MODERN TRENDS IN TROPICAL PHARMACEUTICAL INDUSTRY DESIGN

by

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DECLARATION

I hereby declare that, except where it has been cited as reference, this dissertation is the outcome of my own research.

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ABSTRACT

Modern trends are being shaped by Science and Technology today and the pharmaceutical industry is not excluded in this technological age as manufacturers and other stakeholders seek more advanced methods, as in any other sector, to run their businesses.

In Ghana, though at a slower pace, the industry is gradually embracing the idea of advanced trends in technology systems in the daily running of their industries. Among the advantages is an improvement in quality of products, a larger customer base and an increase in sales, which are priorities for any business – minded person.

Technology has become an integral part of the industry, beginning at the conceptual stage of the design of the facility. Aside function, intelligence and aesthetics have become integral in modern trends in technology and is being applied in the kind of machinery and equipment being manufactured, security systems, construction materials and finishes, control of parameters such as lighting, temperature, humidity, ventilation, maintenance schedules among others.

The extents of evolving trends, especially in terms of technology in the industry, like any other sector, cannot be foretold. This study therefore identifies key areas of the industry and the evolving trends there.

Set in a tropical background too, the study also explores how modern trends can become adaptable in a generic tropical zone. Also as the industry is health related, trends regarding regulations, procedures and requirements are continually being changed and upgraded and these are also explored.

For a better appreciation, all these, culminate in a design proposal highlighting possibilities to modern trends in a tropical setting and the possibilities to the way forward.

CONTENTS PAGE

LIST OF FIGURES **PAGE**

LIST OF ABBREVIATIONS

ASHRAE	-	American Society of Heating, Refrigerating and Air Conditioning Engineers
ISPE	-	International Society of Pharmaceutical Engineering
ISO	-	International Organisation for Standardization
AHU	-	Air Handling Unit
OSD	-	Oral Solid Dosage
HVAC	-	Heating, Ventilation and Air Conditioning

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DEDICATION

To you Alison, you have come into my life and it will not be the same. You are a jewel!

Mum

CHAPTER ONE

1.1 PREAMBLE

Pharmacy can be defined as the profession that deals with the art and science of preparing suitable and convenient materials from natural and synthetic sources, for the distribution and use in the treatment, control and prevention of disease.[1]

The manufacturing of pharmaceutical products in Ghana began as mere preparations of mixtures and suspensions as instructed by the medical doctors in charge of health institutions or Diploma Pharmacists in charge of pharmacies. In 1958 the Faculty of Pharmacy, KNUST, (now Faculty of Pharmacy and Pharmaceutical Sciences) was created offering Diploma in Pharmacy. This was upgraded in the early 1960s to a Bachelor of Pharmacy Degree.

Between the 1960s and 1980s there was a gradual growth of pharmaceutical industries such as Aryton Drug Manufacturing Limited, Major and Co. Manufacturing Limited, Pharco Laboratories (now KAMA Industries Limited), GIHOC Pharmaceuticals Limited (now Phyto-Riker [GIHOC] Pharmaceuticals Limited) and Sterling Products Limited (now Starwin Products Limited). These companies pioneered the growth of pharmaceutical industries in Ghana. As of now what most manufacturing companies do is what is known as compounding. This involves the importation of raw materials for predetermined drugs and adding some unessential products of their own, such as a sweetener or flavor and labeling it as their own.

Over a period of about fifty years, phenomenal heights in health care delivery have been achieved through science and technology worldwide. Many discoveries have been unearthed, increasing our knowledge of our surroundings and better adjusting to it. Consequently life expectancy has risen substantially in developing countries. The pharmaceutical industry in the

country continues to grow and pharmacists are beginning to make an impact on the industry's landscape. Through the hard work of the pharmacist, the Ghanaian public has become conscious of health issues such as counterfeit drugs, expiry dates, and also the dangers of drug abuse. Interestingly the World Health Organisation has decided to set up a Pharmacovigilance Centre (centre for the monitoring of available drugs on the market). That is where all complaints about side effects of drugs are sent and if necessary the drugs are withdrawn from the market. This centre, located in Accra, the capital of Ghana is to serve the West African sub - region. The Pharmacy Council has also set up a National Drug Information and Resource Center with a data-base which would be networked (be accessible from all the regions) to provide information on all drugs.

1.2 PROBLEM STATEMENT

Drug production is a specialized area. Drugs are chemical based and chemicals too are sensitive to changes in weather conditions and radiation. Therefore drugs can kill very fast. Pharmaceutical industry design therefore demands specialized knowledge, a good understanding of how the industry is run and how best to ensure the production of efficacious and quality products for the consumer. Again the regulatory requirements for production facilities within the pharmaceutical industry are being continually and incessantly tightened.[2] It is imperative therefore that manufacturers be abreast with changes in the industry.

Having interviewed workers in the industry and touring some of them, it is evident that most industries in the country are, by the World Health Organization guidelines, substandard and that implies that drugs are not being produced under the most hygienic conditions. At some industries, lighting fixtures and machines are out of order, temperature levels are not controlled and simple working procedures especially for hygiene are not followed. The efficacies of the products are obviously compromised consciously or otherwise. It was observed that one major contributing factor was that most plants had a wrongly planned layout resulting in a lot of

backwards and forwards and crisscrossing movement patterns. Then again, issues such as lighting, ventilation, temperature and finishes were also below the standard. These gradually culminate in the degradation of products and their efficacy. Indeed, this should not be allowed to happen because of the direct effect drugs have on the consumer.

Today the pharmacist is being charged to take more stringent measures in ensuring better quality control services for their products. The medical and paramedical societies are tasked, time and again to work hard to improve health care in Ghana.

1.3 JUSTIFICATION

Having designed a pharmaceutical industry for a post graduate thesis design, one challenge that was encountered was designing to suit the tropical environment. Most information pertaining to design that was gathered was with respect to temperate conditions. Another issue was that specific data on architectural components such as basic required spaces, spatial arrangement, exterior and interior finishes and lighting issues was scanty.

Presently most of these industries in Ghana are not purpose built but the pharmaceutical industry is one that has its regulations and procedures upgraded constantly worldwide. Manufacturers in Ghana are now coming to the realization of the impact of a good layout for a plant on their business. To begin with, there is the need for spaces that are built to World Health Organisation (WHO) specifications, standards and requirements.

A pharmaceutical industry designed to international standards and suited to the tropical environment will help improve Ghanaian pharmaceutical products and produce quality and efficacious medicinal products that ultimately have the African in mind.

1.4 OBJECTIVES

In respect of the afore mentioned problem statement this research seeks to highlight the following through studies and design:

- The importance of standardizing procedure in a health related industry
- The benefits for a pharmaceutical industry of a purpose built industry with a well planned layout through a design proposal.
- To explore how a design can possibly be made to suite the tropics without compromising on standards and quality in production.
- To explore modern trends in technologies that can be employed in an industry such as a pharmacy.

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[1] definition of pharmacy from *wordnet.princeton.edu.com*, accessed on 10/03/2007

[2]Summarized from Graham Cole's book - Pharmaceutical Production Facilities - Design and Applications - second edition

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 INTRODUCTION

To serve as background information to ultimately aid in the creation of a good design, written documentation on related topics of interest and concern were sort. This search was to inform on general requirements of such an industry, possible spaces or areas required, some technical information on achieving cleanliness and prevention of contamination and critical requirements or needs of specific areas in a manufacturing plant.

Since most products are to be consumed good health practices and sanitation are also explored.

2.2 BACKGROUND INFORMATION - PHARMACEUTICAL INDUSTRIES

Reading through ISPE Baseline Pharmaceutical Engineering Guides for New Facilities – volume 2 : Oral Solid Dosage Forms – First Edition, it is realized that contamination control, hygiene, sanitation, security and proper control of parameters as lighting, temperature, humidity and ventilation are of prime importance throughout production, ultimately to ensure the quality of the product.

The main mode of contamination is through dust particles airborne or by contact. Recent advancement in dust control systems used in plants includes the use of extractors, air showers and airlocks to arrest dust particles at the source.

In the design and construction of the facility, emphasis on details too, such as window edges flushing with walls, doors being opened by elbow pads or foot kicks, well sealed floors and ceilings help to reduce contamination.

It is also observed that sequential arrangement of procedure, through equipment and personnel positions and material movement through production would also prevent contamination as there would be no crisscrossing movement patterns. The positions of personnel and equipment with a

good idea of how materials would move smoothly through production should be well thought of by the designer. Indeed a good understanding of procedure should be sort by the designer or more effectively a design team involving experts from any technical field beyond the expertise of the architect. 'At the design stage, issues such as hazardous materials, effluent problems, equipment to be used and also automated systems'……. 'every aspect of the design should be considered : manufacturing process, personnel flow support areas(ancillary)'[1], should be considered and well planned for. A good plant layout will therefore be a collaborative effort of experts with the technical knowhow.

It would also be advisable for the designer to research and be updated on recent developments in the industry and facility design.

2.2.1 Quality Control

The Quality Assurance of Pharmaceuticals – A Compendium of guidelines and Related Materials - volume 1, states that quality control areas should be separated from production areas. The publication explains that the Quality Control department should even have a different air supply from production areas. Different types of chemicals are employed in this department in their daily investigations. Slight changes in a chemicals formation could cause an imbalance that could be fatal. Therefore with this knowledge it would be prudent to totally separate this unit from production to avoid possible contamination of products.

2.2.2 Waste Disposal

On the issue of waste, the ISPE Baseline Pharmaceutical Engineering Guides for New Facilities – volume 2 : Oral Solid Dosage Forms – First Edition states among others that 'Provision should be made for the proper and the safe storage of waste materials awaiting disposal. Toxic substances and flammable materials should be stored in suitably designed, separate, enclosed

cupboards as required by national legislation.' For this to be undertaken effectively waste disposal should be part of the design thought process. It is important for the designer to know the type and nature of waste to be generated by the plant and how best these can be safely disposed off as directed by national regulations.

2.2.3 Personnel

The ISPE Baseline Pharmaceutical Engineering Guides for New Facilities – volume 2 : Oral Solid Dosage Forms – First Edition quotes 'personnel should be instructed to wash their hands before entering production areas. Signs to this effect should be posted and instructions observed.' 'To ensure protection of the product from contamination, personnel should wear clean body coverings appropriate to the duties they perform, including appropriate hair covering.'

For a good design for personnel, their movement patterns should be studied and designed accordingly to avoid crisscrossing movement patterns.

A good design for personnel should be such that workers enter the plant into a changing area for their change routine guided by the design of the area so that they enter actual production environment having successfully gone through all the required change routine. A reverse design route should then lead personnel out of the production area to avoid the risk of contamination. A similar design route should be applied for others entering production such as inspectors, visitors, senior staff, temporary workers and contractors.

On good manufacturing practices for Heating, Ventilation and Air Conditioning (HVAC) Systems for non-sterile dosage forms, ASHRAE Handbook 2000, explains that, HVAC system design influences architectural layouts, with regards to items such as airlock positions, doorways and lobbies. And that the architectural components have an effect on various issues including cross contamination control. Therefore the design of the HVAC system should be considered at the concept design stage of a pharmaceutical manufacturing facility.

Temperature, humidity and ventilation should be appropriate and also controlled and checked periodically. With modern technology these parameters and others as lighting levels and security, can all be managed effectively under an automated program known as Building Management Systems (BMS). [2]Building Management System (BMS) is a computer software program, usually configured in a hierarchical manner, to control, monitor and manage all the equipment installed in the building. This equipment can include heating, ventilation, cooling, security, and lighting.

BMS manages these parameters effectively basically by the use of sensors. It is for the manufacturer to research and find out which best suits their needs and their budget. The designer or team can then design accordingly. These automated systems can even identify faults in a particular location as the whole structure is zoned. This makes it easy for problems to be rectified quickly before it becomes fatal especially where the facility is a large one. Another advantage is that it can possibly lead to a better allocation of resources. As against other methods the initial cost might seem expensive but the running costs will reveal it to be a better alternative and for that BMS should be given a keen interest.

