Bilcare Research | Global Clinical Supplies

Services Overview

Bilcare GCS Objective

To Provide Reliable and Credible Long-term

Clinical Trial Material Supplies

Partnering with Global Sponsor/CRO

to successfully conduct the Clinical Trials, Worldwide

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Bilcare GCS Highlights

Established in 2006 as a division of Bilcare Ltd. (Global Leader in Pharmaceutical Films and Foils)

1st GMP facility for Clinical Trial Material Supplies in Asia

Team of professionals having required qualifications in respective fields

Experienced Top Management with collective work experience of over 150 years

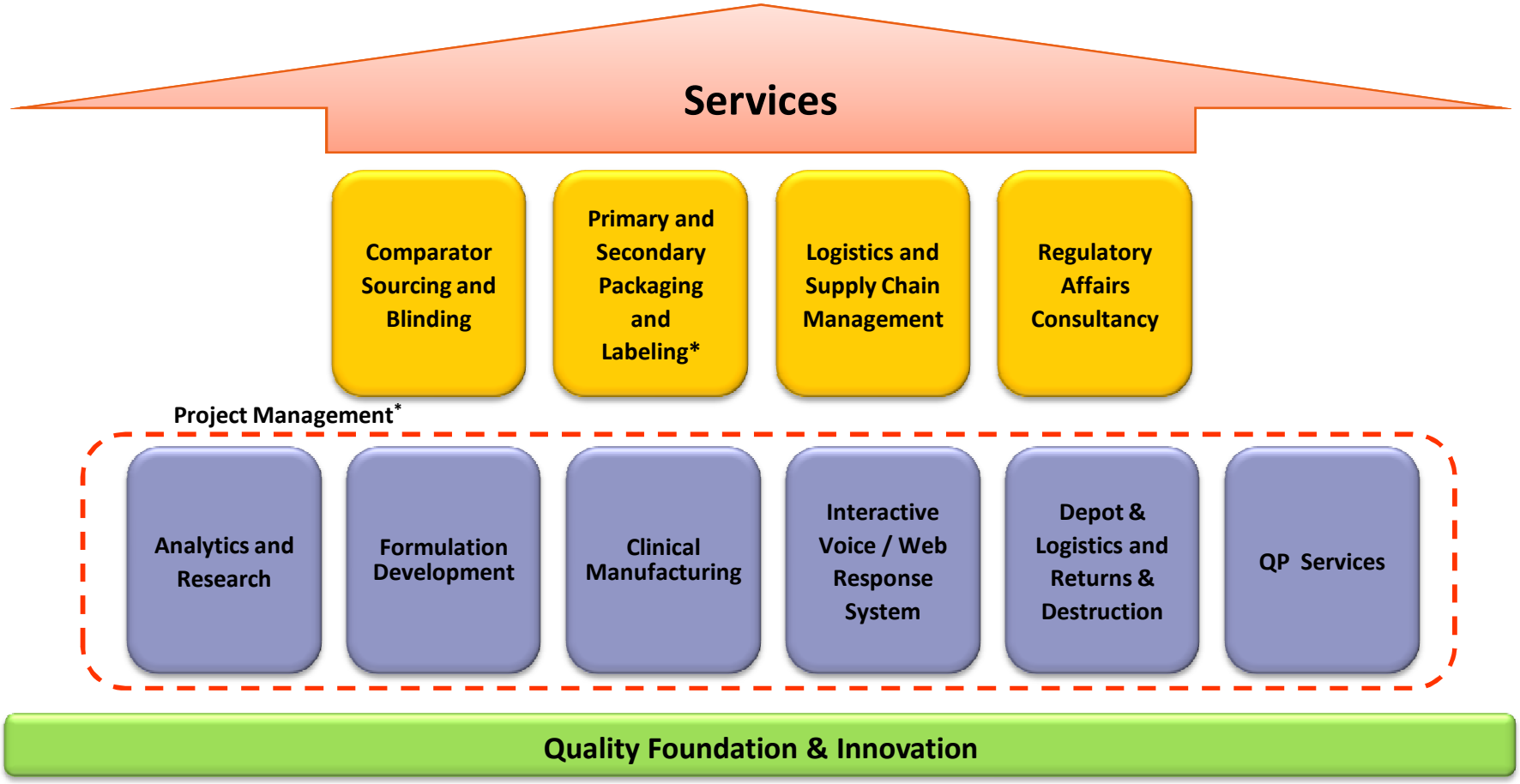
Achieved CAGR 70% in revenue since inception, Profitable venture since start-up with RoC of over 30% p.a.

