CAD Middle East Pharmaceutical Industries LLC

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Overview

First cGMP compliant export oriented API facility in **MENA region**.

Multi-purpose facility having (6) manufacturing modules.

Designed by **Foster Wheeler**, a leading International designer, engineering, construction and project management contractor (Pharma design EU office).

Located at King Khalid International Airport, **Industrial Area and** developed under Economic Offset Programme.

Spread over 35,000 Sq. meters area **expandable** to 65,000 Sq. meters.

Our Vision

Redefining APIs
Market Values

To lead an ethical and quality oriented API manufacturing philosophy, CAD is committed to produce safe API governed with state-of-the-art services and logistical support, while walking the extra mile to exceed customer's satisfaction.

CAD Partners

TAKAMUL

ACDIMA

الدوائية
SPIMACO

dishman
PHARMACEUTICALS & CHEMICALS LIMITED
Capital Advisory Group
Acted As Project Advisor

Quality Policy

- ✓ CAD is built as state-of-the-art facility that shall be well known, trusted and respected organization in the pharmaceutical industry as an Active Pharmaceutical Ingredient (API) manufacturing company by ensuring that all our products are consistently produced and controlled as per the current local and international regulatory requirements and Good Manufacturing Practices (GMP).
- ✓ CAD Quality is the responsibility of all persons involved in manufacturing; accordingly CAD shall work towards building and maintaining a competent qualified team by enhancing the awareness and knowledge of employees through training and education.
- ✓ CAD shall work towards a common goal of achieving total customer satisfaction and confidence, and continual improvement by implementing the Quality Management System effectively.
- ✓ CAD Quality involves a wide range concept that covers the matters which individually or collectively influence the quality of a product.
- ✓ CAD Quality system has been established over the concept of that quality is built into product.

