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**TECHNICAL REPORT ON**

**Student industrial work experience scheme (SIWES)**

**UNDERTAKEN AT**

**FECCOX PHARMACEUTICALS LIMITED**

**BY**

**ADAMU UMMULKULTHUM DAUDA**

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**SUMITTED TO DEPARTMENT OF PHARMACOLOGY AND THERAPEUTICS**

**COLLEGE OF MEDICINE AND HEALTH SCIENCES**

**AFE BABALOLA UNIVERSITY, ADO EKITI.**

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**DEDICATION**

I dedicated this write up to my beloved parents, my father Alhaji Dauda Adamu and my mother Hajia Lauratu Abubakar. My Gratitude to my family members for their support. Thank you.

**ACKNOWLEDGEMENT**

I express my gratitude and sincere thanks to my supervisor for checking up on me during the course of this training, also to my supervisors at feccox Pharmaceutical Limited for their invaluable suggestions, constant encouragement and general advice.

**UMMULKULTHUM DAUDA ADAMU**

**ABSTRACT**

My student industrial work experience scheme (SIWES) was undertaken at a private Pharmaceutical Industry, at feccox Pharmaceutical Limited kano State. They produce both human and vet drugs. Examples include; Sambezole, Bicosam, Dapsosan, Folisam etc.

I was an Industrial Attache to the quality control department. My SIWES training was based on chemical Pharmaceutical analysis which include; assay, disintegration, dissolution, moisture analysis, preparation of solvent, hardness test, weight variation, friability test and calibration.

**VISSION AND MISSION STATEMENT OF SAM PHARMACEUTICAL LIMITED**

* Production of drugs that are of good quality.
* Production of drugs for both human and veterinary to cure infection and diseases.
* Provision of employment opportunities.
* Ability to raise competent and skilled trainee officers.

**UNITS IN SAM PHARMACEUTICAL LIMITED**

* Store room
* Weighing room
* Granulation department
* Tablets quarantine sections
* Paste room
* In - process section
* Quality assurance department
* Quality control department

**QUALITY CONTROLDEPARTMENT**

It is a place that identifies and corrects defects in the finished products.

**OBJECTIVES OF QUALITY CONTROL DEPARTMENT**

* The quality control department is responsible for all chemical and microbial analysis on drugs to ensure its quality.
* It ensures that only drugs of best quality are made available for human and animal use.
* It fixes the expiration date and shelf life of drugs.

**UNITS IN QUALITY CONTROL DEPARTMENT**

* Chemical laboratory
* Microbiology laboratory.

**PHARMACEUTICAL ANALYSIS**

Pharmaceutical analysis is a practical that involves a series of process for identification determination quantification and purification of chemical compounds. It is necessary for safety and effectiveness of drugs. Pharmaceuticalanalysis carried outincludes;

**PHYSICAL ANALYSIS**

* Calibration
* Friability test
* Moisture content test
* Weight variation analysis
* Drug hardness test

**CHEMICAL ANALYSIS**

* Dissolution test
* Disintegration test
* Assay analysis

**PHYSICAL ANALYSIS AND IMPORTANCE**

**CALIBRATION;**

It is a comparison between known measurements (standard) and using your own measurement. It is the processing of configuring an instrument to provide a result within an acceptable range. The range of calibration is $\pm $**4.** Balance is very important in the manufacturing of drugs, if the weighing balance used in weighing raw material is not balanced i.e. if it is not accurate it cannot be used for production. Calibration should be done before production of any drug.

**WEIGHT VARIATION ANALYSIS;**

Weight variation analysis is a method of verifying whether a compressed drug falls within a specified range in order to prevent overweight and underweight and it is also done to check the functionality of the compressing machine .it is carried out using Analytical balance.

Procedure:

* 20 drugs are being weighed from different samples and recorded and the average is being recorded, if less than specification or more than, the drugs will be taken back to the granulation department for amendment.

**MOISTURE CONTENT ANALYSIS**

Moisture content analysis determines the amount of water present in drug granules i.e. the percentage of water content present in a drug. It is done to minimize the action of micro-organisms in the produced drugs. If the amount of water present in a drug is more than required the compatibility will be low and there will be growth of microbes. It is carried out using Moisture content analyzer or Hot air oven.

Procedure:

* The weighing pan is firstly weighed using analytical balance and analytical balance is taken back to zero
* 5g of drug granules is measured on the weighing pan and recorded.
* Repeat for different samples and record the result,
* The weighing pan +drug granules is kept in the oven for 1hour at a temperature of 105
* The weighing pan +drug granules is brought out of the oven and re-weighed
* The final value is subtracted from the initial value and divide by 5%

**HARDNESS TEST**

Hardness test is done to determine the resistance to vibration of a drug and also the breaking point of a drug under conditions of storage, transportation and handling before use. Hardness test is done only on uncoated tablets. Drugs have different hardness, structural integrity and breaking force. It is carried out by the use of a hardness tester.

