

AZIDUS

Laboratories Ltd.

Organisation Overview



- Azidus laboratories is a fully owned unit of **ATOZ group** of companies, India.
- Provide end-to-end solutions for BA/BE studies for all dosage forms.
- World class infrastructure audited successfully by USFDA, ANVISA, EMA, WHO, ISP Chile, MoH Turkey & DCGI.
- Global presence with independent BA/BE centres in India, USA and Brazil.
- 130,000 Sq. ft. world class BA/BE infrastructure; Professional workforce of 180 trained team members.

Clinical Research Services

BA/BE Studies

Bioanalytical Services

Diagnostics Laboratory services

Clinical Trial Management

Medical Writing

EDC, Data Mgmt. & Biostatistics

Regulatory Affairs

Quality Assurance

Clinical Set Up

- **Conducted over 2000 BA/BE studies till date.**
- Experienced in conducting BA/BE studies on various dosage forms: **Tablets, Suspensions, Injectable, Liposomes, Oral Films, Sublingual tablet, Capsules, ER, Nasal formulations, Topicals, Transdermals.**
- Experienced in conducting BA/BE studies under various study designs: **Crossover, Parallel, Multiple dose steady state, Replicate, Patient Based Studies.**
- Supported large numbers of complex ANDA submission and first to files.
- Large database of healthy male & female volunteers: 30,000 +
- Volunteer Management (VM) is done using state of the art electronic tools - **Online Volunteer Information System (OVIS) & SENTINEL Software.**

Human Pharmacology Unit: Infrastructure

- State-of-the-art clinic (8 clinics) with **336 beds (Expanding to 480) & 13 ICU beds.**
- Managed by a team of 70 researchers, including 9 physicians
- Dedicated area for all activities: Counselling, Housing, Recreation, Dining, Sampling, Sample processing, Pharmacy.
- Separate housing facility for female volunteers.
- 24/7 ambulance & contract with tertiary care hospital for emergencies.





ICU equipped with Multipara monitors for continuous cardiac monitoring

ICU: Infrastructure

- ICU equipped with
 - ✓ Mechanical ventilator, Oxygen cylinders
 - ✓ Fowler's Cot
 - ✓ Boyle's apparatus
 - ✓ ECG machine & Defibrillator
 - ✓ Multi parameter monitor with recorder
 - ✓ Crash cart, Suction apparatus
 - ✓ Nebulizers and Infusion pumps.



Bioanalytical Infrastructure



Bioanalytical Lab

- State-of-the-art Instrumentation.
- Team of 65 qualified and experienced researchers with experience in method development, validation and sample analysis for wide range of chemically diverse drug molecules.
- Analysis of drugs and/or metabolites in biological specimen (Viz. blood, plasma, serum, urine) to support BA/BE studies.
- **Total Mass Specs: 24 & 3 ICP MS**
- **Over 380 validated methods available as per USFDA/EMA/ANVISA guidelines.**



Diagnostics Lab: Infrastructure

- Offers clinical testing service exclusively for BA/BE studies.
- Certifications & Accreditations:
 - College of American pathologists (CAP)
 - NABL
- Equipped with automated equipment's including:
 - Random access Biochemistry analyser
 - Haematology analyser
 - Urometer
 - Refrigerated Centrifuge
 - ESR analyser
 - ELISA reader
 - ELITE analyser



Experience With Different BA/BE Study Designs

- Specializing in **Highly Variable Drugs** – semi replicate and replicate design studies.
- Optimal Cross Over Designs.
- Parallel Designs for long half life drugs.
- BE on **Narcotic Drugs**.
- Studies on **locally acting drugs** - GIT
- BE studies on **specialized populations** – post menopausal females, patients, elderly population

Regulatory Track Record

- Azidus facilities are audited by major pharmaceutical Co's & Regulatory agencies.
- Major regulatory approvals are:
 - ANVISA, Brazil
 - College of American pathologists (CAP)
 - Drug Controller General of India (DCGI)
 - EMA
 - GLP Poland
 - ISO Certifications, Rhineland
 - ISP Chile
 - MoH Turkey
 - MoH UAE
 - NABL, India
 - USFDA Inspected
 - WHO



