KIARA

Where **SCIENCE** meets **NEED**

SERVICE OFFERING

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ABOUT US

Kiara Health (Pty) Ltd is a 100 % black-owned, African **pharmaceutical manufacturing** and **healthcare solutions** company headquartered in Johannesburg, South Africa.

We serve as the local, non-exclusive manufacturing partner for a Global, Top 5 pharmaceutical company and as a commercial partner for several other pharmaceutical companies.

OUR **VISION**

Progressing African Healthcare

OUR **MISSION**

Restoring, Preserving and Advancing the health of all patients

STRATEGIC **INTENT**

... by providing World-Class Healthcare Solutions

INTRODUCTION

"With imports comprising as much as 70 to 90 percent of drugs consumed in most countries in sub-Saharan Africa, many governments are considering whether it's time to promote more local production. Drug imports, including both over the counter (OTC) and prescription drugs, do considerably exceed those into China and India—where comparable populations import around 5 percent and 20 percent, respectively. And it does put a strain on government and household budgets and already limited foreign exchanges."

– McKinsey & Company (2019)*

Answering the need on the continent, Kiara Health acquired a **52,000 m² World-class Pharmaceutical Production Site**. The site is located very close to OR Tambo International Airport – the gateway to easy access into the rest of the African continent.

* **Reference:**
Conway, M. et al. McKinsey & Company. https://www.mckinsey.com/industries/public-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs#/, January 2019.

MANUFACTURING

The Kiara Health Manufacturing site has the capability to produce its own Marketing Authorised products as well as operate as a Contract Manufacturing Organisation (CMO).

Key manufacturing types:

- Capsules
- Tablets
- Sugar-coating
- Film-coating

Key Process Technologies:
Dry mixing, wet granulation, encapsulation, compression and coating (film-coated and sugar-coated)

PACKAGING

PRIMARY PACKAGING:

- **Blister**
  - Tablets
  - Capsules
- **Securitainer**
  - Tablets
  - Capsules

SECONDARY PACKAGING:

Contract packaging
Effervescent tablets, tablets/ capsules, blisters, bottles, nasal sprays, eye drops, suppositories, and ampoules/vials for injection/ infusion.

QUALITY ASSURANCE

The Kiara Health community spans over 200 employees[#], with an average length of service of 22 years. The majority have been trained under International Quality Standards and Regulations.

As a responsible corporation, we are committed to operating at the highest standard in every aspect of our work.

Our **Quality Control (QC)** and **Quality Assurance (QA)** departments comprise a team of over 40 members[##]. The QC laboratory is made up of a team of skilled professionals with years of training and expertise in multinational pharmaceutical testing.

The Kiara Health Quality Assurance team is responsible for defining and executing systems and processes across the company that ensure that goods and services meet all quality, efficacy, and safety requirements. The Team is intricately involved to ensure that the highest quality standards for the following are met:

New Product Planning	Subcontracting	Production
Analytical Method Transfer	Purchasing	Marketing
Technical Transfer	Process Design	Distribution
Testing	Trial Production	After-Sales Service

213 employees (at 30 September 2023).
At 30 September 2023, this number stood at 48.

QUALITY MANAGEMENT SYSTEM

In the pharmaceutical manufacturing space, software controls the HPLC (High Pressure Liquid Chromatography) systems used for the analyses of products, raw material, and active pharmaceutical ingredients (API). Furthermore, the data obtained from these analyses is converted to results, reports and is securely stored. An integral part of the process is the maintenance of data integrity, as the data reports are used for the release of product to the market, and raw material or API for product manufacturing.

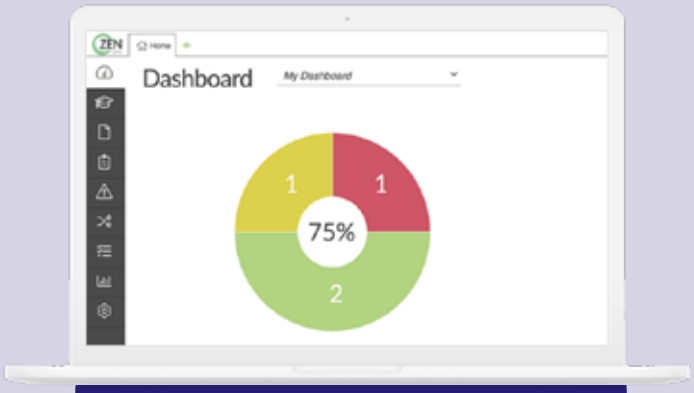

Figure 2 – ZenQMS Quality Management System Dashboard

Kiara Health utilizes ZenQMS as its all-inclusive Quality Management System. ZenQMS is fully validated for GxP per GAMP 5 guidelines for a Category 4 system (e.g., Configurable Software), and FDA General Principles of System Validation: Final Guidance for Industry and FDA Staff, January 11, 2002.

