

Sajjala Bio Labs





SAJJALA BIO LABS

**API's Manufacturing Plant driven by
Research and Innovations.**

**Incorporated in 2011 and headquartered in
Hyderabad – India.**



SAJJALA BIO LABS

Manufacturing Driven by Innovations

Anti
Coagulants

Enzymes

Polysaccharides
and
Polypeptides

Therapeutic
Peptides

Enoxaparin

LAsparaginase

Leuprolide

Liraglutide

Teriparatide



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Approach



Infrastructure and Assets

R&D Facilities housing the best practices facilitated by Digital Assets – Processing, Storage, Analytics, Libraries and Retrieval.

Key laboratory assets include Fermenters ,PCR, Centrifuge, Incubator shakers, LAFU, Autoclave and FPLC's and preparative HPLC's.

Analytical

RP-HPLC, RI-HPLC, Moisture Analyzer, KF titrater, Plate reader, UV-Vis Spectrophotometer.

Continued in
the next slide



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- **cGMP Manufacturing area**
 - Key manufacturing assets include Fermenters, continuous centrifuge
 - Lyophilizer, Miller, Shifter and Vacuum tray dryer, Incubator shakers, LAFU.
- **Utilities**
 - DW, RO water and DM water plant, Vacuum, Air, Nitrogen, O2, Chilled water, Hot water and Steam.

Summary of Infrastructure and Assets

- State-of-the-art GMP certified manufacturing and research facility.
- WHO GMP audit underway for certification.
- Class 100,000, 10000, 1000 facility.
- ICT enabled secured and networked data storage and management infrastructure.
- Manufacturing processes driven by Data acquisition software and systems.
- Barrier maintained facility with 3 level pressure gradient system.
- Dedicated service corridor for better barrier management.
- Adequate infrastructure for isolation of experiments.
- Well-equipped areas to handle upstream, downstream and polishing process.
- Independent AHUs for upstream and downstream processes.
- Tiered Biometric Access Control with restricted entry.