US FDA Inspection History

- First FDA Inspection: 16th June to 21st June, 2014 (Mr Scott Laufenberg & Dr Gopa Biswas) – Clinic and BA lab. (form 483 issued and responded)
- 18th January – 26th January, 2016. FDA inspection (Ms. Laverne Puckett) – Clinic only inspection (No 483 issued)
- 14th March – 18th March, 2016 FDA BA lab inspection (Dr Sripal Mada, Mr Dipesh Shah, Dr Melkamu G) (483 issued and responded)
- 1st September – 9th September, 2016 FDA BA lab inspection (Dr Sripal Mada, Dr Gajendiran M, Mr Daniel Roberts) (483 issued and responded)
- 15th October – 23rd October, 2018 FDA clinical inspection (Ms. Brandy davis brown) (No Observations & Recommendations)
- 3rd December – 7th December, 2018 FDA BA inspection (Dr. Hasan Irier, Dr. Mohsen Rajabi) (No Observations & Recommendations)

ANDA Approvals

Drug Product	Date of Approval
Doxorubicin Hydrochloride (Liposomal)	Feb 04, 2013
Acitretin Capsules	May 22, 2015
Tetrabenazine Tablet	August 17, 2015
Milnacipran Tablet	October 09, 2015
Olmesartan Medoxomil Tablet	March 18, 2016
Potassium Chloride Tablet	August 19, 2016
Memantine Hydrochloride Capsule	January 09, 2017
Fingolimod Capsule	March 22, 2017
Olmesartan Medoxomil and Hydrochlorothiazide Tablet	April 24, 2017


ANDA Approvals (Continued)

Drug Product	Date of Approval
Losartan Potassium Tablet	August 14, 2017
Oxybutynin Chloride Tablet	October 23, 2017
Dofetilide tablet	March 26, 2018
Nitroglycerin Sublingual Tablet	May 07, 2018
Ciprofloxacin Hydrochloride Tablet	June 22, 2018
Asenapine Sublingual Tablet	July 17, 2018
Topiramate 200mg Capsule	Sep 24, 2018
Dofetilide Tablets	Oct 09, 2018


ANDA Approvals (Continued)

Drug Product	Date of Approval
Dofetilide Tablets	Oct 09, 2018
Clobazam 20mg Tablets	Oct 22, 2018
Albuterol Sulfate	Oct 26, 2018
Anastrozole 1mg Tablets	Nov 09, 2018
Letrozole 2.5mg Tablets	Nov 14, 2018

Recent Inspections at Azidus



Clinical inspection on Oct 18'
with NO OBSERVATIONS



Bioanalytical inspection on Dec 18'
with NO OBSERVATIONS



Clinical & Bioanalytical
inspection on Jun 18' with NO
OBSERVATIONS



World Health
Organization

Clinical & Bioanalytical
inspection on Nov 17' with NO
OBSERVATIONS

- We have a dedicated clinical & bioanalytical facility in Wisconsin, USA.
- The facility is equipped with 60 beds and 3 LC MS/MS for Bioanalysis.
- It is operative since Q4 FY'18.



- Azidus laboratories, India acquired Lal Clinica, in Brazil on October 2016 and started BA/BE services under the name Azidus Brazil.
- It has state-of-the-art Clinical facility and specializing in controlled substance and biologics research.
- The facility is equipped with 57 beds.
- Clinical Research Services :
 - BA/BE studies
 - Phase 1-4 Studies
 - Specialised in controlled drug substance clinical research
 - Biosimilars clinical development



Why AZIDUS ?



AZIDUS Business Focus – Science Driven

- Making Science of research simple and affordable to all.
- Bridging the technology gap in developing countries and striving for innovation in developed countries around the globe.
- Science and Ethics come first !