Over 50 current Clients consisting of Global Innovator companies, Indian Pharma MNCs, International & Domestic CROs and Global NGOs

Company Qualified itself with ISO Certification, TuV Germany and PIC/S certification besides by 7 QPs from EU

Bilcare GCS Service Offerings

Bilcare GCS delivers end-to-end solutions that offer support through the entire clinical trial life cycle



* Services through strategic partners; Bilcare Optima

Comparator Procurement & Ancillary Supplies

Comparator Procurement for Global Clinical Trials from any region of the world

Global partnership with manufacturers and whole-sellers to ensure credibility

Ability to source whenever, wherever

Pedigree of the Product from manufacturer's warehouse to the final destination.

COA and MSDS form the basis of procurement

Facilitate Import & Export compliances together with Logistic support

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Packaging & Labeling Expertise

Primary Packaging
Blister Packaging: Any combination of Solid dosage forms and Child Resistant Packs *(Source: Bilcare Pharma Packaging Innovations)*
Bottling: Solid dosage forms (tablets/capsules)
Sterile dosage forms
Liquids / Ointments/ Creams
Encapsulation and Over encapsulation
Barrier packaging solutions for Oxygen Sensitive Products
Secondary Packaging & Labeling
Protocol specific pack designs (Patients Cards, Patient Kits, Wallets etc.) and Kit assembly
Label Design and generation (Single Panel/ Double panel, Booklet Labels)
Cold Card Sealing & Walleting
Operations at Controlled ambient (15-25 Deg C), Refrigerated (2-8 Deg C) & at Frozen condition (-20 Deg C)
Blinding of Inhalers and Pre-filled syringes

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Packaging & Labeling

Bilcare Optima™

An extensive research based Patented Innovative Packaging Solution for identification of optimum packaging for pharmaceutical formulations

Scientifically developed method that identifies the optimum packaging of any pharmaceutical dosage by understanding the degradation pattern of the formulation and correlating it to the barrier property of the packaging material without conducting the conventional stability studies

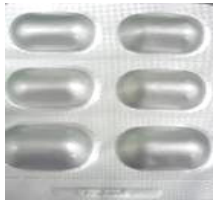
Very useful for stabilizing new formulations as well as optimizes the packaging requirement of existing formulations. Ready QBD (Quality by Design) data for regulatory Submissions

Helps create pharma brand identity through safe and secure packaging material and packaging design – saves on Primary & Secondary Packaging and thereby logistic cost

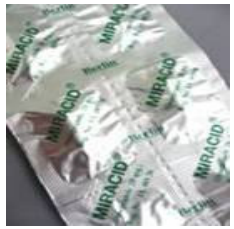
New formulations

Bottles

Blister



Alu-Alu



Alu-Strips

Double Packs

Optimum Packaging for your formulations from Pre Clinical to Commercialization Stage

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Packaging & Labeling

nonClonableID™ Technologies

Next-gen Smart Labels

Labels with the power of detecting counterfeit and also enabling secure track and trace

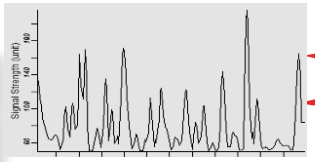
ncID is a path breaking technology developed by Bilcare with the core focus to arrest counterfeit and have a secure track and trace for effective Supply Chain. The ncID Labels are tamper evident and provide information about the product along-with its location by way of simple scanning devises developed by Bilcare.

Seamless process of application for nCiD Technology

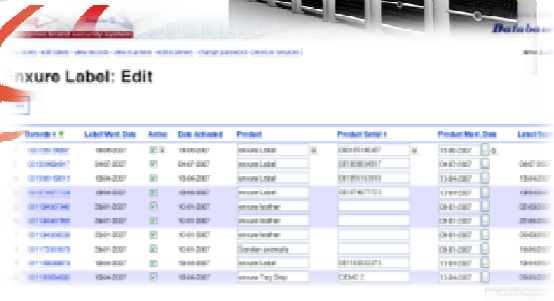
Tamper evident nCiD Chip

Tamper evident nCiD Chip

Scanners & Mobile Device



Central Server



Client portal

Supply Chain - Global Logistics & Distribution

Global supply chain & logistic network
Strategic tie ups with depot partners across the globe for global distribution
Tie-ups with well known courier agencies for domestic & international Shipping
Cold Chain Shipment Capabilities and secure Narcotics handling
Shipment Temperature Monitoring and Retrieval System
24x7 Customer Portal for Inventory & Delivery Status
SAP Inventory Management System

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Storage Capabilities

Storage of Drugs & Biological

Controlled Ambient (15 - 25 deg C) & (20 – 25 deg C)

Refrigerated (2 - 8 deg C)