CAD Facility

A State of the Art Solution for The World

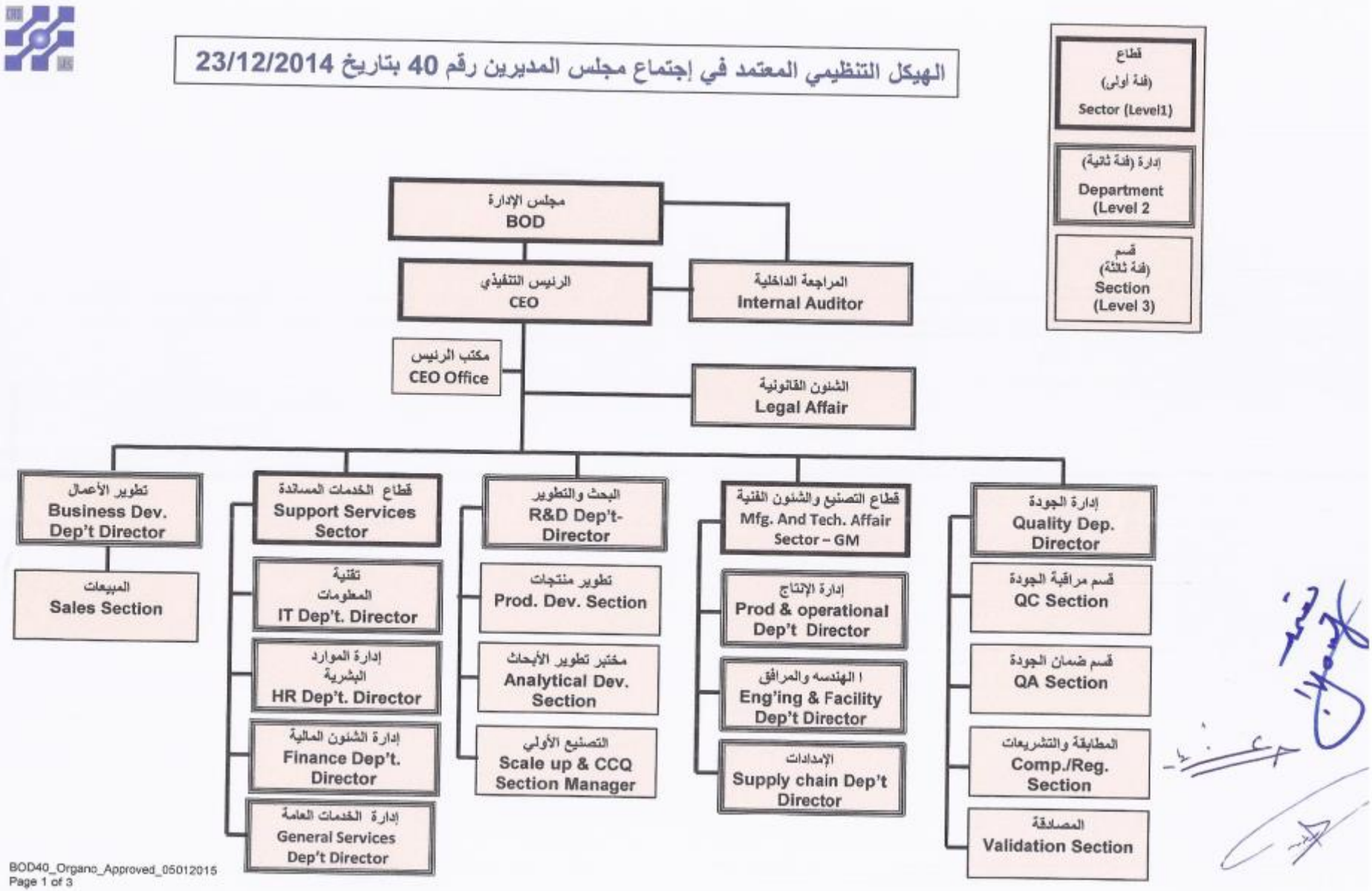






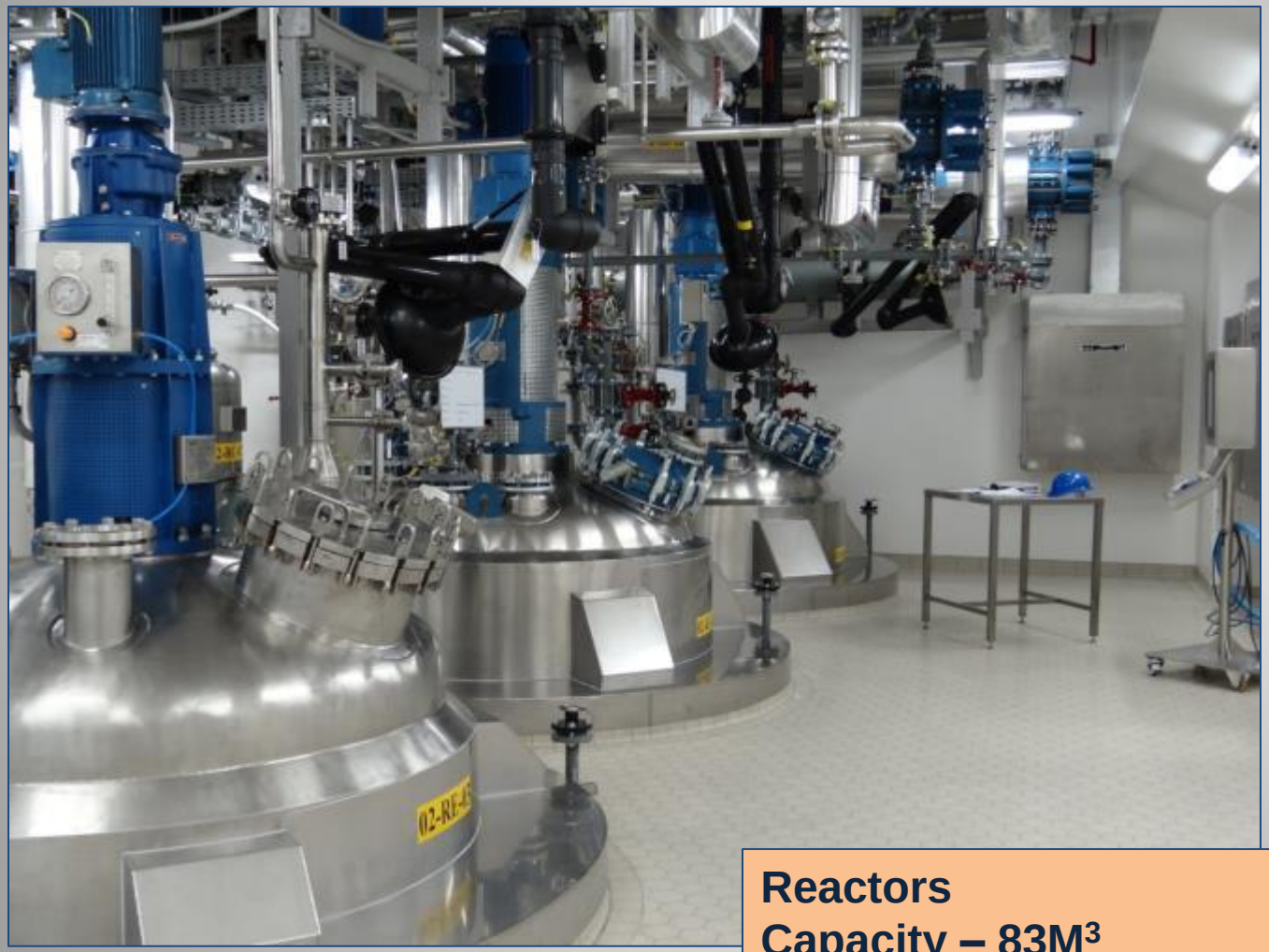



CAD Organizational Structure



CAD Technical Capabilities

Manufacturing Capabilities…



Reactors
Capacity – 83M^3
400 – 8,000 Liters
Stainless Steel, Hastelloy, Glass Lined

Manufacturing Capabilities

Closed Product Isolation System
Agitated Nutsche Filter Drier (ANFD),
Peeler Centrifuges,
Rotary Vacuum Drier (RVD)

Manufacturing Capabilities

Water Supply
Purified Water is generated 1,000 Liter/Hour output.

Utility Capabilities

Heating, Ventilation and Air Conditioning (HVAC)
Designed to prevent contamination and cross-contamination

Utility Capabilities

Chilling Capacity of 1,000 TR
(Ton of Refrigeration)
0r 3,500KW (Kilowatts)

Automated Mono fluid system for temp gradient from -30°C to +160°C.
Oil fired boiler
100% Power backup

Utility Capabilities

Gaseous Nitrogen supply from liquid Nitrogen system.

Environment Capabilities

Effluent Treatment Plant
Efficient Treatment Facilities for Handling Solid and Liquid Wastes

Safety System

Complete emergency handling system. Explosion proof design in accordance with IEC (International Electro-technical Commission, working under inert N_2 atmosphere.

CAD
Quality Management System

Quality Assurance

- **Well established Quality Management System (QMS) is in place to ensure the product quality, safety and efficacy as per the national and international guidelines such as SFDA, USFDA, EU-GMP, ICH,WHO and ISO.**

Quality Assurance

- **Quality Assurance core functions are as follows:**
  - Vendor Qualification