According to Ivor H. Seeley's Building Maintenance (2nd edition) 1993, the advantages of Building Management Systems are numerous and include the following:

- Reduction in clerical staff and management costs
- Reduced risk of human error and increased reliability
- Provision of checks on work done
- Possible instant updating
- Easy adaptation to alterations to building
- Incorporation of various management and administrative functions

2.2.4 Contamination and Control

The International Cleanroom Standards – ISO 14644 Parts 1 to 6 writes that some ways through which products can be contaminated are a poor plant layout and also inappropriate building finishes. This goes to emphasize again the importance of planning well for the architectural components of the facility.

Finishes to the interior, as much as possible should eliminate or minimize dust collection and therefore contamination. [1]Graham Cole's Pharmaceutical Production Facilities gives good examples of floor finishes for such facilities as epoxy resin, welded sheet PVC and epoxy terrazzo and epoxy coating and polyester coating as wall finishes.

The immediate environment should also not be a source of contamination to products. It also states that possible sources of contamination at the plant should pose little or no threat to the quality of the products. Constructive measures should be taken such as in dust generating areas to prevent contamination and cross contamination.

In recent times, different dust extractors are introduced at the point of dust creation, depending on the amount of dust created as a measure for controlling contamination and cross contamination.

2.2.5 Contamination by HVAC plant

Materials for components of an HVAC system should be selected with care, as the materials from which these are manufactured can liberate particles into the supply air stream. In choosing the most appropriate system therefore, properties of the necessary components should be determined by the HVAC team to ascertain its appropriateness for the particular area it is to be used in or linked to. The design of the system too should allow for easy maintenance to prevent it from being a source of contamination.

2.2.6 Contamination by Staff

Staff or operators are a source of contamination and the facility design and operating procedures should be such as to minimize their contamination.

Use of elbow pads on doors, dust extractors, airlocks and air showers are effective in controlling contamination by personnel, designing operator locations such that dust moves away from the operator would also help in controlling contamination. This also protects the operator from dust inhalation.

2.2.7 Herbal Medicine

[3]Herbal medicine is also known as 'botanical medicine', 'traditional medicine' or phytomedicine'. It can be defined as using a plant's seeds, berries, roots, leaves, bark, or flowers for medicinal purposes or preparing medicinal remedies. The use of herbal medicine is rapidly becoming popular and more acceptable worldwide as the demand for more natural and organic remedies rose and also as the cost of conventional drugs increased.

[4]Today, the World Health Organization estimates that about 80% of people worldwide use herbal medicine for primary health care. [4]In Ghana, Mali, Nigeria and Zambia, the first line of treatment for 60% of children with high fever resulting from malaria is the use of herbal medicines. The Government of Ghana like many other African countries encourages the practice of herbal medicine side by side with conventional medicine. To further stress the importance of herbal medicine in Ghana, the position of a Director of Traditional Medicine has been created within the Ministry of Health.

The practice of herbal medicine is gradually being improved through research, analysis and quality control. It is now being taught in Medical as well as Pharmacy Schools. In Ghana, recognized institutions such as the Centre for Scientific Research into Plant Medicine at Mampong Akwapim, in the Eastern Region of Ghana, Amen Scientific Herbal Hospital and the

Natural Healing Centre are setting the pace in standardizing herbal medicine preparation, packaging and distribution in Ghana.

2.3 CONCLUSION

[1]'The challenging business environment is putting pressure on each business function within a company and each function is trying to meet the challenges by:

- bringing in as many of the technological innovations as it can convince management
- investing in, computer aided engineering and flexible manufacturing systems'

At the pace which technology is moving our world today, one cannot help but be a part of it to survive, especially in the business world. It is awesome what can be achieved today through technology. Simultaneously technology can be very confusing and potentially harmful if accurate and sufficient knowledge is not acquired.

It is imperative therefore to be continually updated on new trends in ones field of business or interest. This would enable one to be competitive, continually producing quality products or services, introducing new ones and delivering in record time.

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[1]Quoted from Graham Cole's book - Pharmaceutical Production Facilities - Design and Applications , second edition

[2]Culled from:http://en.wikipedia.org/wiki/Computerized_Building_Management_System on 17/02/ 2007

[3]Culled from http://www.who.int/mediacentre/factsheets/fs134/en/ on 02/12/2010

[4] Culled from www.gradschool.umd.edu/ on 02/12/2010

2.4 CASE STUDIES

2.4.1 Tanzania Pharmaceutical Industries Limited (TPI)

Reason for study: 1**.** Built to high standards

2. Situated in the tropics
3. Production of non – sterile dosage forms

Background

Tanzania Pharmaceutical Industries Limited is a limited liability company incorporated in the year 1976 for manufacture of pharmaceutical products. The company was owned by the Government and started its commercial production in May 1980. A rehabilitation programme has made the plant capable of producing tablets, oral liquids, and capsule dosage forms. The company is located in Arusha the third largest town in Tanzania.

The facility is relatively close to the main port city of Dar es Salam from where their imported raw materials are received and also the facility is also about five kilometres from the centre of town.

Infrastructure

- WATER

Water for production is supplied by a bore – hole. Water analysis report is done by the Urban Water Supply and Sewerage Authority Laboratory in Tanzania. The main water storage tank has a capacity of 45000Litres and is cleaned after every three months.

- ELECTRICITY

Aside the power supplied through the mains there is a power generator installed as a support system having 250KVA capacity to ensure continuity in production.

Facility

The factory has the following independent structures:

Main building: Production and Warehouse

Annex: Quality Control, Engineering Workshop and Change Rooms

Construction is by the use of reinforced concrete with reinforced concrete slab with well laid waterproofing. Gables and hipped roof styles are also used as roofing for main building, annex

The walls are angularly slanted for low dust settlement and easy cleaning. The floor is made of silica bidded cement tiles and is adequately polished.
The tablet/ liquid / capsulation coating and packaging areas are segregated. Compression machines have been put into cubicles. These are various means of preventing contamination and cross contamination.
The walls and ceiling are painted with anti – fungal treatment

Security

Airlocks are provided at entrance, weighing area and compression corridor.
Air curtains have been provided at the warehouse entrance and production corridor entry points.

Observations

- Ground water has been put to good use and there is surety of continual water flow.
- Facility enjoys adequate supply of services such as water and electricity and this ensures the smooth production of quality products.
- Employees would have to move quite a distance to get to the canteen which would reduce production time
- Facility is secured by there being a number of security checkpoints
- The facility is also close to the centre of town and the port city
- A conscious effort has been made to incorporate soft landscaping to make the environment less harsh and cool which goes a long way to make the air conditioning system more efficient.
- Facility is not in an area specifically zoned out for industries. It could possibly be releasing minute amounts of particles into the air which might be harmful to the residential area it shares a boundary with.
- There is ample area for future expansion.
- A lot of emphasis placed on the good health practices of the employees.
- Compression machines in cubicles help to reduce contamination as the process generates a lot of dust particles.
- Packaging rooms have not been segregated into primary and secondary areas and this promotes cross contamination.
- Air curtains are useful in areas where there is a need for unimpaired movement from one area to another without causing contamination.

- The changing rooms could have been a part of the production area but separated by air locks instead of being annexed to it which would be more costly.
- As prescribed by standards[1] the Quality Assurance department is separated from the production area.

Conclusions

Some consideration has been given to the tropical setting in which the plant is situated in the construction method and materials used.

An obvious attempt has been made at standardising and modernising procedure at the facility; however, the location is not the most suitable as it is close to a residential area and might have a direct or indirect effect on the residents now or in the future. This should be a major consideration in choosing a site for a plant. In this age of biological weapons, extra modern security checks especially in the plant are essential to avoid compromising the quality of the products and harm to personnel.

Air locks and air curtains are modern technologies used to prevent or minimise contamination in production areas.

An attempt would be made at integrating areas such as quality control, maintenance and changing areas with the production area with air locks separating them. This would make the design more compact and each area accessible.

Security would be well taken care of by technologically advanced systems for security which would involve less security personnel. The system should be able to ensure restricted access by use of measures as access cards and code numbers.

2.4.2 Ernest Chemists Limited – Manufacturing Plant

Reason for study: 1. It is one of the few industries in Ghana built to a high standard and also purpose built.
2. It is situated in the tropics
3. The plant produces non – sterile dosage forms

Background

Ernest chemist is one of the leading pharmaceutical industries in the country. It was established in 1986 as a sole proprietorship. Presently, it is a limited liability company with an office complex, warehouse facilities and a manufacturing plant. The company boasts of a modern, purpose built manufacturing plant situated at Tema Industrial Area which serves the whole country, a wholesale / retail outlet and administration office block in Accra serving the Southern sector of Ghana and another wholesale / retail outlet in the Ashanti Region of Ghana (Kumasi), serving the Northern sector of Ghana. Aside these facilities, Ernest Chemists also has a number of retail outlets in the capital city, Accra. The company produces non – sterile dosage forms of tablets, capsules, liquids and sachets.

Premises

The facility is located at Tema and close to the Tema Harbour from where imported raw materials are received. It is also about 7 minutes drive unto the Tema Motorway into Accra, the capital city. It is also approximately five minutes unto the Afloa road which is a distribution route to neighbouring countries like Togo. The manufacturing plant is located at Tema in the Tema Industrial Area. The plant is surrounded by non – polluting industries such as nails and rubber industries. All the units in the facility are housed in one block with a security house. This block houses the administration, warehouses, maintenance, quality control, canteen and production units.

Infrastructure

- WATER

The water technology employed here is that water ,from the mains is channelled into a reservoir can hold water supply for about three working days in case of water shortage. Water from the

reservoir is pumped into tanks. Water for production is directed through a water treatment system to purify the water to acceptable pharmaceutical standards.

- ELECTRICITY

The Hydroelectric power is tapped from a 3 face LV lines, through a transformer and then connected to a generator plant.

- SECURITY

Premises is fenced and well guarded by security personnel for twenty four hours. External lights, put on at night also aid to secure the facility.
Workers undergo a daily security check conducted by security personnel before and after working hours to ascertain that no harmful substance is being introduced into the plant and also that no product or material is being stolen from the premises.

Facility

- CONSTRUCTION TECHNOLOGY

Walls and doors are oil painted for easy cleaning and prevent dust. The floors have a smooth terrazzo finish for ease in cleaning. Ramps are used in the warehouses and from there to the production unit to facilitate movement of heavy materials and equipment. A hoist at the ground level transports materials, products and equipment between the two levels to the various units. The plant has a floor to ceiling height of 4.5m. Air conditioning supply ducts are housed in bulk – head ceiling made of Plaster of Paris which is non – porous. Externally columns have been used as a design feature as well as drain paths for rain water from the roof through drain pipes that open at the bottom of these columns into gutters covered with grills.
The different areas at the production unit are segregated to prevent contamination. Circulation areas are a spacious width of 2 meters.

Observations

- There is a fire fighting system in place which includes extinguishers, hose reels, sprinklers and fire escape doors.
- There are alternative supplies of water and power to ensure continuity in production.
- The layout is compact therefore the various departments are easily accessible.

- Relatively all units at the plant are well equipped to safely produce efficacious drugs and products.
- A conscious effort has been made to design all the facades with similar features and this is even extended to the security house at the entrance.
- A system of dust extraction is in place. It begins with flexible arm extractors let down into spaces where dust is created and sucked up through a network of ducts and emptied into a settling machine from where the dust particles are collected and disposed off appropriately.
- Circulation spaces has taken into consideration the movement of products, machines dimensions and personnel and given a convenient width of 2.5m.
- A network of underground drains run throughout the plant beginning with drain holes in the production rooms and terminating in gutters outside. The drains are flushed periodically with neutralizing solutions to halt the reaction of chemicals.
- A floor to ceiling height of 4.5m has taken into consideration the height of machines and air condition supply ducts.
- Smooth terrazzo finish enables easy cleaning and movement of mobile equipment.
- There are sinks in all offices at the plant and this promotes good hygiene practices.
- Flammable raw materials are stored in sheds outside. This could reduce the risk of fire to the main structure but a fire outbreak could still get out of control since it is open to Oxygen in the air.
- The maintenance unit found in the plant serves the whole facility including the administration. This could be a possible source of contamination.
- Loading and off loading bay is not well lit and not well sheltered from the vagaries of the weather.

