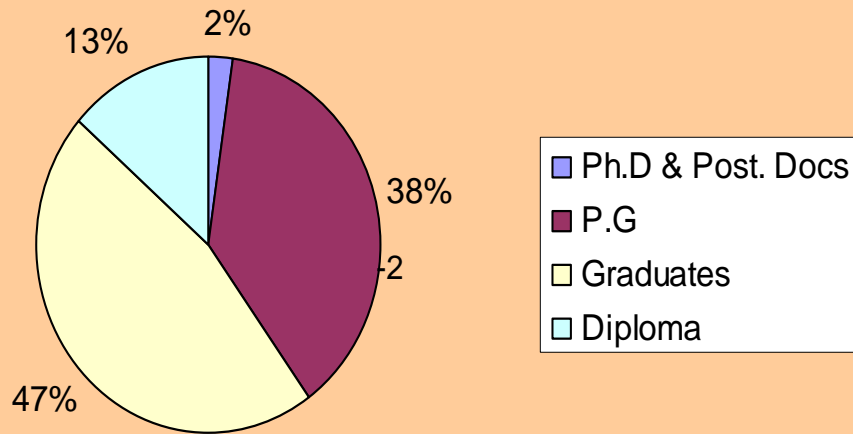
2006

Solid Phase Peptide Synthesis (30-80 Amino Acids Chain Length) 固相にて30-80残基の合成に成功



JUPITER GROUP

Human Resources 人材



Qualifications	Persons
Ph.D & Post. Docs	8
P.G	140
Graduates	173
Diploma	50
Total	371



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BRIEF PROFILE OF THE INFRASTRUCTURE 製造基盤

	<u>Unit II (Cheriyal)</u>	<u>Unit IV (Cherlapally)</u>
• Site Area -	47000 SQ. Mt.	- 6800 SQ. Mt.
• Process Block -	9000 SQ. Mt.	- 1500 SQ. Mt.
• Green Belt -	28500 SQ. Mt.	- 1500 SQ. Mt.
• Manufacturing Blocks - 10 Nos.		- 6800 SQ. Mt.



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PROCESS EQUIPMENTS

Reactors 反応設備

S.No	Material of construction	Capacity	No.
1	Glass Lined Reactors	100 lit, 250 lit, 500 lit, 1000 lit, 1600 lit, 2000 lit, 3000 lit, 5000 lit	18
2	Stainless Steel Reactors	50 lit, 100 lit, 250 lit, 500 lit, 630 lit, 1000 lit, 1600 lit, 2000 lit, 3000 lit, 5000 lit	52
3	Graphite Reactors	250 lit, 500 lit, 1000 lit	5
4	All glass assembly	10 lit, 20 lit, 50 lit	12

Centrifuges

1	Stainless Steel Centrifuges	12", 24", 36", 48"	32
2	Rubber lined Centrifuges	24", 36"	4



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PROCESS EQUIPMENTS

S.No	Equipment	Capacity	No.
1	Autoclaves (SS)	10 lit, 20 lit, 100 lit, 250 lit, 1000 lit, 2000 lit	10
2	Vacuum Tray Driers	24 trays & 12 trays	5
3	Fluidized Bed Driers	60kgs	3
4	Tray Dryers	48 Trays, 24 trays	18
5	Micron Filters, Pressure Filters	Varied Capacities	30



JUPITER BIOSCIENCE LIMITED

QUALITY POLICY 品質重視

We at Jupiter believe in ジュピターは

- ❖ Total customer satisfaction by providing superior quality standards. 顧客満足を第一として第一級の品質標準を提供する。
- ❖ Stringent quality norms, systematic approach and continual improvement as key factors for success. 厳格な品質管理に基づいた、体系化された品質向上を目指す。

- Chairman & Managing Director 経営と製造の分離
- Global presence through advancement in science and process technology; offering a complete chain of products in Peptide chemistry including Peptides. 世界的な見地からもっとも優れた技術の導入。完成されたペプチド製品及び同誘導体の提供
- Market leadership through best facilities, people and validated systems of international standards. 世界水準の設備環境を備え、業界のリーダーを目指す。

Venkat.R.Kalavakolanu ベンカット. R. カラヴァコラス



JUPITER GROUP

QUALITY CONTROL EQUIPMENT 品質保証

- High Performance Liquid Chromatograph
- (HPLC) (Analytical, Amino Acid Analyzer)
- Gas Chromatograph (GC)
- Polarimeter
- UV-Vis Spectro photometer
- FT- IR
- Stability Test Chamber
- Access to Mass, NMR & Elemental Analysis



JUPITER GROUP

Expertise プロフェッショナル

- Strong R&D facilities for Developing New Processes.
強力なR&D設備による新規プロセスの開発
- On going process development with focus on the existing products 既存物質のプロセス改善
- Dedicated facilities from lab to Pilot scale quantities.
ラボからパイロットスケールまで一体化した開発
- Trouble shooting トラブルシューティング



JUPITER GROUP

Unit II (Cheriyal) 第2プラント

- Certified ISO 9001:2000 Quality Systems
- Total Documentation complying WHO, cGMP and ICH norms.
- Quality Manual & Site Master File are in place.
- Independent Q.C & Q.A functions at each site.