Frozen (- 20 deg C)

Deep Freeze (- 70 deg C)

Liquid nitrogen (-150 deg C)
Vaccines, Injectables and Biosimilars

Storage of Controlled Drug Substances

Equipped with Alarm system and Access control

Double Lock & Key system

24x7 surveillance through closed circuit cameras

Compliant with local and international regulations

Secured data through regular system back-up

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Global Regulatory Affairs Consultancy

Liaison services with Regulatory Authorities for:
Global Clinical Trials Phase II to IV
BA/BE (Bioavailability and Bioequivalence) studies
Controlled Drug substances approvals
Drug Import & Export Licenses
Shipping & Transportation Regulation
Label Design & Translation Services with regulatory support

"Global network of Regulatory experts with Local Knowledge"

Analytical & Formulation development and Clinical Manufacturing

Clinical Trials Manufacturing - Analytical and Formulation Development through USFDA and MHRA approved facilities globally
Analytical method development and validation
Qualification and validation
Phase I – IV development and pre-formulation
Active and placebo manufacturing
Blinding and encapsulation
Stability testing

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Interactive Voice/Web Response System (IVRS/IWRS)

New generation IVR/ IWR System

21CFR part 11 Compliant, User friendly, enables data entry direct from the source, available 24x7 call support, multilingual

Phone or web management during site initiation, patient enrolment, randomization and drug management

Patient enrolment, randomization, tracks clinical supplies inventory and automatically re-supplies CTM

Calculates overages which reduces usage of IMPs resulting in Cost optimization

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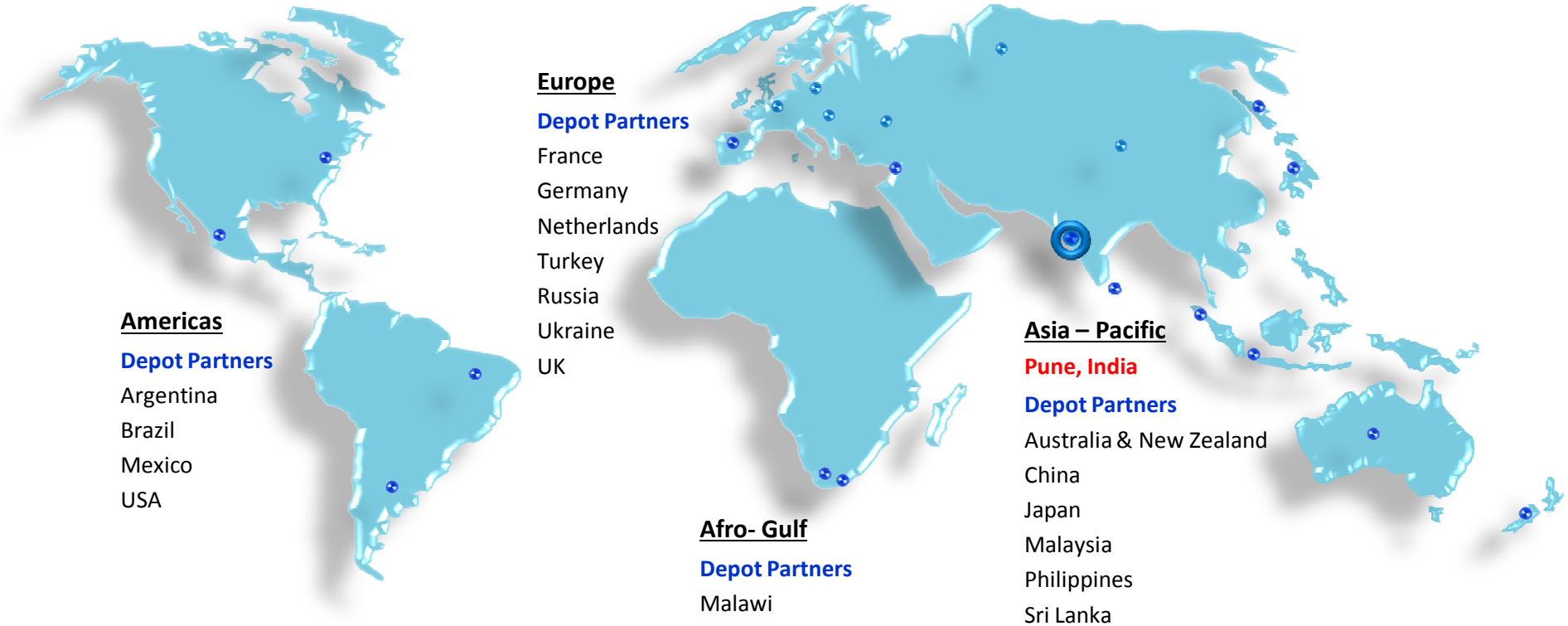
Global Depot Network