Conclusion

Generally compared to most pharmaceutical industries in Ghana, the Ernest Chemist plant is better planned and more organised and also better equipped for the production of efficacious drugs and products.

The plant is also well located in an industrial setting. Adjoining industries are not a threat with regards to contamination and pollution. Issues such as location and environmental impact should not be overlooked in planning for such an industry as the health of consumers is vital. The lower

the risk of contamination internally the better as in a contrary situation more expensive filters would have to be used to eliminate the risk either to the surrounding community or to the plant. At the plant the quality control unit is within the production unit and that, according to standards, [1] is not the right arrangement for these spaces. The unit, according to the standards[1], should be linked to production but not have direct access to it as that could be a source of contamination. The packaging unit has to be subdivided into a primary (where the packaging material is in direct contact with the product) and secondary (where the final packaging is done). This is to reduce or eliminate cross contamination.

The idea to store flammable raw materials outside the main structure is laudable but an open shed for storage is not the best as explained in earlier text. A better design solution could be storage in a reinforced and enclosed space. Fenestrations should not be included. Rather a fire escape door should be introduced. Again in designing one should consider whether an external storage or internal one would give a good design. In the design proposal a better design solution would be sort that would also be safe.

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[1] culled from The Quality Assurance of Pharmaceuticals – A Compendium of guidelines and Related Materials - volume 1

2.4.3 Aryton Drug Manufacturing Limited (ADML)

Reason for study:

Aryton was the client for the design as such a tour of their existing facility was important for one to be familiar with the day to day activity pattern of the company to define the design.

Aryton Drug Manufacturing Limited is one of the pioneer pharmaceutical industries in Ghana. It was established in 1965 and has been operating to date. The company is situated in Accra, Tesano. The administration and plant are on different sites separated by a distance of about 250m. The plant is an old one (been in use since 1969) within which time a lot of practices accepted at the time are no longer acceptable as such its design is not very functional. Many features and structures look as though they were not part of the original design and the process flows are also not functional.

After touring the facility the following observations were made:

- The production rooms were not air conditioned. Ceiling fans employed are obviously inadequate, making rooms warm. There are insufficient extractor fans in the production rooms.
- Floor area for production areas is inadequate for equipment, materials and movement of personnel. There is little area for circulation as materials and equipment take up most of the floor area.
- Production flow patterns are not in a sequential manner thereby encouraging contamination and /or cross contamination.
- There are no ceilings and roof members are exposed into the interior spaces where drug production is ongoing.
- Electrical wiring is exposed in some of the production units.
- There are no intermediate storage areas as such granules yet to be processed are stored in racks in the granulation area with temperature levels higher than the required 20^0C - 22^0C.
- Grooves in the floor tiles have not been sealed off.

CONCLUSION

A tour around the facility reveals that the construction of a new facility by the client is justified. The heating, ventilation and air conditioning is a major area that needs to be well designed for

such a facility where sterility is of prime importance. Some of the machinery and equipment are abreast with modern technology with great work output but they could easily break down given the conditions under which they are used. The humid conditions under which workers operate are also not conducive for effective output of work. Perspiration from workers could also affect the sterility of the atmosphere. The efficacy of drugs produced cannot be assured as the right parameters such as lighting, temperature and humidity levels for production are not checked.

The present location is mainly a residential one and at a serious risk of contamination and cross contamination of products. The industry could also be introducing harmful chemicals into the immediate environment consequently being a hazard to the community. Liquid waste from the plant runs through a main open drain along the street that borders the site. As one walks along the drain, the pungent smell of chemicals can be experienced. This could also possibly be harmful to the community as the drain is shared with residences in the community.

A new design located in an industrial area is therefore not overemphasised for the observations stated above. This would give the company a new image and possibly increase client list thereby directly increasing sales. Under the right parameters machines would work better and the efficacy of products can be assured. Last but not the least; workers would be physically and mentally refreshed to give their best at work.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter explains how data has been gathered for this research and also how it has been put together and categorised.

3.2 METHODOLOGY

An initial literature review was undertaken to give the author a broad overview of what pharmaceutical facilities entailed. Data was gathered from pharmaceutical publications on issues of drug production and the industry in general. The internet was also another source of information. In gathering information, the search was stretched and diversified to include other sectors that might not be directly linked to drug production but adaptable and of interest especially in modifying the industry such as new technologies in security systems, lighting systems and automation.

Issues on hygiene, sanitation, achieving quality in products and how these can be translated and appreciated architecturally were also explored. Other areas of concern such as proper waste disposal and movement patterns for both personnel and materials and how these can also be solved architecturally were also looked at.

Case studies were also conducted on the following pharmaceuticals:

- Tanzania Pharmaceutical Industries Limited
- Ernest Chemists Limited – Manufacturing Plant
- Aryton Drug Manufacturing Limited

With the exception of Tanzania Pharmaceutical Industries Limited, tours were taken in and around the other industries to make personal observations that were not captured in interviews, discussions or documents received.

Informal interviews and discussions were conducted with manufacturers, senior and junior staff at the plants to be acquainted with basic procedures and required spaces needed and any other relevant information. Such discussions were also held with architects that had ever designed such plants. Informal discussions held were found to be valuable as relevant issues not thought about initially came up during interactions.

Observations of interest were documented under each case study as comments. These were observations that generally pointed either towards standardization or modernity or the lack of it. Conclusions were then drawn as to strong points of the industry worthy of emulation or adaptation in the thesis design.

Technical studies concerning factory design such as vehicular types and turning angles, factory hygiene and circulation in warehouse and production areas were also studied prior to the commencement of the design.

To spearhead the design proposal some special studies were undertaken such as:

i. flow charts for different production lines in a typical non sterile dosage facility
ii. activities and special needs for specific production rooms or areas
iii. production machines, uses and their dimension

A good understanding of these was thought important to avoid issues of contamination, stable temperature and humidity levels and to maximising machinery output. Again knowledge of needed machines, uses and dimensions would enable a good design of room heights and comfortable areas around machinery for personnel to operate comfortably and safely.

The design proposal then follows which sort to be a solution to a modern and tropical design of a pharmaceutical facility.

Conclusions were then drawn highlighting how the objectives of the author have been achieved in this research. Recommendations were also made from the findings as the design proposal evolved.

3.3 SUMMARY OF INFORMATION FROM INTERVIEWS AND DISCUSSIONS

Leading to the writing of this report, information was gathered from a variety of experts and professionals directly or indirectly linked to the pharmaceutical industry such as architects, pharmacists, workers at of pharmaceutical plants, manufacturers and technicians through informal discussions and interviews. Some of these discussions had guideline questions because some specific information was sought but most often the author brainstormed a variety of issues of interest as the discussion progressed and through this means other issues probably not thought of initially would be brought up and discussed. People spoken to were willing to share their knowledge and more information was gathered this way.

- **Strategies to stay in business**

Advertisements are placed through television, radio, posters, promotion fairs, bill boards etc.., especially for new products, upgraded and repackaged ones. To keep up in business, manufacturers may purchase better machines and equipment or upgrade them especially machines for products that are doing well on the market. With this background knowledge, a designer should know and make allowances through the design for machine upgrades and new ones to be purchased. When a manufacturer purchases a new machine or upgrades, he should be able to estimate or be informed by the machine manufacturers how long the machine would function effectively depending on the efficiency level expected with time.

- **Modern Trends**

The issue of modernity came up as business strategies were further discussed. It was deduced that manufactures are realising that modern trends in the industry is not just about machinery but covers every aspect of the industry. Modern trends should be embraced in every aspect of the daily running of the industry.The planning and designing of the facility is a collaborative effort of a team of experts (mentioned in earlier text) informing each other in their area of expertise. With modern trends the efficiency of workers improves and so is the quality of products.

The choice of finishes, especially for interior spaces should be chosen primarily to avoid contamination of products. Positioning and designing of doors and windows are planned to avoid contamination and regulate solar ingress and natural day lighting. In this way, parameters such as temperature, humidity, lighting levels are planned and controlled. To be abreast with issues such as these, there is the need for regular research. Aside books, manufacturers stay abreast on recent trends via the internet. The need for access to the internet has therefore become a necessity and also a means for business transactions.

- **Security**

Security in and around a facility is also essential for reasons of theft and even biological weapon attack possibly by competitors. Most industries employ security personnel as the only security measure but manufacturers are now taking a keen interest in the use of modern trends in the security system such as the use of a Closed Circuit Television (CCTv) system.

- **Siting the facility**

The location of the facility was also seen as prime. Proximity to the source of raw materials and distribution routes is an advantage. It would be better to site a facility in an industrial area away from residential areas where there was the possibility of a short or long term toxic effect on residents. This could result in a law suit against the company. Siting the facility surrounded by

toxic producing industries could result in the contamination of the products especially where incoming air into the production area is not well filtered. In such a situation very expensive filters would be needed to detoxify the air. As a pharmacovigilance agency is to be setup in Ghana, complaints could be made by unsatisfied consumers and products could be recalled from the market.

- **Is there much thought about tropical designs?**

It was also gathered that with the exception of the few purpose - built ones, not much thought was given to designing the facility to suit the tropics without compromising on quality of products. It was deduced that this could be because layout is generally not well planned and not purpose built by qualified designers. If the design turned out to be favourable to the climate it was fair, otherwise what has been important to the manufacturer was to have spaces available for production.

Gradually, the mindset of the manufacturer is changing though as he sees the need and advantages of a purpose built facility. It is now necessary for stakeholders of the industry to be educated on the need to build to suite the climate without compromising on the proceedings especially in the production area.

- **General Information**

Due to the frequent power outages and interruption in the flow of water from the mains, generators and water tanks and reservoirs are employed to ensure continuity in production. Solar energy is also to be considered as an alternative source of power as there is abundance of solar energy in the tropics.

Good hygiene practices are also emphasised especially for personnel at the production unit. It was agreed that much more could be done such as personnel showering before entering

production and linking sanitary areas to production areas but separated by air locks or better still air showers.

The need for better control of parameters such as temperature and humidity was also discussed to ensure uniformity in the quality of the products. For instance rather than the use of fans to regulate temperature in which case windows would be open to the environment, all production rooms should be air conditioned and monitored to suitable temperature levels for the products being produced there.

On machinery it was gathered that there was the need to change or update machinery according to the manufacturer's manual, aside maintenance works. Machines and machine parts age with time and materials from which machinery are made may begin to react with materials from which products are made. It was explained that the position and movement of personnel around machines and in moving materials through the flow should be well coordinated. Through the discussions and interviews, information was used to draw a pattern flow or flow charts for the various production lines and that is very important for any manufacturer and designer.

In designing the structure a convenient grid system should be established. As most machines used are large covering a lot of floor area as well as ceiling heights, column centers should be large enough and allow for easy movement of personnel and materials being processed around machines. Ceiling heights should also be convenient and allow for a machine highest above the ground and still space above the ceiling to hold service lines to be passed through the top. A fair knowledge of dimensions of machines to be used is therefore necessary.

3.4 CONCLUSION

Throughout the research it is to be observed that information and data has been carefully selected not only to be useful in a pharmaceutical facility setup but generally in factory design and also to broaden or inspire the reader to possibilities in modern trends and the way forward.

3.5 LIMITATIONS

As stated above, upon pursuing this research, it was realised that access to data or information on the architectural aspect of pharmaceutical industries was difficult.

Most publications were on technical information about water used in production, heating, ventilation and air conditioning (HVAC). To assess recent architectural information on pharmaceutical facilities one needs to be a registered member of pharmacy related organizations, order the publication from the internet or some similar limitation.

Obtaining permission to undertake case studies at chosen industries by manufacturers was also an obstacle to overcome. Since quite a number of plants visited were visibly not in good shape, manufacturers were unwilling to expose their facilities to scrutiny. Others saw it as plots by competitors seeking information. It took a lot of convincing to be allowed to tour some of these facilities. Again, for security reasons, one had to go through some security searches and be approved by different departments to gain access to certain areas. Some areas too were strictly out of bounds.

CHAPTER FOUR

4.0 RESEARCH FINDINGS AND DISCUSSIONS

4.1 TECHNICAL STUDIES

This study helps to mainly justify the spaces provided both horizontally and vertically.

