NAMES: NURUDIN MUHAMMAD FARIDAH – LAH

MATRIC NUMBER: 16/MHS07/021

COURSE CODE: PHA 408

COURSE TITLE: STUDENTS INDUSTRIAL WORK EXPERIENCE SCHEME

ABSTRACT

The 3 months Students Industrial Work Experience Scheme (SIWES) which is a requirement for the completion of my course of study, Pharmacology and Therapeutics, was undertaken at Pal Pharmaceuticals Industries Limited, Kano, Kano State.

I was an Industrial Attaché (IT) at the Quality Control Unit. The Industrial Training was based on carrying out quality control analysis (chemical, physical, in – process and microbial) on drugs, raw – materials and water used for production of drugs.

INTRODUCTION

PAL PHARAMCY was incorporated in Nigeria since 1992 to deal in retail and distribution of essential drugs, within a period of four years, it witnessed a rapid growth leading to the establishment of a manufacturing outfit called Pal Pharmaceutical Industry Limited with certificate of incorporation no 210546.

PAL Pharmaceutical Industries Limited is a fast growing Indigenous Pharmaceutical company engaged in manufacturing and marketing a broad range of pharmaceutical products within and outside Nigeria. The company products ranges from; oral liquids and external preparations to tablets and dry powder for reconstitution. These products are duly registered with National Agency for Food Drug and Control (NAFDAC).

VISION

The vision is too established as a foremost Pharmaceutical Manufacturer in Nigeria.

MISSION

The mission is to provide high quality essential health care products that will be accessible and affordable to the public.

Pal Pharmaceutical products includes; **Palmol** syrup and tablets (acetaminophen; paracetamol), **Palvite** (multivitamins), **Pal Ibuprofen**, **Palgyl** (metronidazole), **Palquine** suspension and tablets (quinine), **Gripe water**, **Kufcof** (cough expectorant), **A – Mag** (Magnesium Trisllicate, magnesium carbonate, sodium bicarbonate), **Diafix** (kaolin), **Methylated Spirit**, **Kaphenicol** (chloramphenicol), **Wormzel** (albendazole), **Kerythromycin** (erythromycin), **Palin** tablets (diclofenac), **Vitamin B complex** tablets and syrup, **Kapiclox**, **Promethazine**, **Haemolic**, **Kapicillin** (ampicillin & cloaxcillin), **Kamoxil** (amoxicillin & cloaxcillin), **Vitamin C** suspension and tablets, **Paltrin**, **Allerton** (chloramphenamine), **Calamine** (calamine lotion), **Sil – G**.

The pharmaceutical company consists of five (5) production sections; **SECTION A – E** (are in charge of production of syrup and suspension) and **TABS SECTION** (tablets section). Other sections include;

- Packaging unit
- Storage unit
- Quarantine unit
- Marketing unit
- Quality control unit;
  - Microbiology laboratory
  - Chemistry laboratory
  - In – process unit
- Raw material section
- Assembly unit
- Archive section

Pal pharmaceutical is located at plot 101/102 Maganda Road, Bompai Industrial Area, Kano State Nigeria.

QUALITY CONTROL (QC)

According to World Health Organization (WHO), the term quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical product. Quality control (QC) is an essential operation of the pharmaceutical industry.

This unit specializes in the quality analysis of drugs, raw – materials and water used in the production of the products before it reaches the final consumer or the public. Sections under the quality control unit include;

- Microbiology laboratory
- Chemistry laboratory
- In – process unit

FUNCTIONS OF THE QUALITY CONTROL

- Quality Control department functions for assuring the quality of all the batches manufactured, at every stage of manufacturing/processing drug Products.
- Stability testing and evaluation of shelf-life of products.
- Sampling, inspection & testing as per specifications of raw material, packaging, in – process product and final products for release or rejection & its documentation.
- Microbiological analysis of raw material, finished products, water and environmental bio-burden monitoring.
- Release or rejection of every batch of Drug Products for distribution and sale.
- Analysis of Returned products (salvage and disposal).

MICROBIAL ANALYSIS

Microbial analysis is the use of biological, biochemical, molecular or chemical methods for the detection, identification or enumeration of microorganism in a material/pharmaceutical product. It is often applied to disease causing and spoilage microorganism.

Microbial analysis helps to keep under control the proliferation of viruses, bacteria, microorganism which may cause contamination, intoxication and disease. In the microbiology lab, analysis carried out includes;

- Effectiveness of disinfectants
- Environmental analysis
- Analysis on suspension bottles/syrup bottles (swab bottle test)
- Water analysis from production units, borehole and plant water
- Drug analysis
- Equipment analysis
- Raw materials analysis

Crucial step in microbiology analysis are;

- Sampling
- Filtration
- Culturing
- Incubation; final stage before enumerating an organism.