Americas

Depot Partners

Argentina
Brazil
Mexico
USA

Europe

Depot Partners

France
Germany
Netherlands
Turkey
Russia
Ukraine
UK

Afro- Gulf

Depot Partners

Malawi
South Africa
Israel

Asia – Pacific

Pune, India

Depot Partners

Australia & New Zealand
China
Japan
Malaysia
Philippines
Sri Lanka
Singapore
South Korea
Taiwan
Thailand

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Global Depot Capabilities Matrix

SERVICES	US	MEX	ARG	UK	SA	IND	SING	TAI	PHI	AUS
Visual Inbound Inspection for Chilled Products +2 to +8 Deg. C	√	√	√	√	√	√	√	√	√	√
Visual Inbound Inspection for Ambient Products +15 to +25 Deg. C	√	√	√	√	√	√	√	√	√	√
Booking Product into ERP System	√	√	√	√	√	√	√	√	√	√
Storage Costs for Chilled Products +2 to +8 Deg. C	√	√	√	√	√	√	√	√	√	√
Storage Costs for Ambient Products +15 to +25 Deg. C	√	√	√	√	√	√	√	√	√	√
Pick Material	√	√	√	√	√	√	√	√	√	√
Dispatch Packaging for Chilled Products +2 to +8 Deg. C	√	√	√	√	√	√	√	√	√	√
Dispatch Packaging for Ambient Products +15 to +25 Deg. C	√	√	√	√	√	√	√	√	√	√
Temperature Data Logger	√	√	√	√	√	√	√	√	√	√
Shipping Box	√	√	√	√	√	√	√	√	√	√
Return of Temperature Monitor	√	√	√	√	√	√	√	√	√	√
Destruction Services	√	√	√	√	√	√	√	√	√	√
Road Freight Costs for Chilled Products +2 to +8 Deg. C	√	√	√	√	√	√	√	√	√	√
Road Freight Costs for Ambient Products +15 to +25 Deg. C	√	√	√	√	√	√	√	√	√	√
Air Freight Costs for Chilled Products +2 to +8 Deg. C	√	√	√	√	√	√	√	√	√	√
Air Freight Costs for Ambient Products +15 to +25 Deg. C	√	√	√	√	√	√	√	√	√	√
Road Freight Costs for Chilled Products +2 to +8 Deg. C	√	√	√	√	√	√	√	√	√	√
Road Freight Costs for Ambient Products +15 to +25 Deg. C	√	√	√	√	√	√	√	√	√	√
Import Licence	√	√	√	√	√	√	√	√	√	√
Assembly	√	√	√	√	√	√	√	√	√	√
Relabeling Outer Labeling	√	√	√	√	√	√	√	√	√	√
Relabeling for Inner Labeling	√	√	√	√	√	√	√	√	√	√
Release of Relabeling Process	√	√	√	√	√	√	√	√	√	√
Label Design	√			√		√	√			√
Label Generation	√			√		√	√			√

Global - Returns & Destruction

On request arrangement of return shipment pick up from sites

Handling of Clinical Supply Returns as per Protocol

Reconciliation up to Kit level traceability

Destruction by Approved Agencies

Issuance of Destruction Certificate

QP Services

- EU – GMP audit of manufacturing and API sites outside the EU
- Validation status of facilities, processes and methods
- Examination of finished packs
- Provision of regulatory guidance in all areas of IMPs
- Assistance with creating Product Specification Files/ Investigational Medicinal Product Dossier
- Assistance with obtaining site GMP Certification
- Batch releases

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India Facility Overview

Facilities: Primary & Secondary Packaging

- 03 Primary & 10 Secondary Packaging GMP Suites
- Installed with validated & qualified equipments
- ISO Class 7 (Class 10000) areas for Primary Packaging Operations
- ISO Class 8 (Class 100000) areas for Secondary Packaging Operations
- Dedicated AHU's with Air filtration through 0.3 Micron Terminal HEPA

Facilities: Warehousing, Storage & Distribution

Dedicated areas
Loading & Unloading
Receipt & Dispatch
Quarantine & Inspection
Raw & packaging Material Storage
Semi finished & Finished material Storage
Secured storage for Controlled Substances
Storage & Distribution at Controlled Ambient, 15 -25 Deg C, 2-8 Deg C Frozen (-20 & -70 Deg C) Condition
Return Material Storage
Reject Material Storage

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Facilities: Warehousing, Storage & Distribution