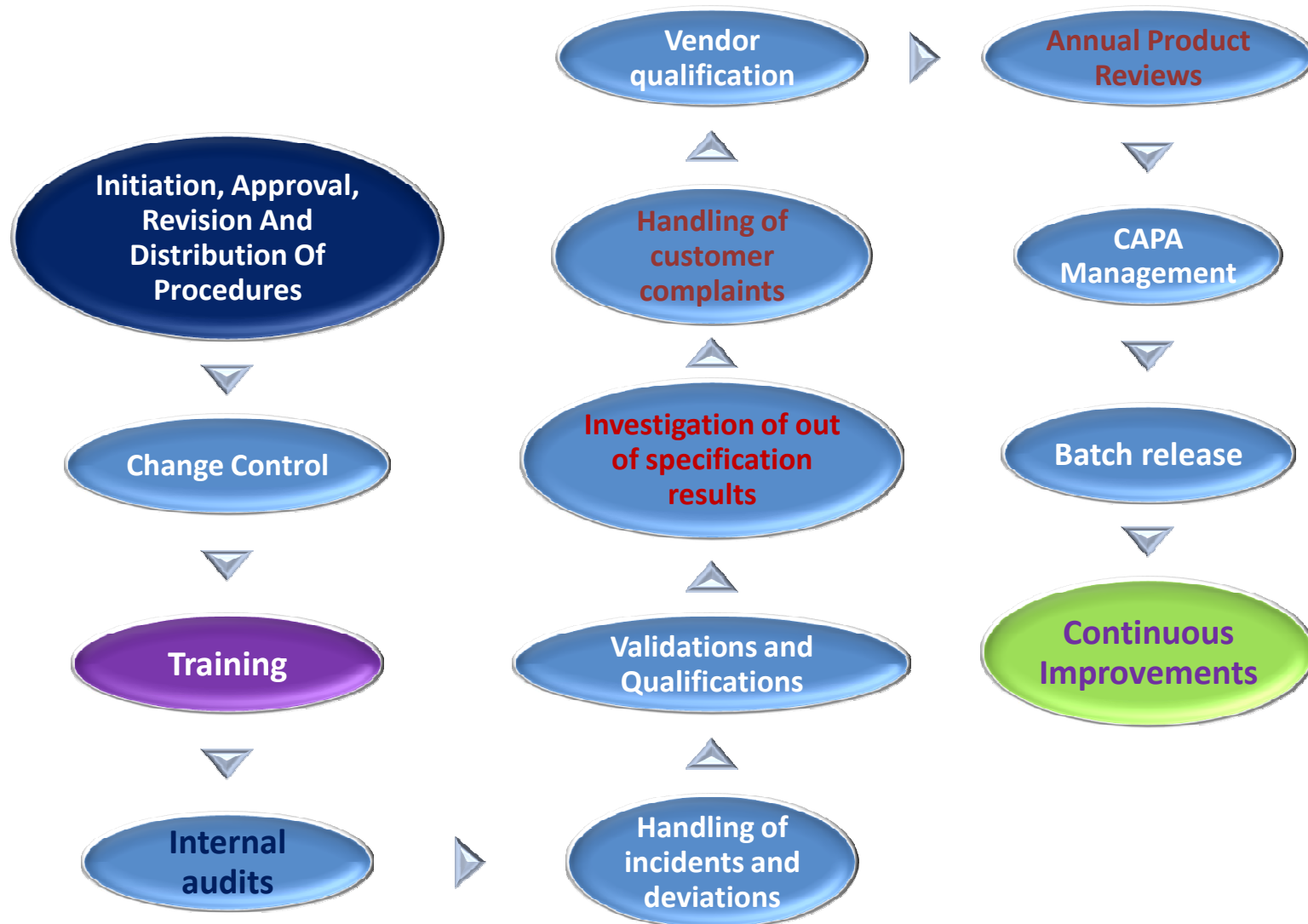
Quality – Key Drivers



Quality Management Systems



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Key Human Resources



Research and Development

Power of Knowledge -Human Resources

- Molecular biologists
- Fermentation specialists
- Purification & Chemistry - Synthetic Chemists
- Analysts
- Support Engineers

Core competence

- Expertise in genetic manipulation - Bacteria and Yeast
- Expertise in PRD and ARD
- Expertise in scaling up and tech transfer to CMO sites



Current Supplies and Near Future Supplies

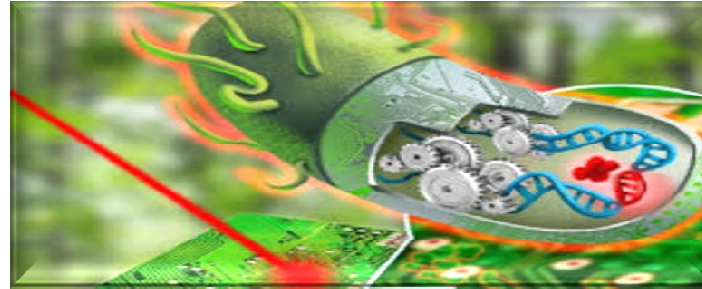
Project	Status of the API	Expected launch date
<i>Anti Coagulant – Critical Care</i>		
Enoxaparin sodium	Shipments in progress	Launched
<i>Enzyme - Oncology</i>		
L-Asparaginase	Shipments in progress	Launched
<i>Therapeutic Peptides – Osteoporosis and Diabetes</i>		
Teriparatide	Apr- 2018	FY 2018
Liraglutide	Mar-2018	FY 2018