  - Standard Operating Procedures
  - Standard Testing and Method of Analysis
  - Document Control Activities
  - Batch Manufacturing Records
  - Batch Release
  - Change Control Management
  - Deviation Control
  - Out of Specification Handling
  - Recalls/ Returned Goods/ Complaints Handling
  - Internal Quality Audit (Self-Inspection)
  - Annual Product Quality Review
  - Trainings
  - Management Review
  - Risk Assessment
  - Data Integrity

Validation

- Building and Facility Qualification
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Water Validation
- HVAC Validation
- Nitrogen Validation
- Process Validation
- Cleaning Validation

Regulatory Affairs & Compliance

- Ensure that CAD products meet legislative requirements.
- Liaising and negotiating with regulatory authorities.
- Drug Master File (DMF) submitted to various regulatory authorities locally and internationally .
- Implements the current changes in regulatory requirements.

Quality Control

- Establish the standard specifications and test procedure for:
  - Raw Material
  - In-process
  - Intermediate
  - Finished Product
  - Packing Materials

- Test and release in line with in-house / pharmacopeia requirements for further usage.

Quality Control

- Conducts stability studies to assign the retest period and storage condition of the API.
- Keeps Retention Samples for future evaluation purpose

Microbiology



- Microbiology Laboratory is part of Quality Control Department, its role is to perform quantitative and qualitative test of the product for identifying the bio load and pathogenic microorganism in the API.