METHODS USED IN MICROBIAL ANALYSIS

- Multiple tube method
- Plate count
- Membrane filtration
- Pour plate method

TYPES OF MEDIA

- Cultural media
- Minimal media
- Selective media
- Differential media
- Transport media
- Indicator media

IN – PROCESS QUALITY CONTROL

In – process analysis are carried out on tablets. Quality control of tablets involves various tests which require keen attention. To ensure that established product quality standards are met, these

tests must be performed during production (in-process controls) and verified after the production of each batch.

Tablets are solid drug delivery system prepared by compressing a single dose of one or more active drug substance(s) with some additives/ pharmaceutical excipients. They may be circular, oblong, oval, triangular or cylindrical in shape and flat-, round-, concave- or convex-faced with straight or bevelled edges. In tablet formulation development and during manufacturing of tablet dosage forms, a number of quality control tests are performed to ensure that tablets produced meet the requirements as specified in official compendium and conventional requirements established by the industries over the years. These tests can be grouped into two broad categories namely:

1. **NON-PHARMACOPOEIAL OR NON-OFFICIAL TESTS:** these are tests that are performed on tablets and which are not listed in official compendia and concern a variety of quality attributes that need to be evaluated, such as the porosity of tablets, hardness or crushing strength test, friability test, tensile strength determination, thickness test etc. Some of these tests have no officially set limits for acceptance or rejection and thus may vary from manufacturer to manufacturer and from formulation to formulation.

    - Tablet Hardness or Crushing Strength Test
    - Friability Test
    - Tablet Thickness

2. **PHARMACOPOEIAL OR OFFICIAL TESTS:** they are called official tests because the test methods are described in official compendia such as the British Pharmacopoeia, American Pharmacopoeias etc. They are standardized test procedures which have clearly stated limits under which compressed tablets could be accepted. These tests are traditionally concerned with the content and the in vitro release of the active ingredient. It must be emphasized that what is presented here should by no means replace what are presented on each of the tests in official compendia.

    - Content of Active Ingredient

- Uniformity of Weight/ Weight variation test
- Uniformity of Content
- Disintegration Time Test
- Dissolution Test

PRACTICALS

(BASED ON MICROBIAL ANALYSIS)

MEDIA USED FOR MICROBIAL ANALYSIS IN PAL PHARMACEUTICALS

PROPERTIES OF MICROBIAL MEDIA

S/N	MEDIA	pH	WEIGHT/ VOLUME	BOILING POINT	TEMPERATURE
1	Nutrient agar **(NA)**	7.0 ± 0.2	28mg	121°C	37°C
2	MacKonkey agar **(MCA)**	7.1± 0.2	47mg	121°C	37°C
3	Mannitol salt agar **(MSA)**	7.4	111mg	121°C	37°C
4	Sabourad dextrose agar **(SDA)**	5.6	65mg	121°C	22 – 24°C
5	*Salmonella shigella agar* **(SSA)**	7.0	63mg	50 °C	37°C
6	Nutrient broth **(NB)**	7.2 – 7.6	13mg	121°C	37°C
7	MacKonkey broth **(MCB)**	7.4	40mg	121°C	37°C

DATE: 22 July, 2019

METHOD: POUR PLATE METHOD

MATERIALS: petri dishes (plates), test-tube, conical flasks, spatula, measuring cylinder, cotton wool, serial bottles, pen, masking tape, autoclave, inoculating chamber, weighing machine, pH meter, colony counter, incubator, thermometer, media, samples obtained from sections, distilled water, gas cylinder, wire gauze, tripod stand, and matches box.