4.1.1 Factory

For factories large spans between column grid points a minimum of about 6m by 6m is preferable especially in heavy duty industries as in a pharmaceutical industry. It allows for ease of movement of materials, machines and personnel. In a pharmaceutical industry, this also aids to reduce contamination.

- **SELECTION STRATEGY**

An industrial building designed to be so closely matched to the initial process or layout can prove as inflexible and costly to operate in the long term as those designed to minimise capital cost.

Multilevel development can be efficient particularly where land value is high. Consideration should be given to personnel circulation and escape routes, fire control, goods circulation and process, trucks and private vehicle access and parking.

Multilevel factories are also economical for process based industries such as for food, pharmaceutics and tobacco where gravity can be used in the process and energy conservation by a compact planning and design.

Compartmentation, so long as it is compatible with the handling and services demands of the production and storage process, can be used to reduce both energy loss and the release of certain harmful substances. In the case of pharmaceuticals, it reduces or eliminates contamination of products or processes.

Floor dimensions at the production area should allow for the unobstructed flow of materials during processing. Enough space should be given around each machine for easy personnel movement during production. For pharmaceutical plants it is imperative that the exact machines locations and their peculiar requirements (eg. some require the intake of filtered fresh air and as such should be close to an external wall) and dimensions should be noted as machines are fixed and immovable. Room heights should also take into account machine heights and air conditioning ducts.

4.2 SPECIAL STUDIES

Some special studies were undertaken namely:

i. flow charts for different production lines in a typical non sterile dosage facility
ii. activities and special needs for specific production rooms or areas
iii. production machines, uses and their dimension

to make well informed design decisions in specific rooms at the plant.

SPECIAL STUDIES

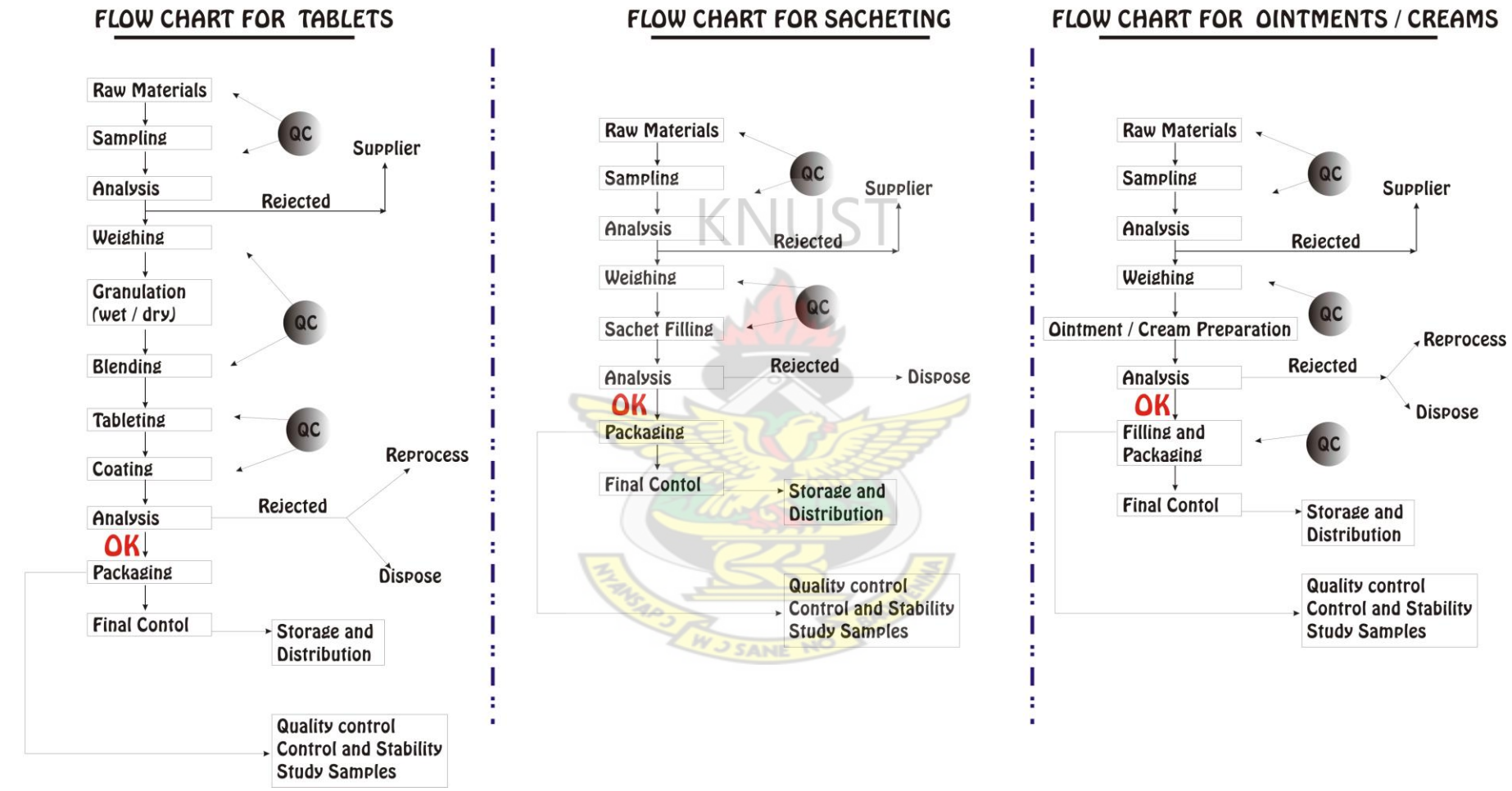


Fig 1: Special Studies – Flow Charts

SPECIAL STUDIES

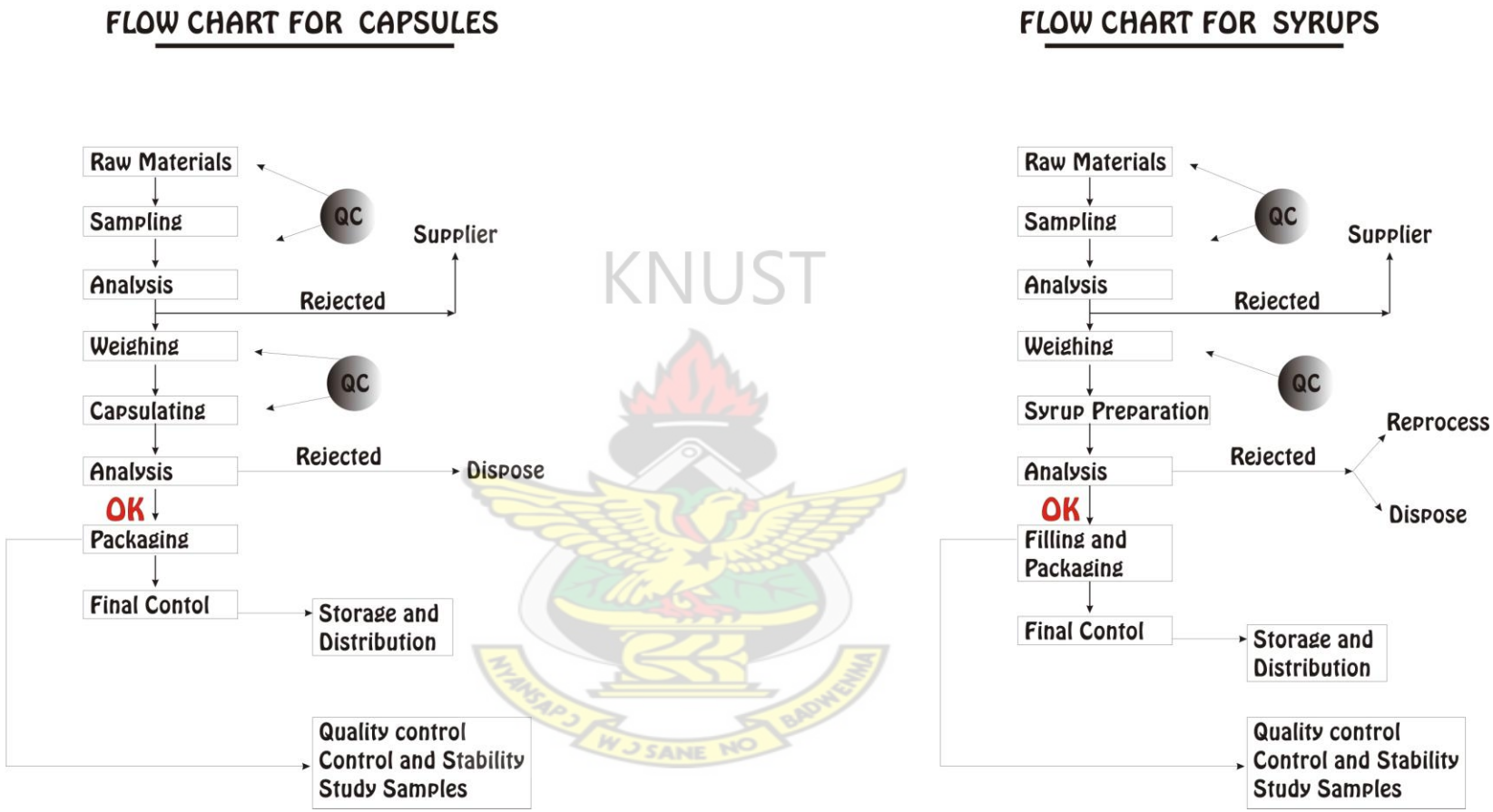


Fig 2: Special Studies – Flow Charts

SPECIAL STUDIES

PRODUCTION ROOMS, ASSOCIATED ACTIVITIES AND SPECIAL NEEDS

SPACE	ACTIVITIES	MACHINES USED	SPECIAL NEEDS
TABLETTING UNIT			
Granulation room	kneading shredding drying sieving blending	rapid mixer granulator multimill fluid bed dryer sifter blender	all the machines should have access to a flexible extractor arm that is connected to the network of extractor ducts for the extraction of powder particles from the processes fluid bed dryer should be placed close to an external wall for fresh air to be ducted into the machine to dry the product and then the used up warm air to be ducted outside
Compression room	compacting of granules to the desired form	single and double rotary tablet press	all the machines should have access to a flexible extractor arm that is connected to the network of extractor ducts for the extraction of powder particles from the processes
Intermediate room	storage of unfinished products and granules yet to be processed and packaged	_____	room needs to be cooled. No natural lighting allowed as materials are affected by change in temperature
In - process quality control	ensuring that the right parameters for products are met such as hardness, friability and alkalinity	table top machines	_____
Coating room	coating of tablets with solutions that forms a crust around the tablet	auto coating machine coating machine	auto coating machine should be placed close to an external wall for fresh air to be ducted in to dry and harden the coating solution around the tablet and the used up warm air to be ducted outside

Fig 3: Special Studies – Activities and Special Needs in Production

SPECIAL STUDIES

PRODUCTION ROOMS, ASSOCIATED ACTIVITIES AND SPECIAL NEEDS

SPACE	ACTIVITIES	MACHINES USED	SPECIAL NEEDS
TABLETTING UNIT			
Coating room			machines should have access to a flexible extractor arms room needs to be dehumidified
Packaging room	blister packing strip packing — primary packaging bulk packing packaging into final packaging containers — secondary packaging	blistering machine strip packing machine tablet counting machine conveyor belt	primary packaging areas to be completely enclosed in cubicles to protect different products being packaged from contaminating each other. after primary packaging products should be sent on a conveyor belt for secondary packaging machines should have access to a flexible extractor arms
ENCAPSULATING UNIT			
Production area	sifting milling blending filling packaging	sifter multi mill octagonal blender capsule filling machine blistering machine	all the machines should have access to a flexible extractor arm that is connected to the network of extractor ducts for the extraction of powder particles from the processes
SYRUP UNIT			
Preparation area	weighing mixing	floor scale mixing vessel	———
Packaging area	filling and capping labelling packaging and wrapping	syrup filling machine labelling machine conveyor belt	

Fig 4: Special Studies – Activities and Special Needs in Production

SPECIAL STUDIES

PRODUCTION ROOMS, ASSOCIATED ACTIVITIES AND SPECIAL NEEDS

SPACE	ACTIVITIES	MACHINES USED	SPECIAL NEEDS
OINTMENTS AND CREAMS UNIT			
Preparation area	wax melting milling uniform blending	wax melting machine colloid mill homogeniser	———
Packaging area	filling into tubes or containers final packaging	filling machine conveyor belt	
SACHETS UNIT			
Preparation area	weighing sifting blending	table top scale sifter double cone blender	machines should have access to a flexible extractor arms room needs to be dehumidified
Packaging area	filling and packaging	sachets machine	

NB

- All production rooms should be air conditioned to a general temperature of between 20C and 24 C unless otherwise specified
- All rooms should be fitted with fixed, air tight windows
- Air locks,(an enclosed space with two or more doors to be used for personnel or products movement) should be used to separate one production unit from another or a different space with differing classes of cleanliness. this is to control the airflow between those rooms and thereby reducing contamination and cross contamination.