**Some of our
Client
TESTIMONIALS**

Sigma Pharma, USA

Spiro Spireas 

12 August 2013 7:34 pm



To: Dad, Rakesh Grover Cc: Arjun Arumugam O, Shilpa Dangeti, Ishari Piya, [and 3 more...](#)

RE: Asenapine 10 mg tablets Study Report

Olaganathan,

Thank you very much indeed for your kind words and herculian efforts to complete the Asenapine study and report on time. We, at Sigmapharm, consider it a privilege to work with such a thorough, reliable and diligent team as is yours at Azidus.

All the best,

Spiro

Spiro Spireas, Ph.D.
Chairman & CEO
SigmaPharm Laboratories, LLC



Sigma Pharma, USA – Potassium Chloride Approval

Drugs@FDA: FDA Approved Drug Products

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Abbreviated New Drug Application (ANDA): 207528

Company: SIGMAPHARM LABS LLC

[EMAIL](#)

Products on ANDA 207528

[CSV](#) [Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	8MEQ	TABLET, EXTENDED RELEASE;ORAL	Prescription	AB2	No	No
POTASSIUM CHLORIDE	POTASSIUM CHLORIDE	10MEQ	TABLET, EXTENDED RELEASE;ORAL	Prescription	AB2	No	No

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for ANDA 207528

Original Approvals or Tentative Approvals

[CSV](#) [Print](#)

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
08/19/2016	ORIG-1	Approval		STANDARD		Label is not available on this site.

EMS, Brazil

----- Forwarded message -----

From: Milena Morita - Bioequivalencia <milena.morita@ems.com.br>

Date: 2013/5/1

Subject: reports

To: "Basilea (basilea@azidus.com)" <basilea@azidus.com>

Cc: ARUMUGAM OLAGANATHAN <olaganathan.arumugam@gmail.com>, Henrique Maia Viana <henrique@molkom.com.br>, Roberta Bozutto - Bioequivalencia <roberta.bozutto@ems.com.br>, Roberta Ferreira - Bioequivalencia <roberta.ferreira@ems.com.br>, Mauricio Magalhães - Bioequivalencia <mauricio.magalhaes@ems.com.br>

Dear Basilea,

Please find attached the evaluation reports of study.

Congratulations for all Azidus team!!! the bioanalytical report has no observation/correction to do.

The clinical and statistical reports have few observations. We are very satisfied with our partnership.

Could you send us the final version until 3rd of May?

Thank you and regards,

Milena



PAR Pharmaceuticals, USA

From: "Vattikonda, Chandra" <Chandra.Vattikonda@parpharm.com>
Subject: RE: Thanks
Date: 11 June 2013 2:52:17 PM IST
To: 'Basilea Gunalan' <basilea@azidus.com>
Cc: 'ARUMUGAM OLAGANATHAN' <olaganathan.arumugam@gmail.com>, 'Arjun Arumugam' <arjun@azidus.com>

Dear Basilea,

It's a great execution of sprinkle study. Big "Thank you" to all of your team. ISR data reflects the quality of data.

Thanks and regards, Chandra

Chandra Vattikonda, M.Pharm., Ph.D. | Executive Director, Biopharmaceutics
Par Pharmaceutical Companies, Inc. | One Ram Ridge Road | Spring Valley, NY 10977
Phone: 845.573.5784 | Chandra.Vattikonda@parpharm.com
www.parpharm.com



Bilim İlaç Turkey

From: "Chandrashekhar MAINDE (Bilim İlaç)" <Cd.Mainde@bilimilac.com>

Subject: RE: Requests about Bilim's studies

Date: 16 December 2013 3:28:38 PM GMT+02:00

To: Müge CİVELEKOĞLU (Bilim İlaç) <Muge.CIVELEKOGLU@bilimilac.com>, Krishnakumar <krishnakumar@azidus.com>

Cc: "Arjun Arumugam (arjun@azidus.com)" <arjun@azidus.com>, "ARUMUGAM OLAGANATHAN (olaganathan.arumugam@gmail.com)" <olaganathan.arumugam@gmail.com>

Dear Arjun

Thanks for expediting the reports. We will do the submissions in next 3 days. AZIDUS speed has been very impressive.