Storage at Controlled Ambient
Closed cubicles of 0.5 Cu M with lock & key arrangements as well as open cubicles of 0.5 Cu M & pallets
Controlled Drug Substances: controlled ambient

Cold Storage
Closed cubicles of 0.25 Cu M & 0.5 Cu M with lock & key arrangement
Dual use freezer rooms -20^{o} Deg C/ 2^{o} -8^{o} deg C
Storage capability at 2^{o} to 8^{o} deg C for controlled substances
-70^{o} Deg C : Deep Freezer for storage of biological products

Power Backup Support

Uninterrupted Express Feeder line from State Electricity Board

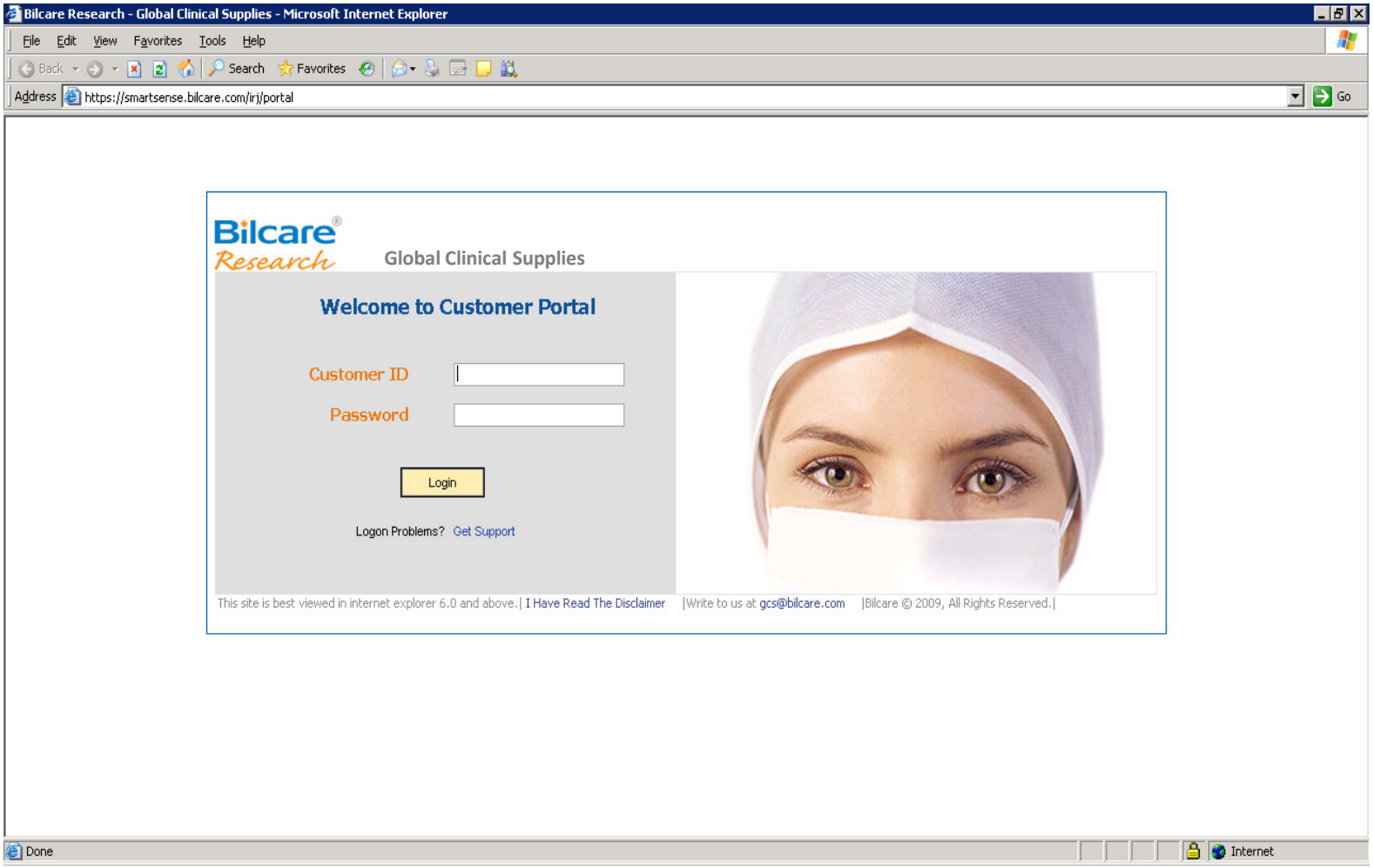
Cold rooms & Critical machines like blister machine etc. on 120 KVA UPS for 30 min.