Procedure:

* A drug tablet is kept in the hardness tester and the hardness tester is screwed to the point where the drug can’t fall then it is being recorded.
* The hardness is continuously screwed till the drug breaks and that is also recorded
* The final value is then subtracted from the initial value and compared with specification.

**FRIABILITY TEST ANALYSIS;**

Friability test analysis is used to determine physical strength of uncoated tablets upon exposure to mechanical shock and attrition. It determines how much mechanical stress tablets are able to withstand during manufacturing, distribution and handling over by the customer. It is carried out using Friability Tester. For hardness test the specification for drugs are different unlike assay test which has a constant specification of 95-105%

Procedure:

* 20 tablets are collected and separately weighed using analytical weighing balance
* The friability tester is being switched on and the 20 drugs are put in the outlet of the friability tester
* The friability tester goes through 100 revolutions clock wise and then stops
* After the evolution it goes anticlockwise and the tablets are reweighed.
* % weight loss =$\frac{wi-w2}{w1}×100\%$; where w1= initial weight, W2= final weight of 20 tablets.(Specification nothing more than 5%).

**CHEMICAL ANALYSIS AND IMPORTANCE**

**DISINTEGRATION TEST**;

Disintegration test is widely used in the pharmaceutical industry for evaluation of disintegration capacity of drugs. This test is carried out to determine the time taken for a tablet to dissolve in the body system under specified condition and to ensure uniformity of drugs. In human system it takes nothing more than 15 min while in animal system it takes nothing more than 1 hour. If more than 15 min or 1 hour as the case may be it takes longer time for the liver to break down the drug which can cause damage to the liver.factors affecting disintegration test are;

* Hardness of drugs
* Temperature
* The nature of water being used.

Procedure:

* The disintegration tester jar was filled with water
* The disintegration tester was switched on and left to attain 37c (normal temperature)
* A tablet of drug was put in each 3 tubes of the basket and was covered with the disc.
* The tubes were immersed in the distilled water inside the disintegration tester and were left for a specific time to disintegrate and the time was recorded.



Disintegration tester

**DISSOLUTION TEST:**

Dissolution test is done to determine the amount of active pharmaceutical ingredient that will be absorbed by the blood plasma.

Procedure:

* Put on the temperature controller
* Press the TEMP key
* Allow it to attain normal body temperature
* Drop each tablet into 0.1ml of HCl inside the jar
* Press RPM +F1+ ENTER
* Press TIME+START+ ENTER
* When the time revolution which is 30 minutes is complete it will stop
* Weigh 0.1g of standard into standard flask, add water and shake well and make up with 100ml of water
* Filter all the samples in the jar into a conical flask
* Fill the standard flask with water (50ml)
* Pipette 1.8ml of the sample filtrate into half-filled volumetric flask
* Pipette 1ml of the standard filtrate into volumetric flask and fill with 50ml of water. Shake well and fill up with water.
* Set your wavelength to 276nm
* Put both the sample and standard into spectrophotometer.
* Read and record the result.

The specification should not be less than 80%.

**ASSAY ANALYSIS:**

An assay is a quantitative analysis used to determine presence and amount (mg/g) of active materials or ingredient present in a drug. In assay analysis different solvents are being used to dissolve different drugs.

* Spectrophotometric and titrimetric methods are the widely used method for assay analysis
* It is used to determine the effectiveness of pharmaceutical drug.

Procedure:

* A paracetamol sample of 0.087g and standard of 0.075g were weighed into separate 100ml standard flasks.
* About 50ml of water and 10ml of 0.1M NaOH solution was added into each flask and the mixture was then shaker for about 5 min using a flask shaker.
* The solutions were then made up to the mark with H2O and the paracetamol solution was filtered.
* 1ml of the paracetamol filtrate and standard solution were pipetted into separate100ml flask and 10ml of 0.1M NaOH was added to each solution and then made up with H20.
* Using spectrophotometer absorbance is set to 257nm.
* Calculation;

% of potency= $\frac{absorbance of sample }{absorbance of standard}×100\%$

 (Specification: 95-105%)

**RECOMMENDATIONS**

**The management should provide enough equipment and whenever there is need for new supplies of chemicals it should be in time for wellbeing of the patient.**

 **CONCLUSION**

**In the 3months of my training I have learned skills of producing syrups.**

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