Thanks and REgards

1



Sun Pharma, India

----- Forwarded message -----

From: <Kirti.Ganorkar@sunpharma.com>

Date: Wed, Feb 6, 2013 at 5:47 PM

Subject: Liposomal Doxorubicin

To: sathish@azidus.com, dryathish@hotmail.com

Cc: Anil.Gite@sunpharma.com, Saumya.Shetty@sunpharma.com

Dear Dr. Olaganathan/ Dr. Yathish,

We are please to inform you that our Liposomal Doxorubicin has been approved by US FDA.

We would like to thank you for your support for this project.

Kind regards,

Kirti Ganorkar

Sr. Vice President (Business Development)

Development

Anil Gite

Manager - Business



Sun Pharma, India

Dear Azidus Team,

Greetings from Sun Pharma!

We are pleased to share with you that Sun Pharma has received final USFDA approval for its Tetrabenazine ANDA.

We thank you for your support in conducting BE study for this product and your extended support in responding to FDA queries. We appreciate your work and we value our partnership. Sun Pharma will continue to work with partners which value USFDA Quality Standards and focus to remain in Compliance

Many congratulations to entire Azidus team for its work!!!

Regards,
Anil Gite
Business Development Manager

Sun Pharmaceutical Industries Ltd
SUN HOUSE, 201 B/1,



Intelli pharmaceuticals, Canada

From: Dr Isa Odidi <IOdidi@intellipharmaceutics.com>
To: Murugan AZIDUS <bd@azidus.com>
Cc: Dr Amina Odidi <AOdidi@intellipharmaceutics.com>, Yogish Kamath <ykamath@intellipharmaceutics.com>, ARUMUGAM OLAGANATHAN <olaganathanarumugam@gmail.com>, Arjun Arumugam <arjun@azidus.com>
Date: 26 August 2015 8:14:54 pm IST
Subject: Re: AZIDUS CRO - trial completion

Congratulations for another great achievement. We are proud to be associated with your CRO.

Prof. Isa Odidi | Executive Education in Innovation for Economic Development (Harvard University, Kennedy School) | MBA (University of Toronto, Rotman School of Management) | B.Sc., Pharmacy (ABU, Zaria) | M.Sc., Pharmaceutical Technology (University of London, Kings College) | Ph.D., Pharmaceutics (University of London, School of Pharmacy) | Doctor of Science, Honoris Causa (University of Benin) |

Chairman | CEO | co-Chief Scientific Officer |
Intellipharmaceutics International Inc. | [30 Worcester Road | Toronto](#) | Ontario | M9W 5X2 | Canada |



Abbott, Netherlands

From: [Peter van Amsterdam](#) >

To: [Imran Mubashir](#) >

Hide

PV

Cc: [Dr. K. P.Aparna Mani CL](#) > [Arjun](#) > [Dr geetha](#) >

[Sudipta Basu](#) > [Carolien Eggink](#) > [Erik Gout](#) >

[Ruchira Jackson](#) > [Elke Kahler](#) > [LiHeng Tao](#) >

[Anca Miclea](#) > [Srinivasgopi CL](#) >

RE: DEVE1001 & DEVE1002: Kick Off meeting

8 November 2018 at 4:52 PM

📧 Found in geetha@azidus.com Inbox

Dear Imran,

I have reviewed the validation report and am quite happy with the data and the way they are presented.

With Kind Regards,

Peter

If guns don't kill people, people kill people. Does this mean toasters don't toast toast, toast toast toast?



Abbott, Netherlands

From: [Peter van Amsterdam](#) >

To: [Srinivasgopi CL](#) >

Hide

PV

Cc: [Arjun](#) > [Arjun](#) > [Dr geetha](#) > [Htar Htar Nwe](#) >

RE: [REDACTED]: bio-analytical method development (?)