Four synchronized Diesel Generators (1000 KVA & three of 500 KVA)

Technology Initiatives

21CFR Part 11 Compliance System
SAP ECC 6.0
Inventory Management System with kit level traceability
24 x7 Inventory visibility through Customer Web Portal and tracking of consignments
Shelf Life Monitoring with provision of auto alerts (Expiry Date Monitoring)
24X 7 CCTV Monitoring for controlled drug substances and entire facility
Escalations of Cold storage temperature variations through mobile and email alerts

Reporting Customer Web Portal: Smart Sense



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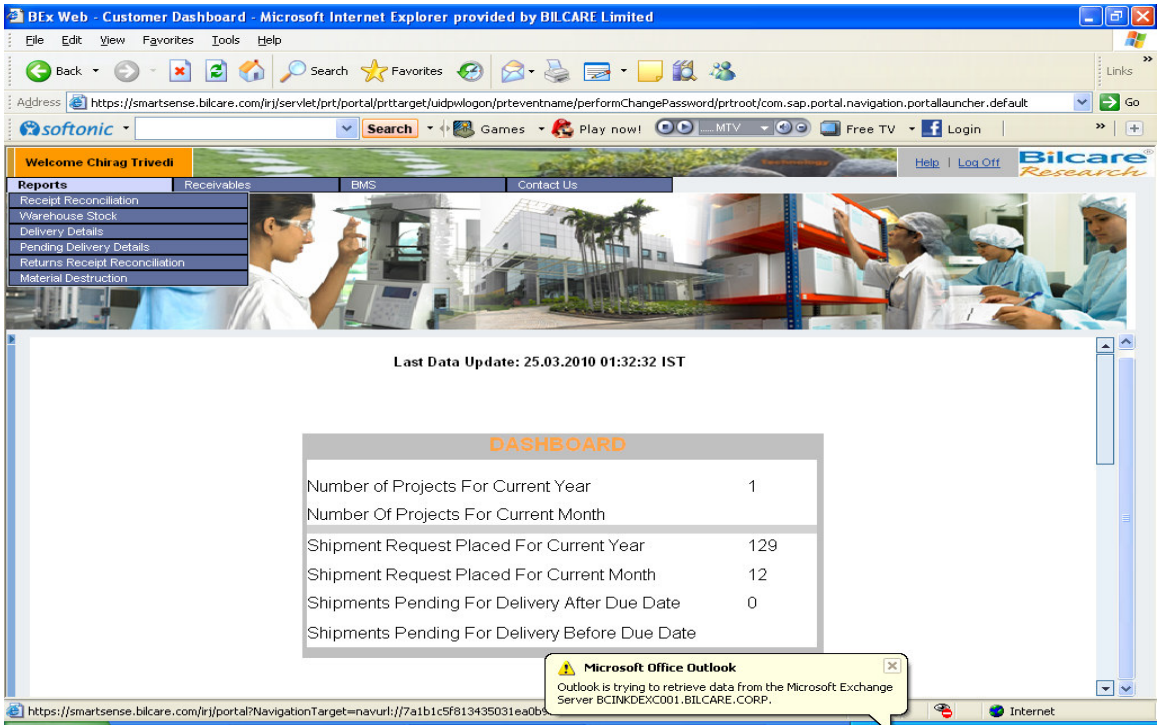
Reports on customer portal

Receipt Reconciliation

Clinical Material Inventory

Pending Shipment



Receivable ageing

Return Receipt Reconciliation

Shipment Distribution

Technology Initiatives : Building Management System

21 CFR Part 11 Compliant System

24 x 7 visibility of Temperature & Humidity of packaging, labelling, storage & Distribution areas through Customer Web Portal

Monitoring, controlling, alarming, trending, reporting and archiving of the same

Monitoring of AHU and Chillers for their running status

Global – Project Management

Project Management

- Leverage partners' expertise to ensure efficiency and speed throughout the clinical trials process

Analytics

- On behalf of global sponsors, carry out method development, validations and stability studies
- Act as bridging manager for monitoring to ensure timely delivery of the project with all the relevant records submitted

Formulation

- Projects accepted from Global Pharma companies include formulation development
- Close monitoring and execution of projects as overseeing manager

Manufacturing

- Projects accepted from Global Pharma companies include manufacturing of Placebo and Actives
- Act as bridging manager between manufacturing company and global sponsor

IVRS / IWRS

- Strategic & exclusive relationship with IVRS service provider in Asia to market IVRS & IWRS services
- Act as a PMO officer in Asia for all our global sponsors
- Marketing concept and business development strategies are defined by Bilcare GCS

Depot and Shipping

- Strategic partnerships with several audited & qualified depots in Asia, Africa, CIS Countries, Europe, USA and Latin America
- Coordination and management of all depots and supply chain management