ROOM TEMPERATURE: 26℃

FRIDGE TEMPERATURE: 4℃

HUMMIDITY: 60%

NUMBER OF SAMPLES OBTAINED: 9

DIAMETER OF PLATES = 15

DIAMETER OF TEST TUBE = 4

PROCEDURE; the temperature and humidity of the laboratory were checked before carrying out microbial analysis. The media was weighed using the weighing balance and each media was put into a labeled conical flask; the specific amount of distilled water (transport medium) for each media was measured and diluted. The conical flask was covered with a cotton wool and shake to dissolve. The volume for each media was checked using the measuring cylinder. The pH was checked using the pH meter. The medias where kept inside the autoclave for first sterilization, the temperature was set at 121℃ apart from SSA which was put on a burner and allowed to boil to 50℃**.** After the first sterilization the pH was checked again. The broths (MCB and NB) where put into test tubes at 4ml each using a pipette and closed with a cotton wool. The broths and agars where kept inside the autoclave for sterilization. The pipettes, petri dishes, serial bottles were also sterilized. After sterilization, the agars, broths, petri dishes, pipettes and serial bottles were kept inside the inoculating chamber. The petri dishes and test tubes were labeled. Serial dilution was carried out in three folds (1×10^{-3}) 1ml was taken out and put into the petri dishes the agar was put into each plate, closed and shake lightly and allowed to solidify and then put into the incubator to incubate at 37℃ for 48 hours, apart from SDA was set at 24℃**.** 1ml was also put into the broths and allowed to incubate at 37℃ for 48 hours.

After 48 hours, the number of colony form unit (cfu) was counted and recorded. The plates and test tubes were discarded using the autoclave.

Reminants of media was stored at 4 - 6℃ in the fridge.

CALCULATIONS

Nos of samples = 9

Agar = 9 ×15 = 135cm^3

Broth = 9 ×4 = 36cm^3

MEDIA	AMOUNT TO WEIGH (g)	VOLUME (cm^3)	pH before	pH after
NA	$\frac{28\times135}{1000} = 3.780g$	135 cm^3	6.7	6.6
MCA	$\frac{47\times135}{1000} = 6.345g$	135 cm^3	6.8	6.5
MSA	$\frac{111\times135}{1000} = 14.985g$	135 cm^3	7.2	6.9
SDA	$\frac{65\times135}{1000} = 8.775g$	135cm^3	5.6	5.4

SSA	$\frac{63\times135}{1000} = 8.505g$	$136cm^3$	6.9	6.8
NB	$\frac{13\times135}{1000} = 0.468g$	$34cm^3$	7.5	7.0
MCB	$\frac{40\times135}{1000} = 1.144g$	$34cm^3$	7.2	6.8

1st STERILIAZATION: start; 10:20am close after 5 mins, 10:25am

First vapor; 10:40am, 15 mins, 10:55am

2nd STERILIAZATION: start; 12:00pm close after 5 mins, 12:15pm

First vapor; 12:50am, 15 mins, 01:05pm

RESULTS

DATE: 22 July, 2019

OPERATION CARRIED OUT BY: NURUDIN MUHAMMAD FARIDAH – LAH

OPERATION CHECKED BY: MRS UCHE OKEKE UCHE

SAMPLE	TVC (cfu)	YEAST	MOULD
SECTION A **H_2O**	**NA: 30** **MCA: 33** **MSA: 15** **SSA: nil** **NB: cloudy** **MCB: growth/colour change**	**Nil**	**3cfu**
SECTION B **H_2O**	**NA: 23** **MCA: 17** **MSA: nil** **SSA: 10** **NB: cloudy** **MCB: growth/colour change**	**5cfu**	**2cfu**
SECTION C **H_2O**	**NA: 60cfu** **MCA: 43cfu** **MSA: 17cfu** **SSA: 11cfu** **NB: cloudy** **MCB: growth/colour change**	**11cfu**	**6cfu**

SECTION E **H_2O**	**NA: cloudy** **MCA: 43cfu** **MSA: nil** **SSA: 16cfu** **NB: cloudy** **MCB: growth/colour change**	**nil**	**5cfu**
TABS SECTION **H_2O**	**NA: cloudy** **MCA: 33cfu** **MSA: 15cfu** **SSA: 10cfu** **NB: cloudy** **MCB: growth**	**9cfu**	**4cfu**
BOREHOLE **H_2O**	**NA: 60cfu** **MCA: 32cfu** **MSA: 17cfu** **SSA: 12cfu** **NB: cloudy** **MCB: growth/colour change**	**7cfu**	**5cfu**
PLANT H_2O	**NA: 19cfu** **MCA: 33cfu** **MSA: 15cfu** **SSA: 16cfu** **NB: cloudy** **MCB: growth**	**4cfu**	**2cfu**
Palmol **5324** **Section A**	**NA: cloudy** **MCA: 20cfu** **MSA: 15cfu** **SSA: nil** **NB: cloudy** **MCB: growth**	**nil**	**1cfu**
M - MAG	**NA: 15cfu**	**nil**	**nil**

2333 **Section B**	**MCA: 22cfu** **MSA: nil** **SSA: nil** **NB: cloudy** **MCB: growth/colour change**		