9 May 2017 at 9:45 PM

Found in geetha@azidus.com All Mail Mailbox

Thanks for sharing, Srinivas.

Impressive data. No questions and no worries J

With Kind Regards,

Peter

If you spill cleaning product, did you make a mess?





Audit Report

Abbott – Established Pharmaceuticals Division, GCP Quality Assurance

Audit Site: Azidus, Chennai, India

DABI1001 trial

Abbott Audit Reference Number: AudiQ # 405109

FINAL AUDIT REPORT

DABI1001 – AZ/BE/11/17/25 – Clinical Study Report

Audit Site Remote
Site involved in the audited purpose:
Azidus Laboratories Ltd.
No.23rd School Road, Rathinamangalam,
Behind Tagore Engg.College (Via) Vandalur,
Kelambakkam Road, Chennai - 600 048.
Tamil Nadu, India

Auditor(s) Yves de Ryck, Senior QA Specialist, Lead auditor

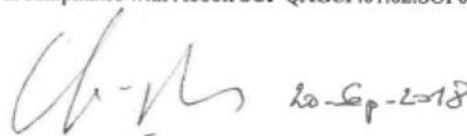
Audit Date(s) 22 March to 23 April 2018

Abbott Audit Reference Number AudiQ # 405109

Items Audited

Purpose of this audit was to evaluate quality of the Clinical Study Report (CSR) for Abbott trial DABI1001. The audit was conducted in compliance with Abbott SOP QAGCP.01.02.SOP01 GCP Audit Management.

Auditor (signature & date)



20-Sep-2018

Distribution List (To)

Azidus :
Dr Geetha Lakshmi, Director QA
Srinivas Gopineedu, Project manager

Distribution List (cc)

Azidus:
Dr. Arjun Arumugam O, Director

Abbott:

Simonetta Astolfi, Director QA GCP/GLP/GVP
Sudipta Basu, Associate Dir Clinical Devpt
Ingrid Meuwsen, Dir Clinical Pharmacology

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Not to be retained in the Trial Master File, if applicable

Audit Report

Abbott – Established Pharmaceuticals Division, GCP Quality Assurance

Audit Site: Azidus, Chennai, India

RIXA1001 trial

Abbott Audit Reference Number: AudiQ # 396697

FINAL AUDIT REPORT

RIXA1001 – Data Management / Statistics Services

Audit Site Azidus Laboratories Ltd.
No.23rd School Road, Rathinamangalam,
Behind Tagore Engg.College (Via) Vandalur,
Kelambakkam Road, Chennai - 600 048.
Tamil Nadu, India

Auditor(s) Yves de Ryck, Senior QA Specialist, Lead auditor
LiHeng Tao, Clinical Data Specialist

Audit Date(s) 28 & 29 November 2017

Abbott Audit Reference Number AudiQ # 396697

Items Audited

Purpose of this audit was to evaluate compliance against RIXA1001 trial requirements outlined in the Data Management Plan (DMP) and Statistical Analysis Plan (SAP) as well as against regulatory requirements for data review and data handling methods. The audit was also conducted in the perspective frame of the formerly conducted trial DYDR1001 against so called "lessons learnt" and related CAPAs, which were designed after a series of evaluation sessions that reflected the need for improving data management and statistics processes within Azidus.

Auditor (signature & date)



15-Feb-2018

Distribution List (To)

Azidus :
Dr Gheeta Lakshmi, Director QA
Srinivas Gopineedu, Project manager

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Dr. Arjun Arumugam O, Director Azidus
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M. Balaji, Statistician

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Simonetta Astolfi, Director QA GCP/GLP/GVP
Heike Dreher, Data Operations Expert
Stefan Driessen, Director Biometrics
Gregor Eibes: Senior Clinical Trial Manager
LiHeng Tao, Clinical Data Specialist

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Email: bd@azidus.com

THANK YOU