Fig 5: Special Studies – Activities and Special Needs in Production

SPECIAL STUDIES

MACHINE	USE	DIMENSIONS (lxbxh)
 square model single sided rotary tablet press	compression of granules into tablets with grooves on one side	1200 x 1200 x 2000
 square model double sided rotary tablet press	compression of granules into tablets with grooves on both sides of the tablet	1200 x 1220 x 2000
 seiving, grading and straining machine	for sieving and straining of powders	1200 x 1200 x 1300
 fluid bed dryer	drying of granules	2000 x 1200 x 3000
 double cone blender	blending of granules	1200 x 1000 x 1500
 shredder / multimill	milling of granules	1200 x 1200 x 2000

Fig 6: special studies – production machines uses and dimensions

Sources: illustrations a, b and c – Brochure of Kaixinlong Pharmaceutical Machinery Works – Rujan, illustrations d, e and f - Ernest Chemist Limited manufacturing plant, Tema

SPECIAL STUDIES

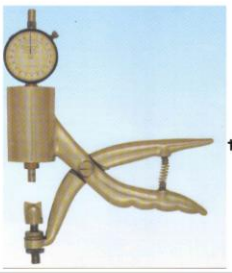
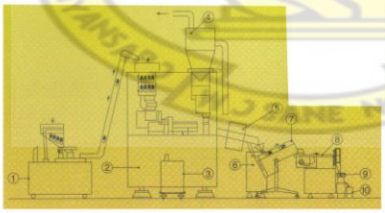
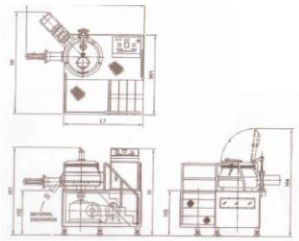
MACHINE	USE	DIMENSIONS (lxbxh)
 mixing vessel	vessel into which liquids are mixed for filling into bottles	1500 x 1500 x 3000
 conveyor belt	for transporting products from one machine or stage of work to another	adjustable length to suit operation
 tablet counting machine	for counting of tablets	1500 x 1200 x 1300
 tablet hardness tester	for testing the hardness of compressed tablets	300 x 225 x 750
 automatic capsule filling machine 	for filling of powders into capsule shells	3500 x 2500 x 2550
 rapid mixer granulator 	first stage in tableting for mixing of active ingredients for a particular tablet	2400 x 2200 x 2050

Fig 7: special studies – production machines uses and dimensions

Sources: illustrations a and b, - Ernest Chemist Limited manufacturing plant - Tema, illustrations c, d, e and f - Brochure of Kaixinlong Pharmaceutical Machinery Works – Rujan

SPECIAL STUDIES

MACHINE	USE	DIMENSIONS (lxbxh)mm
 sifter	sifting through granules to get even or equal particles	800 x 1000 x 1220
 blistering machine	primary packaging of tablets into blister forms	2000 x 1200 x 2200
 auto coating machine	coating of tablets with a solution to preserve it after compression	1500 x 1200 x 3200
 coating pan	coating of tablets with a solution to preserve it after compression	1200 x 800 x 1550
 polishing pan	giving coated tablets a smooth finish and dusting off any residue powders	1200 x 600 x 1200
 strip packing machine	for the primary packaging of tablets into strips	2000 x 1200 x 2400

Fig 8: special studies – production machines uses and dimensions

Sources: illustrations a, b, c, d, e, f - Ernest Chemist Limited manufacturing plant, Tema.

4.3 A DESIGN INTERVENTION

Having put together all the information received a solution was sort where most of the problems that were realised were resolved through a design. The design goes through all the design processes and all these are reflected in the final design. The design includes probable spaces in a typical non – sterile production plant. The brief for the design was further developed to include other facilities that could be a part of the daily running of a pharmaceutical industry such as an administration block and a research unit.

4.3.1 Design Philosophy

- the use of modern building materials adaptable in Ghana
- the use of glass and courtyards for transparency and lightness in the ambience of the facility and also to make the facility make use of the tropical environment
- secure, tangible circulation routes or patterns for ease in movement and smooth transaction of business

These ideas have been summed up in the phrase, 'The building envelope – an image of the content's quality**,'** to be used as a guideline in achieving the design ideas.

4.3.2 Functional Relationship

To initiate the design, functional relationship diagrams were sketched to give an idea as to how the various blocks or units could possibly relate to each other in terms of activity patterns and movement patterns.

One option was preferred and further developed into a conceptual site diagram relating it to the site.

Due to the different activities that take place at the facility, there are different functional relationships for each unit.

- THE GENERAL LAYOUT – There are two main accesses into the site. One access way, which is private leads mainly to the loading bay and is also used by the staff bus to bring staff to work. The other entrance leads to the private cars parking and this is

further divided into customer and staff parking. People then move from these and filter into the different facets of the facility.

There are four main structures on the site and these are positioned from the entrance in this order:

a. the administration and wholesale unit

b. the warehouses

c. the plant

d. the maintenance unit

THE RAW MATERIALS WAREHOUSE

Raw materials are first quarantined for testing to ascertain the quality. Unacceptable materials are further quarantined and disposed off appropriately. Accepted materials are sent to the main storage areas. Orders are placed for them by the production unit as and when they are needed and these are then sent for processing.

THE PLANT

There are two types of movement patterns here as well, namely material and personnel movement.

- **Material Movement**

Ordered materials are tested again by Quality Control for appropriate qualities. If accepted, the products are first weighed at a common area from where they are sent to the appropriate unit for processing. There are also quality control checks during production to ensure that the right parameters for particular products are met. After production, products are packaged and sent for storage.

- **Personnel Movement**

Production personnel converge at a common concourse which has locker spaces for storage of hand held items like bags. Personnel then go through a security check and then disperse to either

the male or female changing areas to first take of their street clothing, take a shower and then get into their work clothing. From the changing rooms they get to a common corridor and filter into their respective units.

- **Research Unit**

Another independent unit is the research unit which is in a wing of the production building. Activities here have no direct link with production. Access to this unit is from the staff parking area to a reception and then to the lab, offices and ancillary facilities.

THE FINISHED GOODS STORAGE

Finished goods from production are first quarantined for quality control checks. Rejected ones are either destroyed or sent for reproduction. Accepted products are then sent to into the storage area attached for despatch when necessary.

THE MAINTENANCE UNIT

Staff at the maintenance unit first go through a changing area where they put on overalls atop their street clothing and then into the workshop.

4.3.3 Conceptual Site Planning

Based on these functional relationships, possible arrangements of the major units were realised graphically 3 - dimensionally. Certain observations were made with each of them leading to the next representation. The final one was picked as the best option as it had a combination of good merits from the former options.

4.3.4 Form Development

The idea of ‘tablets and pills’ was used in developing the design 3 – dimensionally depicting the kind of industry it was. Basic forms of oral dosages such as tablets and capsules were put

together to create forms for the facility. Shapes and variants of shapes such as circles, cylinders and rectangles were realised to be the most used shapes for solid dosages. Some sketches from these forms and shapes were made as to possibilities of the form the design would take, especially the facade design.

4.3.5 The Design

GENERAL

The facility has been designed to blend with the immediate environment and yet be able to stand out of the lot and make a good impression on users and passers – by. The facility has also been designed to ensure the comfort of the staff as they would be using the facility for relatively longer periods.

The facility is oriented in a North North – West and a South South –East direction.

Considering the complexity of the facility, features such as courtyards and glass elements have been introduced, giving the facility a lighter and less imposing look. These features are also to help the facility to be well ventilated and well lit from natural day lighting as much as is permissible as it is situated in the tropics.

The facility has access to basic services such as electricity, water, telephones and internet services to ensure the effective running of affairs. Alternative provision has been made for electricity and water supply to avoid disruption of activities at the facility.

An attempt has been made to make all units self reliant in terms of amenities so that there is little or no interference to daily schedule of activities. The various units in the facility have been positioned giving consideration to relationships existing between them.

For security reasons the facility has also been divided into public, semi – private and private zones with the public zone being the first point of call especially for visitors and the private areas

being restricted to workers. The public zone consists of customer parking areas and the research units (excluding the laboratories), the wholesale and the administration. The semiprivate zones are the staff parking area, canteen and the maintenance units. These areas are easily accessible to all staff.

The private areas are the plant, warehouses, quality control and the research laboratories. Access to these areas is highly restricted for security and health reasons. Access is by the use of cards which are activated for a determined period of time that is, a day, for staff in these areas and others of relevance to these areas.

LAYOUT

Access to the facility is from a main road in front of the site. There are two entrances into the site. The first one is used by both pedestrians and people commuting by private vehicles. The other entrance is a private entrance for delivery and off – loading trucks and also for the staff buses that bring staff from Accra and Tema.

There is also a lay – by at the entrance to be used by commercial vehicles bringing people to the facility.

There are four main blocks on the site that is:

- Administration and wholesale block
- Warehousing block
- Production block
- Maintenance block

The administration sees to the planning and organisation of the facility and the wholesale unit is a sales outlet for bulk purchasing of the company's products.

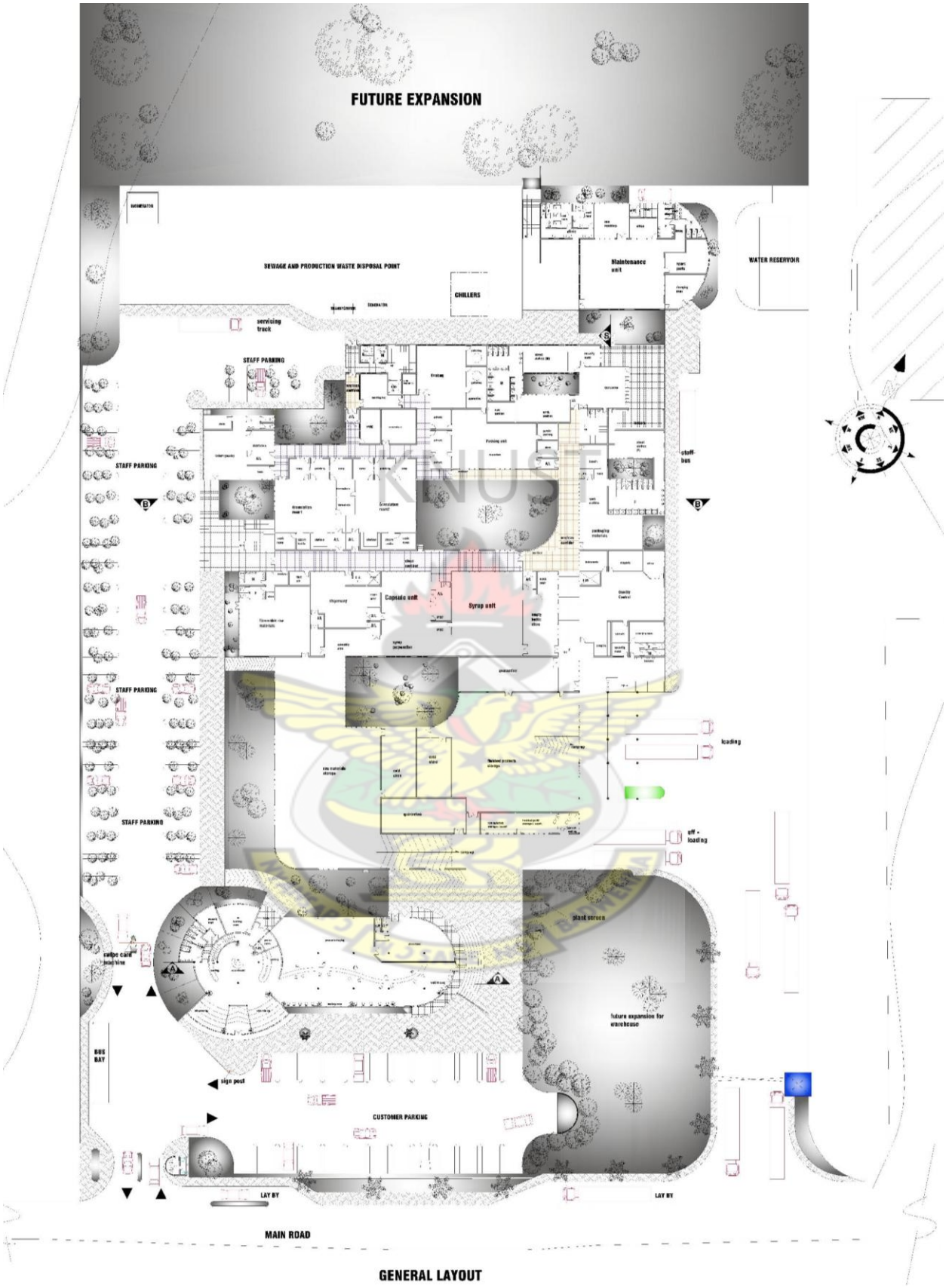


Fig 9: General layout of facility

The warehousing block has storage areas for both raw materials and finished products.