Production Department

- Manufacturing products as per Batch Manufacturing Record (BMR)
- Manufacturing Building has 6 (six) suites designed as per highest GMP standards and facilitated with different size of Reactors ranging from 400 Liters to 8,000 Liters and different material of construction like Hastelloy and Glass lined.
- Each suite is designed and equipped with drying facility like Rotary Vacuum Dryers (RVD) or Vacuum Tray Dryer (VTD) or Agitated Nutsche Filter Dryer (ANFD).

Production Department

- Operation is carried out by Process Control System (PCS).
- Solvents Tank Farm Area having capacity of 120 KL (6 Storage tanks are available, each 20 KL capacity)
- Production block is facilitated with its own cold storage and daily storage area to take care of chemicals / raw materials.

Warehouse



- Well designed facility for material storage & distribution:
  - Raw Material
  - Packing Material
  - Engineering Materials
  - Finished Product

Research & Development (R&D)

- Process development and validation through QbD.
- Scale-up and trouble shootings
- Process optimization.
- Preparation of Laboratory Development Report.
- Technology Transfer.
- Analytical method development and validation.
- Analytical method transfer.

Health, Environment & Safety



- HSE Department is ensuring the safety of worker and company assets by creating the awareness on the following:
  - Importance of Safety in the company.
  - Usage of Personnel Protective Equipment (PPE) such as Helmet, Safety Shoes, Goggles etc.
  - Usage of Fire Extinguishers.
  - Usage of Water Hydrant System.
  - First Aid to Injured Person.

Safety Precautions

- Smoking is strictly prohibited at CAD site except for designated smoking areas only.(Adjacent to Admin Block & Near Security Gate)

- Use of Mobile Phones and

- Use of Camera are strictly prohibited in manufacturing facility.

All visitors during visit to any facility at the site should:

- Wear Safety Helmet
- Wear Safety Goggles
- Wear Apron
- Wear Visitor Badge

Assembly Points & Emergency Control Center (ECC)

Designated Smoking Area

Accreditations

- SFDA GMP
- SFDA DMF Approval
- WHO GMP
- ISO 9001:2015
- ISO 14001:2015
- OHSAS 18001:2007

SFDA GMP Certificate

الهيئة العامة للغذاء والدواء قطاع الدواء
Drug Sector Saudi Food & Drug Authority

Good Manufacturing Practice (GMP)

شهـــادة ممارسة التصنيع الجيـــد

Saudi Food And Drug Authority, Kingdom Of Saudi Arabia
Certifies that:

CAD middle East Pharmaceutical Industries LLC
Kingdom of Saudi Arabia – Riyadh
P.O. Box 26721, Riyadh 11496

Is registered in Saudi Food And Drug Authority (SFDA), Kingdom of Saudi Arabia under the licence No: 901/2013 Dated 02/12/2013
And from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 18/12/2016, it is considered that it authorized to produce and export the registered Active Pharmaceutical Ingredient (API) and certifies that it fulfills the SFDA (GMP) requirements, and the (GMP) requirements laid down by (WHO) and its premises is subjected to periodical inspection every three years.
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 Saudi Food and drug authority should be consulted.
The authenticity of this certificate may be verified with The Saudi Food and Drug Authority.
The manufacture is entitled for the following activities stated in annex 1.

تشهد الهيئة العامة للغذاء والدواء بالمملكة العربية السعودية أن:

شركة كاد الشرق الأوسط للصناعات الدوائية

المملكة العربية السعودية – الرياض
ص ب ٢٦٧٢١ الرياض ١١٤٩٦

مسجلة لدى الهيئة العامة للغذاء والدواء بالمملكة العربية السعودية تحت رقم : ٩٠١/ ٢٠١٣ في ١٤٣٥/٠١/٢٩هـ الموافق ٢٠١٣/١٢/٠٢م.
وبناءً على نتائج آخر زيارة تفتيشية على مصنع الشركة والتي تمت بتاريخ ٢٠١٦/١٢/١٨م فإن المصنع يعتبر مصرح له بإنتاج وتصدير المواد الأولية الفعالة، كما أنه ملتزم بشروط ممارسات التصنيع الجيد (GMP) الموصى بها من قبل الهيئة العامة للغذاء والدواء السعودية ومنظمة الصحة العالمية ، كما تخضع الشركة لزيارة تفتيشية دورية كل ثلاث سنوات.