Core Competencies

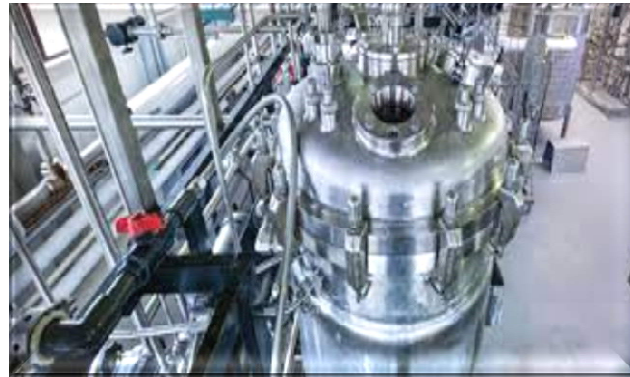
Recombinant technology based platforms for expression of peptides



Synthetic Biology and Bio-transformations



*Analytical development
(IPQC, intermediates
/Finished APIs & Stability)*



Process Development (Fermentation and Purification capabilities)

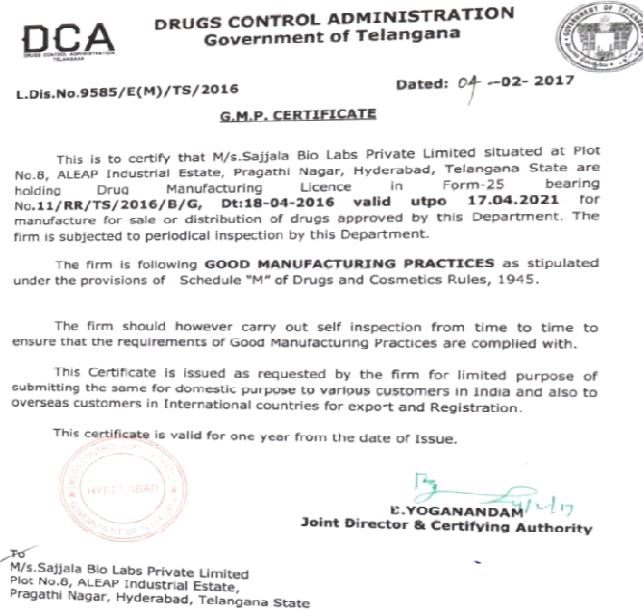
Large scale fermentation capability



Certifications and Standards



- ❖ ISO 9001: 2015
- ❖ GMP
- ❖ WHO GMP – Inspection in progress by the regulatory authorities



Licenses



- ❖ Manufacturing license for Enoxaparin Sodium
- ❖ Manufacturing license for L Aspraginase
- ❖ Drug license number is 5/MDCHL/TS/2017/B/G

DCA DRUGS CONTROL ADMINISTRATION
Government of Telangana
L. Dis. No.6516/E(M)/TS/2017
Dated:16-05-2017



To
M/s.Sajjala Bio Labs Private Limited
Plot No.8, ALEAP Industrial Estate
Near Pragathi Nagar, Kukatpally
Hyderabad, Telangana State-500072.

Sirs,

Sub:- Drugs and Cosmetics Act,1940 and Rules made thereunder -
Grant of additional product in Form- 28 - Regarding.

Ref:- Your application dt:21-04-2017.

With reference to your application cited, you are hereby permitted to
manufacture the product mentioned below as additional item under your drug
Licence in form-28 bearing No.5/MDCHL/TS/2017/B/G, dated.31.01.2017
valid upto 30.01.2022.

LIS OF THE PRODUCTS

- | | |
|----------------------|-----|
| 1. HEPARIN SODIUM | IP |
| 2. HEPARIN SODIUM | USP |
| 3. HEPARIN SODIUM | BP |
| 4. ENOXAPARIN SODIUM | IP |
| 5. ENOXAPARIN SODIUM | USP |
| 6. ENOXAPARIN SODIUM | BP |

The additional product is granted subject to the following conditions:

1. You are informed that on failure to manufacture any of the drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.
2. The provision of Drugs Price Control Order, 2013 shall be complied with.
3. You should ensure that the drugs approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour combination etc., and shall comply with all the provisions relating to the labelling of Drugs.
4. You should note that the brand names approved herewith are without prejudice to the existing brand names and are liable for review in future.