The production block houses two main units: the plant and the drug research and development units. The plant, which has the highest priority, is for the production of pharmaceutical products. The research and development unit is for the improvement of the company's products.

The maintenance block serves the whole facility in repairing, maintaining, and installation of machines, receiving and storage of new machines.

There is a bus bay for group visitors at the main entrance. Car parking for staff and customers has been segregated with restricted access to the staff parking area to be accessed by swipe cards.

The sewage tank and incinerator serving the whole facility have been placed at the back of the facility. Other services placed at the back of the facility are the air conditioning chillers, a transformer, a chemical waste soak away and a generator plant. To the opposite side is found the water reservoir.

PLAN

Administration and Wholesale Block

This block is a six levelled office block with a podium which houses the wholesale unit. The general plan form of this block is a combination of a circular tablet and a capsule. Even though the two units are housed in one block, there is a clear distinction between where one ends and the other begins and what is common to both.

The main access into this block especially for visitors is through a large products display area. A ramp leads from the entrance and ends at an open lobby or concourse.

There is another entrance to the back of this block from the staff parking area for staff. Much detail is not given about this block as the main emphasis of this publication is on the plant and its procedures.

Raw Materials Warehouse

Drug substances or raw materials are brought to the facility through the service yard entrance to the off loading bay. Quick tests are performed on a sample of delivered materials to check for quality before off – loading. Materials are received by the raw materials manager who is provided with an office at the warehouse. There is a quarantine room for received materials to be released into the main storage area after more elaborate test from the Quality Control department. There is a cold room for storage of excipients and delicate drug substances. The storage area is air conditioned to a temperature range of about 20^{o}C to 22^{o}C. There is an assembly area where drug substances that are ordered for production are assembled. Ordered materials are then sent to a dispensary attached for weighing.

There is also a secured area for the storage of flammable drug substances with restricted access to it. It also has a fire escape door and fire fighting equipment close by in case of a fire outbreak.

There is also a changing area for staff working at both the raw materials and finished products warehouses.

Production Block

Ordered materials from the raw materials storage are all weighed at a common dispensary for security and convenience. Materials are then sent to their respective units for processing. There is a goods lift in the dispensary for conveying drug substances to the processing units above. There are five units at the plant for the five different processing lines namely: tablets, capsules, liquids, sachets and ointments and creams.

On the ground floor of the production unit there are three of the five processing lines namely: tablets, capsules and liquids. The tablets and liquids departments were placed on the ground floor

because of the use of heavy machinery. Also the tablets unit involves a lot of processes and as such is the largest production unit occupying about half of the plant.

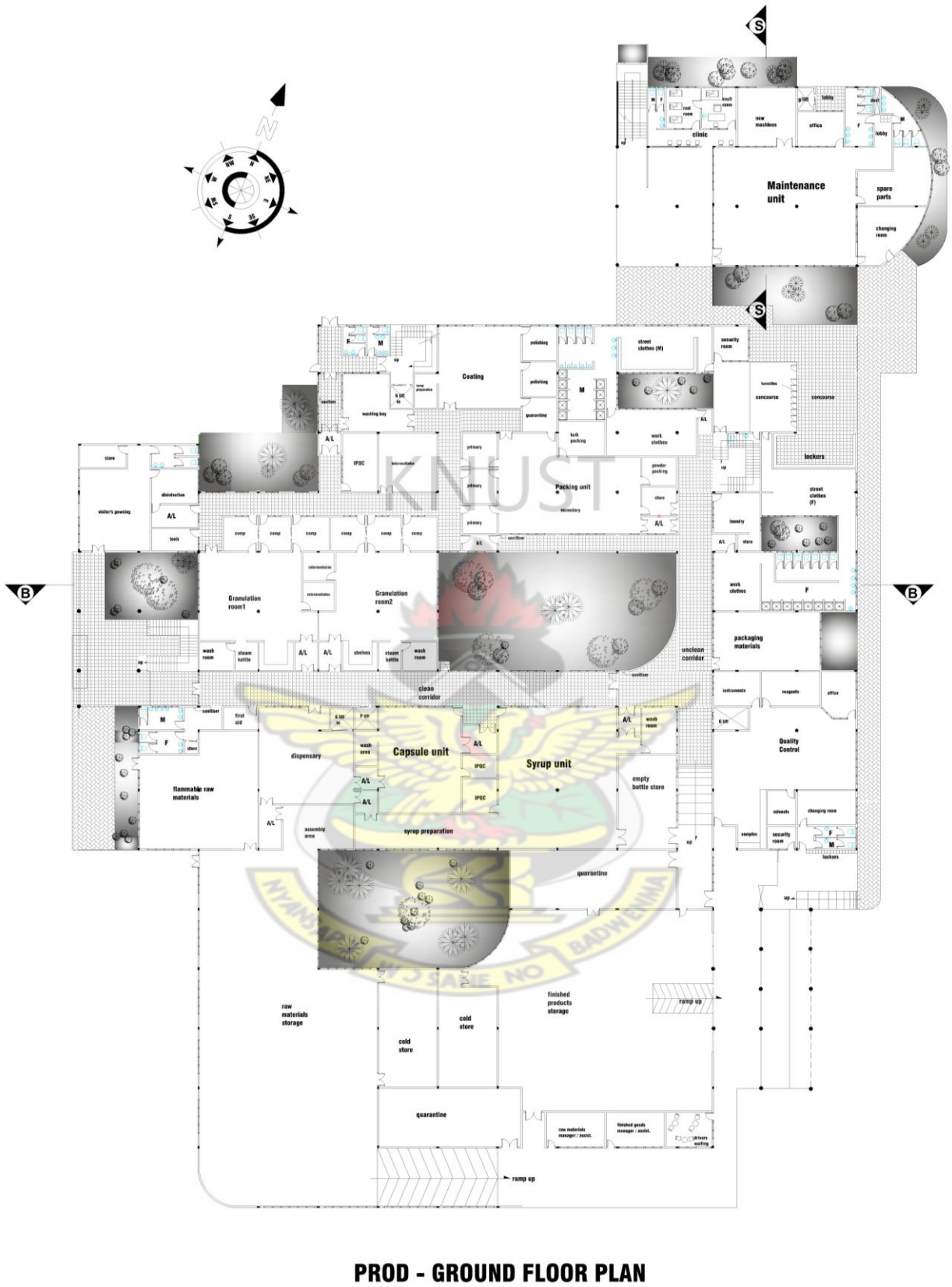
There is also a visitors' gowning room for visitors touring the plant. It also has a disinfection room for the disinfection of the rubber boots worn before entering the plant. There is a passenger lift especially for visitors to the next level and this has been strategically placed at the end of a tour of the ground floor.

Large rooms have been provided for the storage of primary and secondary packing materials on both floors.

The Quality Control (QC) department is also found on the ground floor of the production block. Its location is easily accessible to the warehousing facilities for tests on drug substances that have been brought in and finished products. It is well equipped with a laboratory and rooms for storage of instruments, reagents, solvents and an area for samples of products and materials for observation.

At the finished goods warehouse there is a room for the immediate quarantining of finished products for tests to be performed on them by the QC department. Accepted products are moved to the main storage. It also has cold room facilities for products that need refrigeration. There is also an office for the manager and an assistant.

A drivers' rest room has been provided for drivers waiting for their trucks to be either loaded or off-loaded. They also have access to sanitary facilities.



PROD - GROUND FLOOR PLAN

Fig 10: production unit- ground floor plan

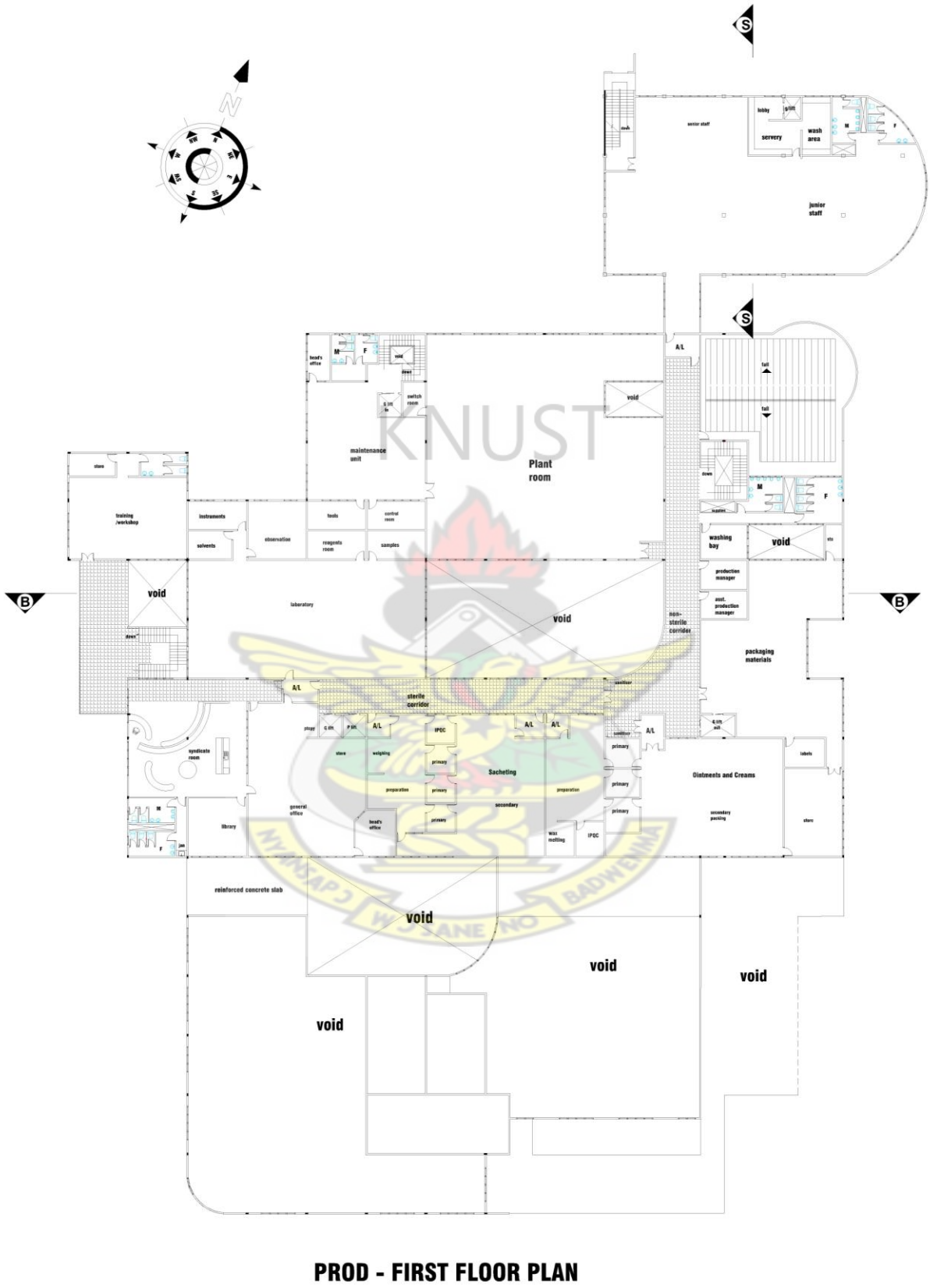


Fig 11: production unit- first floor plan

Second Level

The second level of the production block houses the sachets and ointment and creams unit. Raw materials to these units are conveyed via the goods lift in the dispensary for processing. To the opposite side of the processing units on this level is the plant room.