JUPITER GROUP

CORE COMPETENCIES 核心技術

- Peptide Chemistry ペプチド及び誘導体
- Chiral Chemistry キラル分離技術
- Biotechnology バイオテクノロジー
- Advanced Organic Chemistry 先進的な有機化合物の製造



JUPITER GROUP

PEPTIDE VALUE CHAIN

バリューチェーン

The first ever
Company in the
world to be an
Integrated
Pharmaceutical
Company 世界初
の総合ペプチド企業

PEPTIDE FORMULATIONS ペプチド製剤



PEPTIDE DRUGS ペプチドAPI



PROTECTED AMINO ACIDS 保護アミノ酸



PROTECTING AGENTS 保護試薬



JUPITER GROUP

PRODUCT GROUPS 商品群

- Protecting Reagents 保護試薬
- Coupling Reagents 縮合試薬
- D- Amino Acids Dアミノ酸
- β - Amino Acids ベータアミノ酸
- Protected Amino Acids 保護アミノ酸
- Side Chain Protected Amino Acids 側鎖保護アミノ酸



JUPITER BIOSCIENCE LIMITED

PRODUCTS - Coupling Reagents 縮合試薬

- ❖ HOBT
 - ❖ N-Hydroxy Succinimide
- ❖ HBTU
 - ❖ EDC.HCl
- ❖ TBTU
- ❖ TSTU
- ❖ HATU
- ❖ HOAT



JUPITER BIOSCIENCE LIMITED

PRODUCTS - Protected Reagents 保護試薬

❖ BOC-ON

❖ Z-ONSU

❖ FMOC-Cl

❖ 2-Bromo-Z-ONSU

❖ FMOC-ONSU

❖ 2-Chloro-Z-ONSU



JUPITER BIOSCIENCE LIMITED

PRODUCTS – Protected Amino Acids 保護アミノ酸

- ❖ BOC Protected Amino acids
(BOC-D-Ala-OH, BOC-D-Phe-OH,
BOC-Gly-OH, BOC-Ala-OH, BOC-His-OH, Etc.)
- ❖ FMOC Protected Amino acids
(FMOC-D-Ala-OH, FMOC-Ala-OH,
FMOC-Glu-OH, FMOC-Met-OH, FMOC-Val-OH, Etc.)
- ❖ CBZ Protected Amino acids
(Z-Arg-OH, Z-Asp-OH, Z-Leu-OH,
Z-Glu-OH, Z-Gln-OH, Z-Gly-OH, Z-Pro-OH, Etc.)



JUPITER BIOSCIENCE LIMITED

PRODUCTS – Side Chain Protected Amino Acids 側鎖保護アミノ酸

- ❖ BOC Side Chain Protected Amino acids
BOC-L-Cys(Bzl)-OH, BOC-His(Trt)-OPFP

- ❖ FMOC Side Chain Protected Amino acids
FMOC-L-Tyrosine-(tbu)-OH, FMOC-L-Arg(Pbf)-OH,
FMOC-L-Cys-(trt)-OPFP, FMOC-Glu(OtBu)-OH,
FMOC-L-Serine-(tbu)-OH, FMOC-L-Tyrosine-(tbu)-OH

- ❖ CBZ Side Chain Protected Amino acids
Z-L-Arg(Pbf)-OH, Z-L-Glu(Otbu)-Oxa,
Z-L-Asp(Otbu)-Oxa, Z-L-Asn-OPNP



JUPITER BIOSCIENCE LIMITED

PRODUCTS – Peptides ペプチド製品

- ❖ Oxytocin
- ❖ Desmopressin
- ❖ Leuprolide
- ❖ Glycyl-Glycine
- ❖ Glycyl-Glycyl-Glycine
- ❖ Cyclo(His-Pro)
- ❖ L-Lysyl-L-Proline
- ❖ L-Histidyl-L-Leucine
- ❖ L-Arginyl-L-Leucine
- ❖ Glycyl-D-Alanine
- ❖ Histidyl-Lysine
- ❖ Glycyl-Histidyl-Lysine



JUPITER BIOSCIENCE LIMITED

PRODUCTS

SPECIALITY PHARMACEUTICALS INTERMEDIATES

他APIおよび特殊医薬用中間体

- ❖ Phloroglucinol Dihydrate
- ❖ Phloroglucinol Anhydrous
- ❖ Trimethyl Phloroglucinol
- ❖ Phloro Acetophenone
- ❖ Phloroglucinol Carboxylic acid
- ❖ Pyrogallol, Etc.



