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EFFECTIVE AND INNOVATIVE TECHNOLOGIES AND DEVICES FOR QUALITY ASSURANCE OF LIQUID DRUG DELIVERY SYSTEMS, LDDS. I PARACETAMOL SYRUP IN NIGERIA CLINICS AND PHARMACIES

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ABSTRACT

In this work, we are interested in researching and developing cheap and accurate techniques that will be used to detect genuine or fake liquid drug delivery systems, LDDS in the market, clinics and pharmacies in Enugu, Nigeria. The World Health Organisation, WHO and regulatory agencies such as NAFDAC in Nigeria encourages research and development of Pharmaceutical and Medical devices for quick detection of genuine and fake products especially in developing countries. A calibrated Perspex cylindrical measure was used to release drops of paracetamol syrup from a fixed height of 6cm above a white horizontal paper board. The time taken for 10 drops of the syrup to fall under gravity from a 21 G * 1.5" Hypoject – IV needle was determined. The mean-time, t was calculated for each batch. The CV% and SDs were recorded. It was characteristic for each batch of Paracetamol syrup from a particular manufacturer. The experiments carried out at 27 +/- 1 degrees Celsius in an undisturbed environment showed that genuine products that are not decomposed had mean time that are similar for each product. EP brand of the syrup had a t value of 47.29 +/- 17.46 seconds and CV% of 36.92 per the stable product as against the value of 1.88 +/- 0.47 seconds showing a gross decrease in viscosity. We conclude that this simple technology can be used in challenged hospital clinics, community pharmacies, primary health care centres and laboratories for paracetamol syrup standardisation per manufacturer. It can also be used to compare different brands for rejection or acceptance.

KEYWORDS: ***Effective, Innovative, Devices, Quality assurance, Paracetamol syrup***

INTRODUCTION

Most innovative drug products still appear as liquids be they solutions, injections, nanosomes, emulsion forms to target incorporated drug to the site of action. There is a need to ascertain the quality of the drug dosage forms or medicines given or administered to neonates, infants, adults etc. in our primary, secondary or tertiary health institutions.[1,2] There are increasing reports of fake or expired pharmaceutical products globally especially in developing countries. In fact there is still chaotic drug distribution as citizens, literate and illiterate alike are worse off as they buy whatever is available due to down turn of the economy world-wide. The pharmacists in various settings have to satisfy themselves and their consciences that they are rendering expert services based on their basic training. In our universities and research institutes, there are still grossly inadequate laboratory equipment. Consumer protection laws all over the world have to do with the welfare of consumers of products that must be wholesome, genuine and conform to

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many requirements of the law. Consumer products may be drug products or medicines, foods or drinks formulated by approved pharmacists in the industry or food scientists locally or abroad. Other consumer products include cosmetic products applied to various parts of the body. In life sciences, all these food, drugs and cosmetics (FDC) must comply reasonably to laid down limits of acceptance. In Africa, we lack manufacturing and quality control facilities. Many persons in the villages have not clean water to drink and wash, they do not have access to food and medicines to alleviate or prevent many illnesses. They are therefore exposed to consume anything that come their way. In Nigeria for example, we have foods and medicines of low quality in circulation. In order to check and stop this flooding of our markets with fake adulterated healthcare products, we decided to research and develop very simple methods that can be used to help characterize these products in pharmacies by trained scientists while more complicated research procedures are referred to central hospitals expected to have more sophisticated instruments such as the ultra – microscopes, UV – VIS spectrophotometers, computerized DSC, refractometers, NMR spectrophotometer and other chromatographic analytical equipment. [3]

The properties of a solution can be used to control and confirm the quality of a drug dosage form. In this work we have done preliminary investigations using surface activity or tension, pH variation, solution density etc. to assemble devices that give insight to the quality or characteristics of various manufacturers' brand to predict whether such brands are good or bad! [4-6]. These will constitute further reports.

At controlled humidity and temperature in the tropical regions of the world, expiry dates vary but experts in pharmaceutical dosage form quality control and assurance help to develop both medicines and simple innovative devices and procedures that will help tremendously to reduce fake and counterfeit products in both developed and developing countries in the world.

MATERIALS AND METHODS

MATERIALS

Two brands of paracetamol product from two different manufacturer in Lagos, Nigeria; Company E and Company N. Hypoject – IV, 21G * 1.5" (0.8 *40 mm), Perspex cylindrical tube, Changzhou, Hachun Medical manufacturers, China and Electronic stop watch, Infinix Hot 4 China.