In this QMS, all procedures, master documents, deviations, out of specifications (OOS), change controls, customer complaints, corrective actions and preventive actions (CAPAs), and training are managed, in a GxP compliant manner.

POST IMPORTATION TESTING (PIT)

- Post Importation Testing on all dosage forms.
- Dedicated and highly skilled Analytical Science and Technology Team for Method Development and Transfer.

STABILITY
PROGRAMME SERVICES

- Stability Programme Hosting for stability zones:
  - 25° Celsius/60 % RH
  - 30° Celsius/65 % RH
  - 40° Celsius/75 % RH
- Accelerated and Follow Up Stability (FUST) programmes.
- Stability Chambers linked to online EMS system.

RAW MATERIAL
ANALYSIS

- Wet chemistry analyses using general methods and monographs prescribed in the United States Pharmacopeia (USP) and European Pharmacopeia (Ph. Eur.) including Thin Layer Chromatography (TLC), pH measurements, viscosity, density, etc.
- Instrumentation methods including Fourier Transform Infrared (FTIR) spectroscopy, ultra-violet (UV) spectrophotometry, particle size analysis, optical rotation, potentiometry, High Pressure Liquid Chromatography (HPLC), etc.
- Micro-testing including total aerobic microbial count (TAMC) and the total combined yeasts/moulds count (TYMC), *E. coli*, Salmonella etc., using general chapters from Ph. Eur.

Figure 1 - Master Sizer (Particle Analyser)

FINISHED PRODUCT ANALYSIS

- Physical testing of samples including mean mass, dimensions, friability, disintegration etc.
- **Identity testing** through HPLC, UV spectrophotometry, wet chemistry, TLC and FTIR.
- **Assay testing** through HPLC, UV spectrophotometry, and potentiometric titration.
- Dissolution testing using dissolution apparatus USP 1 and 2 (baskets and paddles).
- Dissolution quantification using HPLC and UV spectrophotometry.
- Related substance and impurity testing using HPLC and TLC methods.

OTHER LABORATORY ACTIVITIES

Cleaning Validation Testing	AS & T	Stability Programme and Testing
Recovery of active substances using HPLC methods. Recovery of detergents using total organic carbon (TOC) methods.	Analytical Method Verification and Validation. Analytical Method Transfer.	Holding of samples and testing.

A core Kiara Health value is **Quality**. To ensure that this key value was maintained at the Quality Assurance (QA) and Quality Control (QC) levels of the business, the company invested in the world-leading **Empower™ 3 Chromatography Data System** by the U.S.-based Waters Corporation. The Empower™ 3 Chromatography Data System is Waters' compliance-ready chromatography data software (CDS) for advanced data acquisition, processing, and reporting that simplifies the management of chromatography test results.

RANGE OF LABORATORY EQUIPMENT

QC Laboratory Equipment

- Polarimeter
- Dissolution baths
- Agilent HPLC's
- Balances
- UV Spectrophotometer
- Fourier Transform Infrared (FTIR)
- Vacuum ovens, Furnaces
- Melting-point apparatus
- pH meter
- Total organic carbon (TOC)
- Conductivity meter
- Stability chambers
- Karl Fisher Moisture analyzer
- Potentiometer
- Refractometer

IPC Equipment

- Friability tester
- Disintegration tester
- Dr Schleuniger AT4 Tablet tester
- Moisture analyzers

Microlab

- Water bath
- Colony counter and camera
- Air sampler
- Incubators
- Autoclaves
- Biological safety cabinet
- pH meter balance

TESTING AND RELEASE ACTIVITIES (including PIT)

Kiara Health's testing and batch release capabilities include the application of HPLC systems – the High-Performance Liquid Chromatography technique is used in analyses to separate, identify, and quantify each component in a sample mixture (tablets, capsules, and granules).