Pg 1 of 2
16/5/2017

DCA DRUGS CONTROL ADMINISTRATION
Government of Telangana
L. Dis. No.2569/E(M)/TS/2017
Dated:17-02-2017



To
M/s.Sajjala Bio Labs Private Limited
Plot No.8, ALEAP Industrial Estate
Near Pragathinagar, Kukatpally
Hyderabad-500072
Telangana State, India.

Sirs,

Sub: Drugs and Cosmetic Act.1940 and Rules made there under - Grant of
Drug Licence in Form- 28 and Addition of Director- Regarding.

Ref: Your application dated: 17-01-2017.

With reference to your application cited, I forward herewith the Drug
Licences bearing No.5/MDCHL/TS/2017/B/G, dated:31-01-2017 in
Form-28 for the manufacture of the following drug. The Drug Licence is valid from
31-01-2017 to 30-01-2022.

Name of the Product in Form-28

1. L-Asparginase
In House(IH)

Further, you are also permitted for addition of Director Mr.Sajjala Bhargava is
approved in your drug licence as requested by you.

The above Drug Licence is granted subject to the following conditions:

1. You are informed that on failure to manufacture any of the drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.
2. The provision of Drugs Price Control Order, 2013 shall be complied with.
3. You should ensure that the drugs approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour combination etc., and shall comply with all the provisions relating to the labelling of Drugs.
4. You should note that the brand names approved herewith are without prejudice to the existing brand names and are liable for review in future.



17/2/2017

Recognition from Government of India



Innovation and Research Centre Recognition

 सूचना का अधिकार

TELEGRAM : SCINDRECH
फ़ोन/TEL : 26962819, 26567373
(EP/IA) : 26565694, 26562123
: 26565687, 26562144
: 26562134, 26562122
फ़ोन/FAAX : 26960629, 26529745
Website : <http://www.dsr.gov.in>


सत्यमेव जयते

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
वैज्ञानिक और औद्योगिक अनुसंधान विभाग
टेकनोलॉजी भवन, गंगा महरोली मार्ग,
नई दिल्ली - 110 016
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
Department of Scientific and Industrial Research
Technology Bhavan, New Mehrauli Road,
New Delhi - 110 016



No. TU/IV-RD/4057/2016

Dated: 18th October, 2016

To

M/s. Sajjala Biolabs Private Limited
Plot No. 8, Aleap Industrial Area
Gajula Ramaram, Near Pragathi Nagar
Hyderabad - 500 072
(Telangana)

Subject: RECOGNITION OF YOUR IN-HOUSE R&D UNIT(s)

Dear Sirs,

This has reference to your application for recognition of your In-House R&D unit(s) by the Department of Scientific and Industrial Research.

2. This is to inform you that it has been decided to accord recognition to the In-House R&D unit(s) of your firm at Plot No. 8, Aleap Industrial Estate, Pragathi Nagar, Kukatpally, Hyderabad, Telangana from 23.09.2016 to 31.03.2018. Terms and conditions pertaining to this recognition are given overleaf.

3. Kindly acknowledge the receipt of this letter.

Yours faithfully,


(Dr. S. K. Deshpande)
Scientist - 'G'