هذه الشهادة تعكس حالة المصنع خلال الزيارة التفتيشية في التاريخ المشار إليه أعلاه ولا ينبغي الاعتماد عليها في حال تجاوزها ثلاث سنوات من تاريخ آخر زيارة تفتيشية ويمكن الرجوع للهيئة العامة للغذاء والدواء في حال تجاوز المدة.

كما يمكن التأكد من صحة هذه الشهادة من خلال التواصل مع الإدارة المختصة بالهيئة العامة للغذاء والدواء.

علماً أن المصنع مخول بالنشاطات الواردة في المرفق (١) .

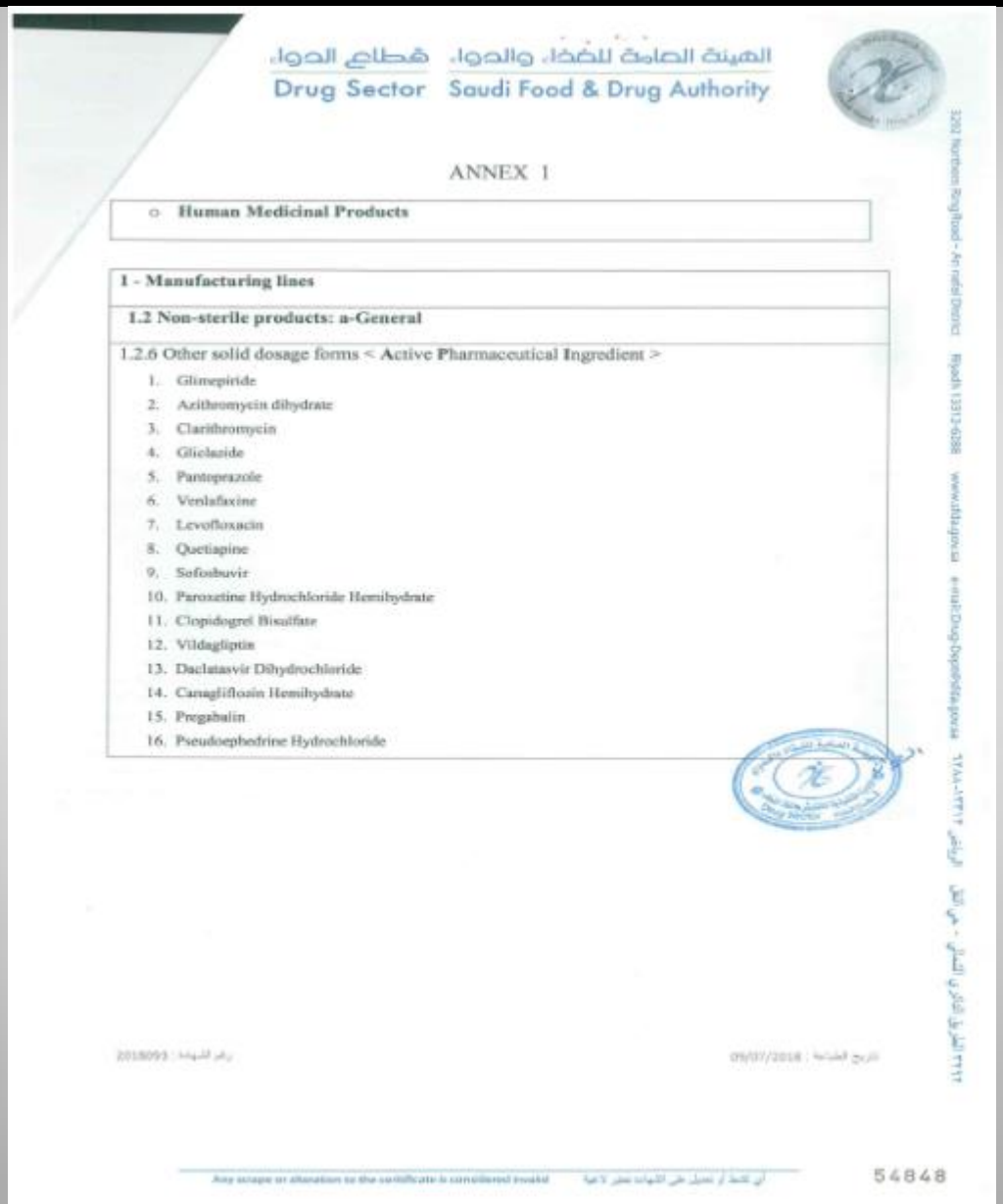
نائب الرئيس التنفيذي لقطاع الدواء
Vice President For Drug Sector