Agilent 1200 (Figure 3) **and 1260 Series HPLC Systems are deployed at Kiara Health Laboratories** – these have a binary pumping system, multi-wavelength UV/ Visible Detector, high-performance vial and microwell auto-sampler, thermostated column oven, and micro-vacuum degasser.

Figure 3 -
Agilent 1200 Series HPLC System

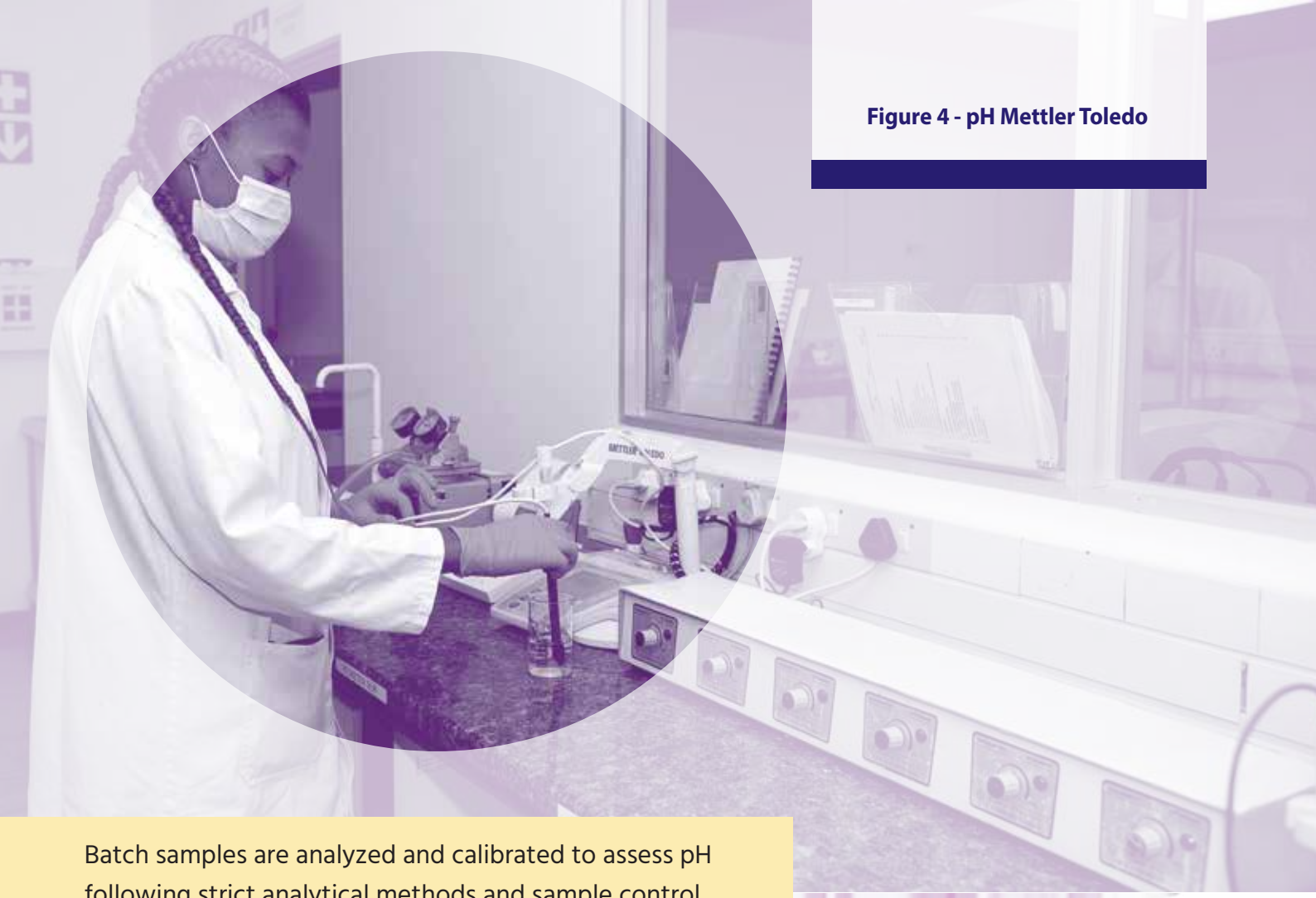

Figure 4 - pH Mettler Toledo

Batch samples are analyzed and calibrated to assess pH following strict analytical methods and sample control (Figure 4 and Figure 5).