COA for Enoxaparin Sodium

SAJJALA BIO LABS PRIVATE LIMITED



CERTIFICATE OF ANALYSIS

Product: Enoxaparin Sodium

Batch Number: EPEXP0200717

Quantity of Lot: 3.015kg

Date of Manufacturer: Jul-2017

Date of Reporting: 21.07.2017

Expiry date: Jun-2019

Testing Specifications		As per IP
Test	Specifications	Results
Material Characters	White or almost white Powder, moderately hygroscopic. Soluble in water.	Complies
Identification	A) Determined by Size-Exclusion chromatography: M ₂₀₀₀ is NLT 12.0% and NMT 20.0% M ₂₀₀₀₋₈₀₀₀ is NLT 68.0% and NMT 82.0%	16.8% 74.2%
	B) The Ratio of anti-X _a activity to anti-II _a activity: Between 3.3 – 5.3	3.60
Appearance of Solution	The solution is clear and not more intensely colored than reference solution BYS6.	Complies
pH	Between 6.2 to 7.7	6.80
Light absorbance	From 14.0 to 20.0	15.71
Heavy metals	Not more than 30ppm	Less than 30ppm
Sodium (Dried basis)	11.3% to 13.5%	12.28%
Nitrogen (Dried basis)	1.8% to 2.5%	2.2%
Loss on drying	Not More than 10.0 % w/w	1.52%
Bacterial Endotoxins	Not More than 0.01 EU/IU of Antifactor X _a activity	Less than 0.01 EU/IU of Antifactor X _a activity
Benzyl Alcohol Content	Not More Than 0.1%	Not detected
Assay (Anti Factor X _a activity)	Not Less Than 90 and not more than 125 IU/mg (Dried basis)	102.07 IU/mg
Anti Factor II _a activity	Not Less Than 20 and not more Than 35 IU/mg (Dried basis)	28.33 IU/mg
*Residual Solvents By GC	i) Methanol : Not More Than 3000ppm ii) DMF : Not More Than 880ppm	94 ppm 81 ppm
Conclusion	The analytical results of the substance show that Enoxaparin Sodium complies with the requirements of IP.	

*In-House Test

Prepared by:

Suresh
21.07.17

Checked by:

[Signature]
21.07.17

Approved by:

M.V. Ravi
21.07.17

Format No: SB-QA-046-F01-02

Plot No-8, ALEAP Industrial Estate, Gajularamaram, Medchal Dist, Telangana state-500090

Tel No.: +91-40-65222258 E.mail Id: info@sajjalabio.com web: www.sajjalabio.com

CIN: U24232TG2011PTC075558

COA for L Asparaginase

SAJJALA BIO LABS PRIVATE LIMITED



CERTIFICATE OF ANALYSIS

Product: L-Asparaginase

Batch Number: SBL/ASP/043/07/17

Quantity of Lot: NA

Date of Manufacturer: Ju1-2017

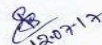
Date of Rep: 12.07.2017

Proposed Shelf life: Jun - 2019

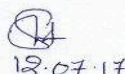
Testing Specifications	IH	
	Tests	Results
Description	A White crystalline powder.	A White crystalline powder.
Solubility	Freely soluble in water; insoluble in ethanol (or) ether.	Freely soluble in water; insoluble in ethanol
Identification A) By chemical test B) By HPLC	A blue violet colour should be produced. The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the Standard preparation.	A blue violet colour is produced. Complies
Acidity or Alkalinity (pH)	6.5 to 7.5	7.27
Loss on drying	Not more than 10.0%	3.54%
Heavy metals	Not more than 0.002%	Less than 0.002%
Appearance of solution	The Solution should be clear & colorless.	The solution is clear & colorless
Potency/ Assay (Enzymatic)	Not less than 120 IU/mg.	191.77 IU/mg
Content of Protein	Not less than 0.55 mg/mg	0.77 mg/mg
Purity by HPLC	Not less than 98.00%	99.87 %
Specific Activity	Not Less than 220 L-Asparaginase unit per mg of protein on dried basis	258.19 IU/mg (on dried basis)
Bacterial Endotoxins	Not more than 0.0145 EU/IU of L-Asparaginase.	Less than 0.0145 EU/IU of L-Asparaginase
Undue Toxicity	Conforms to the requirement	Complies
Conclusion	The analytical results of the substance show that L-Asparaginase complies with the requirements of IH.	

Note: Store the sample at -20°C

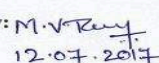
Prepared by:



Checked by:



Approved by:



Format No.: SB-QA046-F01-02

Plot No.: 8, ALEAP Industrial Estate, Gajularamaram, Medchal District, Telangana state - 500 090, India

Tel No.: +91-40-65222258 E.mail Id: info@sajjalabio.com web: www.sajjalabio.com

CIN: U24232TG2011PTC075558



SAJJALA BIO LABS

Thank you