METHODS

A 5ml quantity of the paracetamol syrup was measured and introduced into a clean calibrated Perspex cylindrical measure fitted with 21G * 1.5" hypoject – IV needle. The tip of the needle was placed at a height of 6cm above a white paper board. The temperature was fixed at 27 +/- 1 degrees Celsius. The time, t in seconds taken by 10 drops of the syrup to fall under gravity from the hypoject – IV needle was recorded. The experiment was repeated three times and the mean determined for each batch of syrup. The CV% and standard deviations were calculated. The procedure was also carried out for the N batch of the paracetamol syrup.

RESULTS AND DISCUSSION

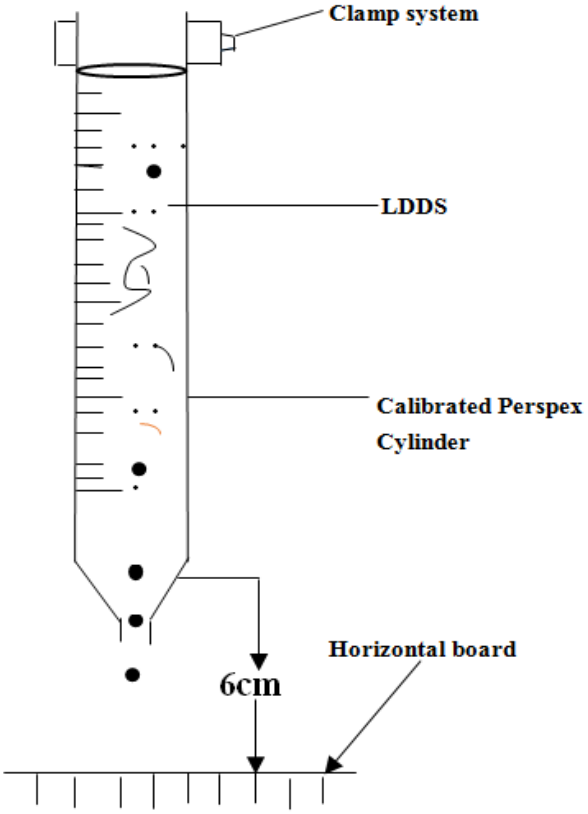

Figure 1: Schematic diagram of system for determining time, t, for syrup to fall under gravity.

Figure 1 shows the schematic diagram of the simple set up for determining the time of fall of the paracetamol syrup under gravity. The time for 10 drops of the paracetamol syrup to fall is specific and characteristic for each of the brands. It means that as long as the manufacturer does not change or vary his standard operating procedure, it is

constant and can be used to identify each brand at the temperature of the experiment in an undisturbed environment. The mean time for brand EP was 47.29 +/- 17.6 seconds and the coefficient of variation was calculated to be 36.92%. The expired EP paracetamol syrup had a mean time of 1.88 +/- 0.47 seconds. This very wide margin in time may be attributed to gross degradation of the product and incorporated viscosity enhancers during the formulation of the paracetamol syrup. There might have been various interactions of the drug and added excipients or excipient – excipient interactions that caused deterioration or spoilage in the LDDS.

In the case of the NP brand of the same paracetamol syrup, the mean time of drop off of the ten drops was 50.29 seconds with a standard deviation of 2.6 and CV of 38.53%. This variation is attributed to the fact that the two manufacturers used different formula and techniques during the syrup manufacture. Other factors such as quantity and type of excipients added in the paracetamol syrup formulation may never have been the same. We found that each time the experiment was repeated, similar results were obtained for each brand of the product while dissimilar results was the case between different manufacturers even though the paracetamol dose was the same, i.e. 125mg/5ml dose in each case.

The drop off time can be combined with other standards to quickly assess and accept or reject any manufacturers' faked product in the market or clinics when compared with genuine manufacturers' product during the product shelf life.

CONCLUSION

This simple drop off time can be used by manufacturers of syrups and other solution dosage forms to quickly determine along with other quality tests to authenticate products from their lines. Regulatory agencies, community and hospital pharmacies especially in rural areas can use it as a cheap, affordable tool to validate quality of paracetamol syrup sent to them. This can be combined with other tests such as assays and labelling requirements to confirm genuineness or not.

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