The plant room could become a source of noise for the factory if it is located at the factory (which is preferable for ease in ducting of conditioned air and connecting of dust extraction ducts). Resilient material would then have to be used to reduce vibrations. The plant room is separated from the processing units on this level by a void. The plant room being above the main plant floor aids in the effective distribution of filtered, conditioned air into the rooms by laminar flow.

All entrances to the various processing units are characterised by airlocks. The process flows for all the units have been explained in the flow diagrams in earlier text in this report.

Machinery for processing in the various units have been placed in a sequential manner following the logical movement of materials for processing so that there is a smooth flow of production without unnecessary disruptions to control contamination and cross – contamination of products and materials. It also ensures the safety of personnel.

The utility room houses the central air handling unit, switch room, water treatment plant and boiler and also the dust extraction equipment.

The plant has its own maintenance unit which installs and repairs machines for the plant only to avoid contamination. There is a lift that transports machines and machine parts to the maintenance unit above. There is an office for the head with other supporting facilities. There is also a control room from where all machines used in all processing units have been connected so

that if there is a major fault on any of the machines an alarm would go off in the control room for immediate attention.

The research unit is also located on this level. It is accessed from a reception where visitors can make inquiries. There is also general office. It is also equipped with a library with internet connection and sanitary facilities. There is a spacious laboratory with associated facilities. A syndicate room has been provided where staff can rest and share ideas to improve their work.

There is also a training workshop on this level for periodical training of staff.

Maintenance Block

Behind the production block is the maintenance block. It has changing room facilities, spare parts and new machine room, sanitary facilities and an office for the head. This unit serves the rest of the facilities.

Next to this unit on the ground floor is the clinic with a consulting room, rest room, a waiting area and sanitary facilities.

Above the clinic is the canteen. It has a servery, eating area and sanitary facilities. There is a goods lift that transports cooked food to this level.

STRUCTURE

The facility is designed on a modular grid of 6 x 6 meters spacing. The sizes and total number of columns reduces with increase in height so that loads are safely transferred to the foundation. This also reduces the cost implication.

Glass elements have been used to reduce overall loads. The roofing material is of self supporting barrel roofs ventilated by some jalousie openings used also as a design feature.

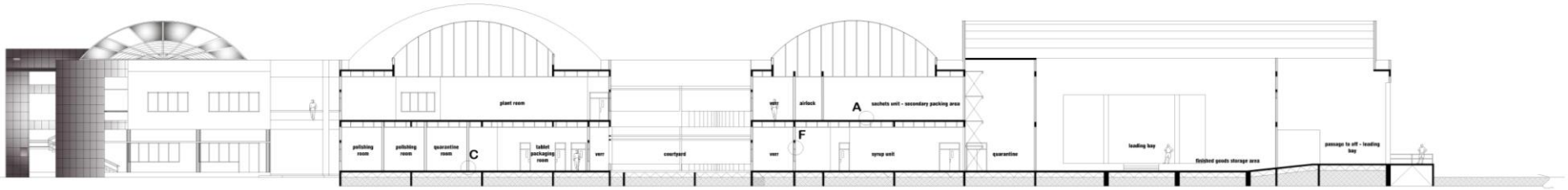


Fig12: Section C- C

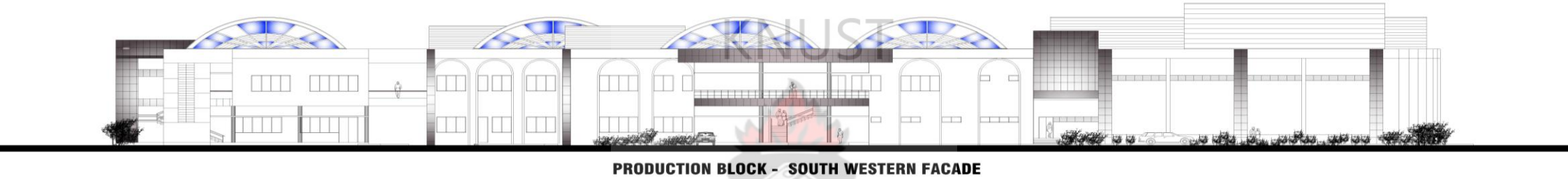


Fig 13: South - Western facade

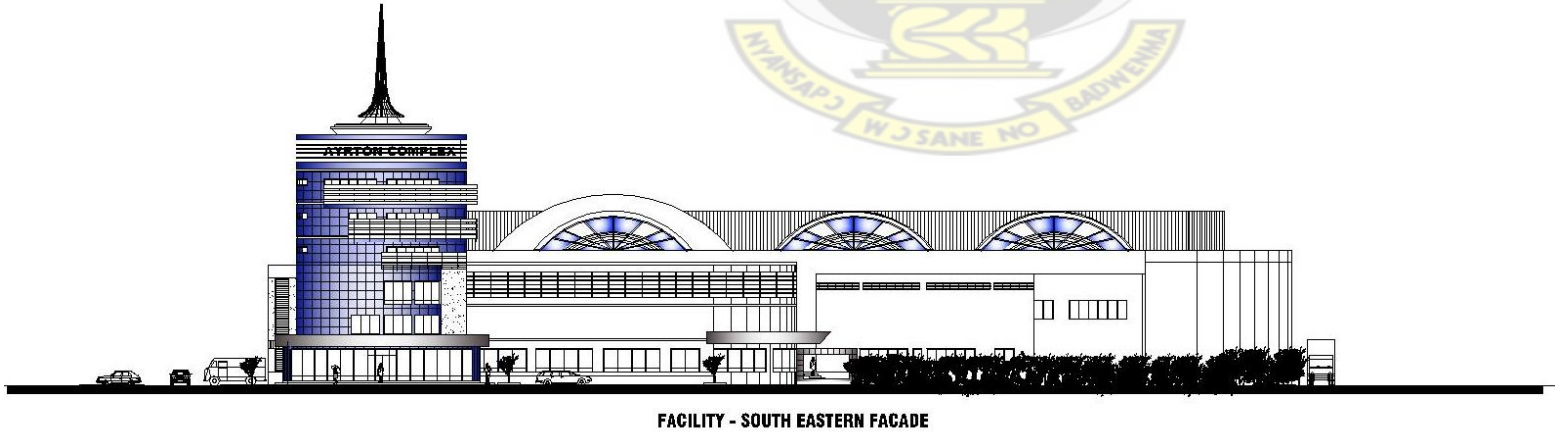


Fig 14: South - Eastern facade

ELEVATIONS

Looking at neighbouring industries one realises that they have similar features that make them industrial. Most had barrel roofs, deep room heights and had imposing, solid looking forms with high level windows. Most of them also had their columns protruding as a design feature to avoid the monotony of flat continuous stretch of walls. The roofs were realised to be a prominent feature in their designs with deep roof heights as well.

On the other hand most of them looked the same with the only differences in the sizes of roof, choice of colours and the names of the industries.

With this background the designs sought to break away from the monotony of repetitive roofs and flat facades. Barrel roofs were used but bearing in mind to make a good impression on the on looker. Using column grids of 6m by 6m some stretch of 6m were skipped to avoid the repetition of 6m wide barrels. The roof sizes and heights were also varied but complementing each other. Shades and shadows were used to create an illusion of different colours and textures. Some columns were used as design features and also function as drainage paths for rain water from the roof.

Glass elements have been used to make the structure look less dense. The roof is ventilated by some jalousie openings used as a design feature.

Horizontal elements such as stretches of continuous windows, different shaded windows, hatches, renderings and shading devices have been used to reduce the imposing height of the structure.

MATERIALS

The method of composite construction has been used, where a mixture of concrete with block work, steel and glasswork are the materials used. Alucobond has also been used as a finish for certain areas of the facade.

SERVICES

ELECTRICITY - The Hydroelectric power is tapped from a 3 face LV lines, which can be located along the main road in front of the site. The electrical power after being tapped from the mains is into a transformer and then connected to a generator plant. This power is then drawn into a switch room where the distribution is done. The electric power is serviced to the various floors through service ducts that have been provided at vantage points.

LIGHTING

The two major sources of lighting have been employed in this design that is artificial and natural lighting. Generally, a lot of consideration has been given to natural lighting so as to make the design tropical and cost effective.

For the plant and the laboratories, even though natural lighting is allowable in most spaces, some level and quality of lighting is needed and this is achieved by the use of artificial lighting. In some spaces such as cold rooms and intermediate rooms lighting is only by artificial means.

Courtyards have been introduced to provide natural lighting where necessary.

The rest of the facility has been designed to use natural lighting unless conditions necessitate the use of artificial lighting.

VENTILATION

Both natural and artificial ventilation have been employed in the design. Generally natural ventilation is employed in most areas with the exception of production rooms of the plant which

relies solely on artificial ventilation, that is, filtered conditioned air at a general temperature of about 22^{o}C and 24^{o}C to avoid contamination from the external environment.

SECURITY CONTROL

This is aimed at reducing theft, biological weapon attack, and other security breeches. Security personnel have been located at all entrances and main accesses into the facility. An attempt has been made to create a secure environment by way of design so that people who use the building are not overwhelmed by the presence of security personnel. Areas which require a high level of security can only be accessed by access cards which would be acquired from the security department at the time of need for a particular duration after which the card expires. Staff has access cards restricted to areas in their movement patterns in the day.

The whole security system is controlled from the security department which is equipped with modern technologically rich machinery including CCTVs connected to cameras placed at vantage points to enable viewing of the whole facility to ensure good security. All security personnel are equipped with walkie talkies for easy communication.

External and internal artificial lighting have been provided to light up the facility at night to discourage intruders.

FIRE FIGHTING

In case of a fire outbreak, provision has been made for to control possible fire outbreaks by the use of water sprinkles, hose reels and fire extinguishers. Fire exits have been located at vantage points and fire assembly points have been created where people would gather in case of fire for identification. Water Hydrants have been provided.

SURFACE DRAINAGE

Open and closed drains have been provided on the roof and around the facility to drain rain water from the site.

The rainwater is to be harvested to be used in case there is shortage of water to maintain the sanitary areas of the building.

WATER

Water would be tapped from the mains into a water reservoir which can contain water that can serve the whole facility for about five working days in the event of water shortage from the mains. Water from the reservoir would feed tanks and it is water from these tanks that would be used to serve the whole facility. Water for production use is received into a water treatment vessel from the tanks to be purified to acceptable pharmaceutical standards.

4.3.6 A Modern Design

As the topic states the design proposal has sort to been an improvement on the industry in Ghana to be a modern design as well as a tropical one. Here the modern features have been highlighted and summarised as follows:

SECURITY CONTROL

- This is aimed at reducing theft, biological weapon attack, possible abuse of drugs by personnel among other security breaches.
- The facility has also been zoned by the design into public, semi – private and private units. The public areas are the first point of call and as such easily accessible, then, the other areas follow in that order.
- An attempt has been made to create a secure environment by way of design so that people who use the building are not overwhelmed by the presence of security personnel in that:

a. Security personnel have been located only at main entrances and accesses into the facility.
b. Areas which require a high level of security can only be accessed by access cards which would be acquired from the security department at the time of need for a particular duration after which the card expires.

c. Staff have access cards restricted to areas in their movement patterns in the day.