QP / IMPD

- Bilcare GCS has strategic relationship with 4 QPs in European region for release

Continuous Improvement Processes

Lessons Learned at the completion of each project serves as the primary process improvement initiative

Outcomes of Monthly/Quarterly calls of Bilcare Management with Customer Management on Service level

Customer Feedback Forms outlining areas of improvements

Learning also comes from Self Inspections, External Audits including customer & Regulatory Audit, Participation in Seminars, Conferences and External Trainings

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Project Handling Expertise

Phase II, Phase III, Double Blind, Double Blind Double Dummy, Open label, Safety & Efficacy Studies

Phase III Studies involving Manufacturing, Blinding to Distribution Operations for multinationals

Handled 2-6 arm placebo and active controlled studies

Executed short-term (1 Month) and long term (3 years) study

Handled Phase III double blind, randomized trial on Biologics with EDC control and patient specific packaging and distribution at 2-8 Deg C. to 20 different sites.

Project Handling Expertise (Contd…)

Studies involving packaging operations at low humidity (Less than 30%), 2^{o} -8^{o} Deg C etc
Successfully handled storage, distribution, return, destruction including regulatory support for controlled drug substance
Studies involving import & export from US, EU & Other parts of the globe
12 week Randomized, Double Blind, Triple Dummy, Parallel group, Placebo controlled dose rage finding study. Trial conducted into India, Czech, Poland, Russia and UK, with IVRS in 3 languages

Bilcare GCS Quality Policy

Team Bilcare is committed to offer a wide range of Innovative Services
to the Global Pharmaceutical Industry that includes
Clinical Trial Manufacturing, Packaging Design and Development, Labeling,
Sourcing of Innovator Drug Products, IVRS/IWRS
and Storage & Distribution of Investigational Medicinal Products.

Our endeavor is to provide Credible, Safe, User-friendly, Cost effective and
Creative Solutions for 'Clinical Trial Material Supplies' Business,
together with the Strategic Partners and are aimed at our Customers' Success.

Our focus on Customer Satisfaction through Consistency in Quality,
Cost and Service Standards is benchmarked against the Global best.

Excelling through continual Self Improvement is a way of life at Bilcare.

Bilcare GCS Quality Management Systems

Quality directly reports to CEO thereby ensuring independence
Standard Operating Procedures aligned with USFDA/ MHRA
SOP's for vendor qualification and auditing
Self Inspections
Periodic internal and external training on cGMP, GDP, GWP ,GCP, SOP's etc. and knowledge evaluation
Deviations and Change Control Management System
CAPA Management
Handling of Customer Complaints
Risk Management
Business continuity plan
Validations ,Qualifications and maintenance of premises, equipment utilities & services

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ISO & GMP Certificates

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
Trading as TÜV SÜD South Asia Private Limited
certifies that

Bilcare Limited - Global Clinical Supplies
Gat No. 1028, Village Shiroli, Rajgurunagar, Tal.Khed,
Dist-Pune - 410 505, INDIA

has established and applies
a Quality Management System for

Design of Packing for Investigational Medicinal Products.
Sourcing of Innovator Drugs. Packaging, labeling,
Storage and Distribution of Investigational Medicinal Products
and Innovator Drugs.

An audit was performed, Report No. **707009290**
Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled. The certificate is valid from **2013-06-19** until **2016-06-18**.
Certificate Registration No. **12 100 45767 TMS**

Product Compliance Management
Munich, 2013-06-20

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstraße 65 • 80339 München • Germany

Tel. No.: 020 - 2447 0276
Fax. No.: 020 - 2447 7555

No. Drugs. Mfg./GMP/ 595 -2014/Z-IV
Office of the Joint Commissioner (Pune Divn.)
Food & Drugs Administration [M.S.]
791/93, Lucky Building, New Guruwar Peth
Pune - 411 042, Maharashtra, INDIA

Dated : 02./ 01 /2014

Office of the Joint Commissioner (Pune Divn.) Pune ★ FOOD & DRUG ADMIN., M.S. ★

G.M.P. CERTIFICATE

This is to certify that, **M/s. Bilcare Limited**, situated at **1028, Shiroli, Rajgurunagar, Pune - 410505** is holding Drug Manufacturing Licences No. PD-191 in Form No. 25 and PD-113 in Form 28 dated 17.09.2008, valid upto 16.09.2018 to manufacture for sale, the drug/s approved to them by this Administration under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

The firm, by and large, is following GOOD MANUFACTURING PRACTICES in the Manufacture and Quality Control of Drugs as stipulated under the provisions of Schedule 'M' of Drugs and Cosmetics Rules 1945. The firm is subjected to periodical inspection by this Administration.