JUPITER BIOSCIENCE LIMITED

PRODUCTS – ACTIVE PHARMACEUTICAL INGREDIENTS API商品

- ❖ Enalapril
- ❖ Lisinopril
- ❖ Ramipril

EQUIPMENT-QUALITY CONTROL

品質管理用分析機器一覽

- ❖ High Performance Liquid Chromatograph (HPLC)
- ❖ Gas Chromatograph (GC)
- ❖ Polarimeter
- ❖ HPLC Water Generator
- ❖ Ultra Sonic Cleaner
- ❖ Environmental test chamber
- ❖ Electronic Balance
- ❖ K.F. Titrator
- ❖ Melting Point Apparatus
- ❖ Digital pH meter
- ❖ Ultra Violet Chamber (TLC)
- ❖ Oven
- ❖ Muffle furnace
- ❖ TDS Analyzer



JUPITER GROUP

PRODUCT LINE ペプチド商品体系

1. Custom Peptides カスタム製造
2. Clinical Peptides 臨床試験
3. Peptide Bulk Actives API



JUPITER GROUP

APPLICATIONS OF PEPTIDES ペプチドの用途

- Pharmaceuticals 医薬品
- Vaccines ワクチン
- Diagnostics 診断薬
- Veterinary 動物薬
- Cosmetics 化粧品
- Nutraceuticals 健康食品

PROCESS EQUIPMENT 製造設備

- ❖ Reactors (Glass Line, Graphite & Stainless Steel)
- ❖ Auto Claves (SS)
- ❖ Leaf Filters
- ❖ Micron Filters
- ❖ Pressure Filters
- ❖ Nutch Filters
- ❖ Centrifuges
- ❖ Tray Driers
- ❖ Vacuum Tray Driers
- ❖ Fluidized Bed Driers
- ❖ Sifters
- ❖ Multi mill
- ❖ Blender, Etc.



JUPITER GROUP

TARGET MARKETS (Regulatory & Non-Regulatory)

目標市場(規制管理国、非規制管理国)

For Existing Biopharma Companies 既存のバイオ医薬企業

- Innovative Companies 発明型企业
- Customer Peptide Companies ペプチド受託製造企業
- Research Institutes 研究機関
- Peptide Manufacturing Companies ペプチド製造業
- Universities 大学
- Catalogue Companies カタログ試薬メーカー



JUPITER GROUP

MARKETING 市場戦略

- Global business development team with sales offices in India, USA and Europe. インド、米国、ヨーロッパをつなぐ、グローバルビジネス開発チーム
- Global Alliance for custom research projects and outsourcing with Clariant, Germany. 独クライアント社とのグローバル提携
- Marketing officer in Europe, Mr.Olaf Spinnhorn, formerly an Executive of Aventis with 22 years of Experience. 元アベンティスのMr. Olafによる市場開発
- Jupiter has an established a subsidiary K K Jupiter Biosciences in Japan (株)ジュピターバイオサイエンスジャパンの設立。



JUPITER GROUP

QC & QA 品質管理、品質保証

- In house independent department 自社プラント内での管理
- outsourcing : ^1H -& ^{13}C -NMR
FAB-MS, MALDI TOF etc 他研究機関における委託管理



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Enquiry (H.O.) 引き合い



Literature search (Technical Department) 文献検索



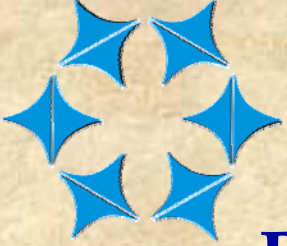
Route selection (Scientific Team) ルート検索



Costing (Purchase department) 価格提示



Quote (H.O.) 見積もり



JUPITER GROUP

PROJECT REPORTING-OVERSEAS

レポートシステム

- Principle Investigator-contact person
専門担当の配置
- Weekly, biweekly reports
週間・隔週のレポートシステム
- Teleconferences
遠隔会議
- Email & fax-transmission Email・ファクスの利用



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PROJECT MONITORING モニター

- Group Leader/V.P
グループリーダー制
- Daily & weekly basis 日報と週報
- Daily written reports
書面による日報管理
- Bar charts 統一書式
- Project report-Process manual
マニュアル化



JUPITER GROUP

Bio-resolution Process development

バイオ法によるプロセス開発

- Cost-efficient synthesis of complex chiral products ラセミ化合物に対する効率的な低コストキラル合成法の確立
- Route selection, substrate synthesis, bio-resolution and purification is integrated 最適なルートの確保、バイオ反応、バイオキラル分離、精製などの諸技術の集合化
- Array of in-house expertise in organic and biochemical process well augmented with biotechnology capabilities. 有機化学と生化学の合体化によるバイオテクノロジー技術
- Gram base to Kilo base, scalable process capabilities GからKGまでの一貫対応
- Substrate to final product, bottoms-up approach バイオ法による最終製品の開発、タンパク質よりの反転アプローチ



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Products commercialized (α -amino acids) 商品リスト α -アミノ酸

1. D-Alanine
2. D-Arginine
3. D-Aspartic acid
4. L-AlloIsoleucine
5. D-Glutamic acid
6. D-Isovaline
7. D-IsoLeucine
8. D-Leucine
9. D-Methionine
10. 3-Methoxy-L-Tyrosine
11. L-Norvaline
12. D-Phenyl alanine
13. D-Serine
14. D-Tyrosine
15. D-Tryptophan
16. D-Ter-Leucine
17. D-Valine
18. D-Proline



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THANK YOU