- The whole security system is controlled from the security department which is equipped with modern technologically rich machinery including CCTVs connected to cameras placed at vantage points to enable viewing of the whole facility to ensure good security.
- Well defined circulation paths throughout the facility
- The use of an intelligent lighting system that have sensors detecting motion
- Parameters such as temperature ranges, lighting levels have been computerised using a system called Building Management System
- A control room from where all machinery can be monitored and faults and breakdowns can easily be detected
- Each unit is self sufficient in terms of activity patterns.
- Some design features such as columns, jalousie windows, and that atop tower block of administration are for aesthetics as well as being functional
- Use of modern materials such as glass and steel and alucobond
- Water and power systems employed ensures continuity in the use of these services

4.3.7 A Tropical Design

The design proposal's adaptability to the tropics is summarised as follows:

- Use of courtyards to admit natural lighting and ventilation. Soft landscaping in courtyards deflect sun rays thereby cooling the immediate environment
- Use of sun shading devices where necessary
- Adequate use of fenestrations
- Jalousie openings in roof helps warm air in the roof to escape thereby cooling it
- refrigerated rooms have been designed to reduce solar ingress

4.3.8 Environmental Impact of Design

Physically, the facility has being designed to blend with the surrounding environment both structurally and aesthetically.

With respect to pollution conditions have been set in place to safely dispose off all waste from the facility.

WASTE DISPOSAL

Liquid chemical waste is treated by a system known as, Advanced Immobilized Cell Reactor Technology. The waste from the plant is channelled through drain pipes embedded beneath slabs and discharged into a soak away tank to the back of the facility. The waste goes through a system of filtration chambers. At the final chamber where all chemical reactions would have been neutralised, the liquid is channelled into another tank for reuse in gardening and for use in water closets.

Solid waste from the whole facility would be collected and emptied into an incinerator provided to the back of the facility to take care of solid waste from the whole facility.

Dust particles from the plant as a result of dust producing processes would be extracted through flexible extractor arms introduced into dust producing areas. These extractor arms are connected to a network of extraction ducts which terminates in a dust collection equipment. The settled dust particles are securely emptied into a plastic container and by a contract with the right authorities these can be collected from the site and disposed off safely.

Soil waste is discharged into the main drain along the site. Waste water from the whole facility is discharged into a septic tank to the back of the facility to be emptied when full.

CHAPTER FIVE

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSIONS

In Ghana some pharmaceutical industries operate from structures let out for shops and offices or generally spaces not built for the production of pharmaceutical products. Others even operate from vehicles from which the necessary machines and equipment are operated. The quality of the products cannot be guaranteed. Issues of hygiene, temperature, humidity, lighting levels and comfortable working conditions for personnel are grossly compromised. These issues cannot be overlooked as they are peculiar to a product.

When the layout of the facility is well planned, the issues mentioned above, as well as others such as machine and personnel positions and movement patterns are resolved on the drawing board. They are therefore an integral part of the design. Possible problems are foreseen and resolved accordingly. It is to be realised that all systems and arms of the facility work effectively and harmoniously. Product quality and customer satisfaction is thus assured. Staff become comfortable and therefore more productive in their working environment because their comfort and safety has been catered for by way of design. This also reflects on sales as sales increases.

In as much as a tropical design encourages openings for good ventilation due to prevalent warm, humid climatic conditions and also natural lighting, the design of such a facility discourages openings for particular areas, a balance therefore should be reached to satisfy both conditions.

A look at the design proposal reveals that where natural lighting and good ventilation are permissible, such as circulation areas, maximum advantage has been taken by the use of courtyards and fenestrations. Spaces that require little or no amount of natural light have been positioned, by way of the design to disallow solar ingress. Sun shading devices have also been used to reduce solar ingress through fenestrations.

In Ghana, taking into consideration frequent power outages, it would be economically advantageous to make good use of natural lighting and good ventilation. [1]Studies have also shown that people working under natural light are more productive and happier in their work environment.

Technology today is continually and incessantly advancing and the limits to it cannot be foretold. Day by day man is exploring new ways to make existence much more comfortable, safer and easier and so it is in the pharmaceutical industry. As stated in earlier text, Building Management System, a form of automation for large facilities, is one major technology advancement that could be explored by the industry in areas such as security, lighting, temperature and humidity control and scheduled and unscheduled maintenance of equipment or machinery. With this system these and more can be controlled, regulated and monitored from one point in the facility. Aside the advantages stated earlier, it generally brings about effectiveness and ensures the smooth running of the facility. The size and requirements of a facility would determine the features of advanced technology required.

A good understanding of all the processes involved in the production of the various products by the industry should be sought. This would aid the designer to locate the various rooms and associated spaces and areas appropriately to ensure the smooth running of the plant.

5.2 RECOMMENDATIONS

It is observed that one main challenge to production procedure is undertaking maintenance works (on machines and in the usable areas) including cleaning without compromising on the quality of products. Stringent hygienic procedures should be documented and strictly adhered to, due to the humid conditions in the tropics. There should be periodical reviews, workshops, seminars especially for new workers to avoid fatal negligence due to lack of knowledge.

Regarding the siting of such an industry, it should be surrounded by non-toxic producing industries. This is economically advantageous in the long term. Money that would have otherwise been used to constantly purchase more expensive filters to filter in coming air is saved, also, in a contrary situation, side effects could be experienced by consumers in the short or long term. With the setting up of the Pharmacovigilance Centre in Accra, Ghana, a company could lose heavily by the withdrawal of their products and possibly sued by consumers for damages.

It is better for industries to be sited away from each other to avoid contamination. Where this cannot be avoided, measures by way of design, should be used to prevent contamination. On large properties, use of wide expanse of plant buffer between the two industries can reduce the risk of contamination. Such plant buffers should be sprayed periodically with chemicals to dissolve dust particles that have been trapped in the buffer zone.

As part of the daily quality control procedure, personnel should be assigned to do periodic routine checks on lighting levels temperature humidity for the different spaces. Automated systems can therefore be installed in assigned rooms from where these parameters can be checked and altered accordingly to ensure uniformity in products.
The different product processes should be well segregated, including the washing and cleaning of machines, materials etc.

The design could be opened up by the introduction of voids or courtyards. It makes the otherwise dense structure of a factory look lighter and allows the structure to ‘breath’. When well designed, such voids could be good views for users of the facility. Psychologically it improves the health and mood of personnel. When workers are comfortable in their environment, they enjoy their work better and are more relaxed. There are fewer mistakes, which cannot be afforded in such an industry and productivity also moves a notch higher. Such areas could also be landscaped well to be a thoroughfare, possibly linking blocks of the facility. A centrally

positioned one could also serve as a security check as personnel from adjoining blocks can view, to some degree, proceedings in the various blocks. It gives the feeling that one can easily be viewed by another from some other points in the facility.

Preferably, cold rooms should be designed away from direct solar ingress either by its location or by the use of sun shading devices for effective cooling. Most of the raw materials and finished products are sensitive to slight variations in conducive storage conditions such as lighting, temperature and humidity levels. Openings should be to the barest minimum or better still these storage areas should have conditioned air to the required level. The required temperature levels have been stated in earlier text.

Storage areas for flammable raw materials should be built in reinforced concrete rather than block work. It should be built to an external wall with fire exits. To reduce combustion in case of a fire outbreak, openings other than fireproof doors are to be avoided. Artificial lighting therefore should be used. It could also be detached from the plant and accessible by an adjoining corridor possibly under the same roof.

There are two movement patterns here, that of personnel and that of material through production. Just as it is required to design around furniture, here the designer should design around the machines and personnel. Machines for a production process should be arranged such that materials are moved in one direction only onto the different machines. An operator's path should not be a crisscross movement and also he should be able to move around each machine comfortably. The placement of machines will determine where the operator would stand. The operator's position should not be hazardous to him in manning the machine such as dust inhalation or injury. Detailed descriptions with dimensions of all machines to be used and also that of future upgrades should also be determined from the manufacturer during the design stage.

For multileveled plants, production processes that make use of heavy machinery, packaging materials and products should be housed on the ground level to reduce the structural loads.

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[1] Culled from, 'The Home Building Industry's Technology Information Resource'

APPENDICES

Fig 15: Aerial view of the facility - 1

Fig 16: Aerial view of the facility - 2

Fig 17: View along the main road leading to the facility

Fig 18: facade view 1

Fig 19: facade view 2

Fig 20: facade view 3

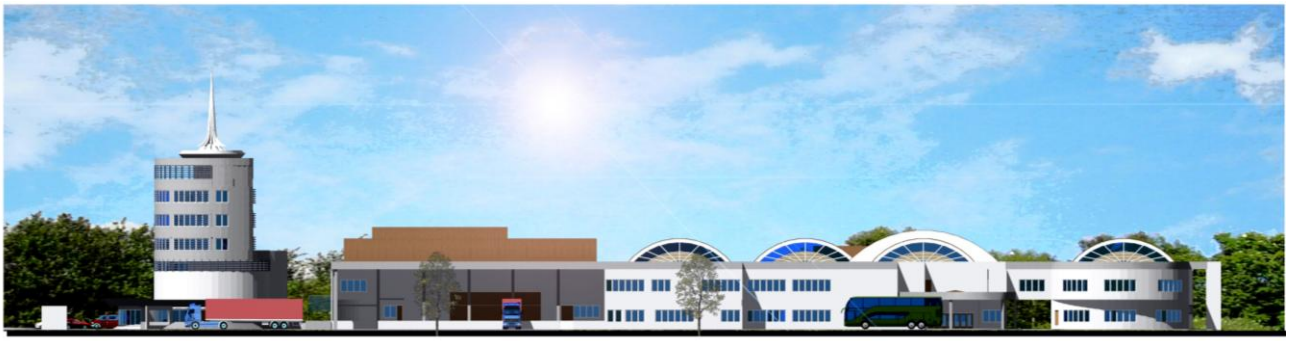

Fig 21: facade view 4

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GLOSSARY

The definitions given for the following terminologies are as used in this report. They may have different definitions in other text.

Air Handling Unit (AHU)

It serves to condition the air and provide the required air movement within a facility.

Airlock

An enclosed space with two or more doors, which is interposed between two or more rooms, e. g. of differing classes of cleanliness, for the purpose of controlling the airflow between those room to reduce or eliminate contamination, when they need to be entered. An airlock is designed for, and used by personnel or goods.

Central Air conditioning Unit

An Air handling unit which is centrally located and supplies air to a number of rooms as opposed to a local AHU which supplies air to only one room.

Clean room

A room or area with defined environmental control of particulate and microbial contamination constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area, and in which other relevant parameters (e.g. temperature, humidity and pressure) are controlled as necessary.

It is a process or device to contain a product, dust or contaminants in one zone, preventing it from escaping to another zone.

Contamination

The undesired introduction of impurities of a chemical or microbial nature, or of foreign matter, into or onto a starting material or intermediate, during production, sampling, packaging or repackaging, storage or transporting.

Cross – contamination

It is the contamination of a starting material, intermediate product or finished product with another starting material or material during production.

Drug Substance

It is a starting material such as excipients and active ingredients, used to make up the final pharmaceutical product.

ECS

Environmental Control System also referred to as Heating, Ventilation and Air Conditioning (HVAC).

Facility

All the structures specified in the design proposal

Plant

It is the built environment within which the clean room installation and associated controlled environments operate together with their supporting infrastructure.

Laminar Flow (Unidirectional Air flow)

It is a rectified airflow over the entire cross sectional area of a clean room zone with a steady velocity and approximately parallel streamlines.

OSD

Oral Solid Dosage – usually referring to an OSD plant that manufactures medicinal products such as tablets, capsules and powders to be taken orally.

Pressure Cascade

It is a process whereby air flows from the cleanest area, which is maintained at the higher pressure to a less clean area at a lower pressure.

Turbulent Flow (Non Uni – directional Airflow)

It is air distribution that is introduced into the controlled space and then mixes with room air by means of induction.

Utility room or plant room

Room that houses the Central Air conditioning Unit, the water treatment plant and water boiler, switch room and other service equipment for the running of the plant