The firm should, however, carry out self inspection from time to time, to ensure that the requirements of Good Manufacturing Practices are complied with.

This certificate is issued on the request of the firm for the limited purpose of submitting the same to the, part of dossier for regulatory authority.

02/01/2014

(B. R. MASAL)
Joint Commissioner (Pune Divn.)
Food & Drug Administration,
Maharashtra State,
PUNE

PIC/S Certification

Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

GMP Certificate No.: 226/14

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Control Bureau, Ministry of Health Malaysia confirms the following:

The Manufacturer : **Bilcare Limited (Global Clinical Supply)**

Site Address : **Gat No. 1028, Shiroli, Rajgurunagar, Pune 410 505, India**

Has been inspected in accordance to Malaysian Control of Drugs and Cosmetics Regulations 1984 and Malaysian Drug Registration Guidance Document (DRGD).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 18 to 20 February 2014, it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-Operation Scheme (PIC/S) GMP Guides.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts I and II.

The authenticity of this certificate may be verified with the issuing authority.

SULAIMAN HJ. AHMAD
Head of Centre for Compliance and Licensing

Date: 22 May 2014

Page 1 of 2

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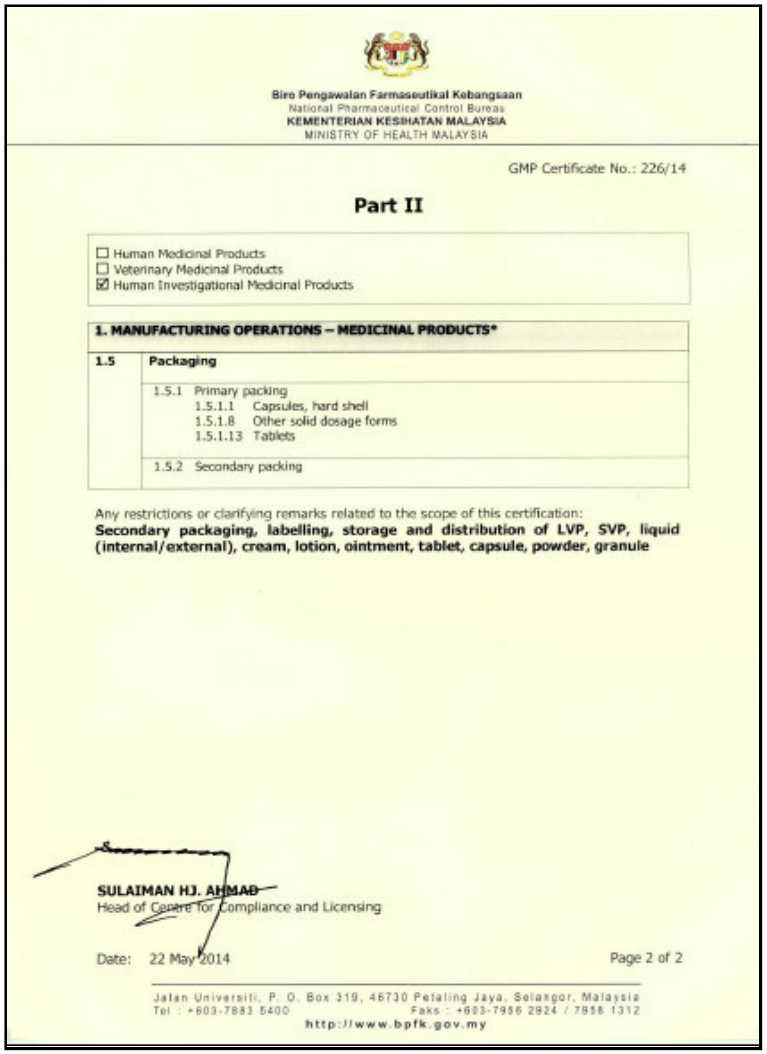
http://www.bpfk.gov.my



Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

GMP Certificate No.: 226/14

Part II

☐ Human Medicinal Products
☐ Veterinary Medicinal Products
☑ Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS*	
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	1.5.2 Secondary packing

Any restrictions or clarifying remarks related to the scope of this certification:
Secondary packaging, labelling, storage and distribution of LVP, SVP, liquid (internal/external), cream, lotion, ointment, tablet, capsule, powder, granule

SULAIMAN HJ. AHMAD
Head of Centre for Compliance and Licensing

Date: 22 May 2014

Page 2 of 2

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Bilcare Research | Global Clinical Supplies

"Experience Bilcare - Experience World Class Services"

www.bilcareGCS.com

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