د. عادل بن عبدالله الهرف
Dr. Adel A. Al Harf

رقم الشهادة : 2018093

تاريخ الصلاحية : 09/07/2018

SFDA GMP Certificate



هيئة الغذاء والدواء
Saudi Food & Drug Authority

قطاع الدواء
Drug Sector

ANNEX 1

- **Human Medicinal Products**

1 - Manufacturing lines

1.2 Non-sterile products: a-General

1.2.6 Other solid dosage forms < Active Pharmaceutical Ingredient >

1. Glimepiride
2. Azithromycin dihydrate
3. Clarithromycin
4. Gliclazide
5. Pantoprazole
6. Venlafaxine
7. Levofloxacin
8. Quetiapine
9. Sofosbuvir
10. Paroxetine Hydrochloride Hemihydrate
11. Clopidogrel Bisulfate
12. Vildagliptin
13. Daclatasvir Dihydrochloride
14. Canagliflozin Hemihydrate
15. Pregabalin
16. Pseudoephedrine Hydrochloride

2018093 : رقم الشهادة

09/07/2018 : تاريخ الصلاحية

Any scrape or alteration to the certificate is considered invalid

54848

ISO 9001:2015 Certificate

TÜV NORD

CERTIFICATE

Management system as per
ISO 9001 : 2015

In accordance with TÜV NORD CERT procedures, it is hereby certified that

CAD Middle East Pharmaceutical Industries LLC
King Khalid International Airport, Industrial District
P. O. Box 26721
11496 Riyadh
Kingdom of Saudi Arabia

applies a management system in line with the above standard for the following scope

Manufacturing and sales of active pharmaceutical ingredients

Certificate Registration No. 44 100 16570512
Audit Report No. 5730 2420

Valid from 2018-03-14
Valid until 2021-03-13

Certification Body
at TÜV NORD CERT GmbH

Dammam, 2018-03-14

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-01-01

ISO 14001:2015 Certificate

TÜV NORD

CERTIFICATE

Management system as per
ISO 14001 : 2015

In accordance with TÜV NORD CERT procedures, it is hereby certified that

CAD Middle East Pharmaceutical Industries LLC
King Khalid International Airport, Industrial District
P. O. Box 26721
11496 Riyadh
Kingdom of Saudi Arabia

applies a management system in line with the above standard for the following scope

Manufacturing and sales of active pharmaceutical ingredients

Certificate Registration No. 44 104 18570012
Audit Report No. 5700 2421

Valid from 2018-03-14
Valid until 2021-03-13

Certification Body
at TÜV NORD CERT GmbH

Dammam, 2018-03-14

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-12067-01-01

BS OHSAS 18001: 2007 Certificate

TÜV NORD

CERTIFICATE

Management system as per
BS OHSAS 18001 : 2007

In accordance with TÜV NORD CERT procedures, it is hereby certified that

CAD Middle East Pharmaceutical Industries LLC
King Khalid International Airport, Industrial District
P. O. Box 26721
11496 Riyadh
Kingdom of Saudi Arabia

applies a management system in line with the above standard for the following scope

Manufacturing and sales of active pharmaceutical ingredients

Certificate Registration No. 44 116 18570012
Audit Report No. 5700 2422

Valid from 2018-03-14
Valid until 2021-03-11
(until 2021-03-13 in case of migration to ISO 45001:2018)

Certification Body
at TÜV NORD CERT GmbH

Dammam, 2018-03-14

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-13007-01-01

Thank You…