Figure 5 – Accurate control and labelling of test samples.

Prepared samples follow a computerized sequence and specification methodology through the HPLC injection process (Figure 6). All methods and Standard Operating Procedures (SOPs) are applied. This includes purging the HPLC to remove latent air bubbles which could destabilized the pressure in the system and impact test sample results (Figure 7). Before sample and standards are determined, small volumes of samples are extracted from the larger volumetric flasks and transferred to vials which are injected into the HPLC system for analysis. Strict practices of labelling and control is enforced through Good Laboratory Practices (GLP) and is imperative for accurate results of test samples Figure 8).

Figure 6 – HPLC units are connected to a computerised system that controls the process flow of the samples.

Figure 7 - Purging of the HPLC unit

Figure 8 - Sample are controlled through accurate labelling of smaller samples

Standards are utilized to generate sample results and the results are compared to product specific specifications as per the product method. A comparative graph is generated and approved by a QC Supervisor/ Senior Team Leader to authenticate the accuracy of the sample tested (Figure 9). This quality assurance process follows strict GLP guidelines to give our customers peace-of-mind.

Figure 9 – Test Sample Results Analysis

Figure 10 - Distek Dissolution Analyser Bath

Figure 11 - Memmert Vacuum Oven (Granulation moisture measure and dryer) - Model VO400

WARE-HOUSING

- Total warehousing capacity of 2,181 m^2.
- Warehousing capacity available for 3,000 pallets.
- Secure areas available to store and distribute Controlled substances.
- Environmental monitored warehouse; linked to online EMS system.
- Control and monitoring of temperature; humidity is monitored.

STORAGE AND WAREHOUSING

COLD CHAIN
STORAGE

Kiara Health can offer Cold Chain Storage with the following capabilities:

- 2 – 8 °Celsius
- Capacity: 300 pallets

AUDITS

Good Manufacturing Practice (GMP) requirements are incorporated into the various quality assurance procedures. Routine activities and guided by documented and approved Standard Operating Procedures (SOPs).

Kiara Health is proud to have passed a **South African Health Products Regulatory Authority (SAHPRA)** audit in March 2021.

Successful audits by **four multinational**, and **three global generic** pharmaceutical companies.

Successful audit by **Medicine Control Authority of Zimbabwe**.

(Kiara MedTech (Pty) Ltd received **ISO 13485:2016** accreditation in October 2022.)

INFORMATION TECHNOLOGY (IT) SUPPORT

As of 2020, Kiara Health was officially named the first and only customer on the African continent with a fully scaled server deployed in the Amazon Web Services (AWS) Cloud for Empower™ 3.

KIARA

amazon web services

datacentrix

Empower™ 3

"... the first and only company in Africa with a fully scaled server deployment in the AWS Cloud"§

Ref.: § https://www.kiarahealth.com/kiara-health-the-first-and-only-company-in-africa-with-a-fully-scaled-server-deployment-in-the-aws-cloud/

FUTURE **INVESTMENTS**
INTO OUR CAPABILITY

Strategic future investment into resources, infrastructure, and equipment to meet our clients' needs for specialised equipment or services not covered in this brochure.

The intention is to build future capability by acquiring equipment to perform the following:

- Atomic Absorption Spectrophotometry
- Gas Chromatography
- PIT enhancement: Ultra-performance liquid chromatography (UPLC)

MANUFACTURING - FUTURE INVESTMENTS

- Suppositories
- Effervescent/Dispersible technology
- Creams and Ointments
- Scale-up Clean Rooms for medical device manufacturing

SUMMARY | SITE CONTRACT OFFERING

Kiara Health therefore has the capability and capacity to assist your business with:

- Bulk Manufacturing
- Primary Packaging
- Secondary Packaging
- Testing and Release Activities (including PIT)
- Stability Hosting Services
- Cold Chain Storage
- Warehousing

KIARA
Where SCIENCE meets NEED

For more information:

| +27 (0) 10 329 0600

| nbo@kiarahealth.com

| www.kiarahealth.com

| www.linkedin.com/company/kiara-health

www.kiarahealth.com

Kiara Health (Pty) Ltd Reg. No. 2011/111283/07
72 Steel Road, Spartan, Kempton Park, 1619,
South Africa

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