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DEVELOPMENT OF A NEW ADDITIONAL METHOD TO DISTINGUISH THE INVALID DRUGS AND DETECT DRUG VALIDITY

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ABSTRACT: The threats and risks of the invalid drugs as expired, counterfeit (cheated drugs), Substandard, spurious, falsely labeled, falsified). The risks and threats of the invalid drugs are many and wide vary, and the countries are trying to prevent these threats by some efforts as the regulatory institution's efforts and the recorded expire date on the drug container, but that are not enough to prevent this problem. As well as, the recorded expire date on the drug container can be cheated and not accurate, too. As it depends on the assumption the drug may be valid till this date if the drug is made and stored in an ideal manner, but in the real conditions the drug may expose to different conditions that may effect on its expire date and validity, as the environmental conditions *e.g.* light and temperature. So, in this research I found some answers about the people and invalid drug, and about the trust in drug use and safety, and I developed an additional, simple, rapid and a more accurate way to distinguish between the valid drugs and the invalid drugs that is suitable for public people, to decrease these threats and increase drug and patient safety.

INTRODUCTION: One of the important issues that related to drug and patient safety is the invalid drug use, as A lot of people around the world may use the invalid drugs (as rotten, expired, Substandard, counterfeit (cheated drugs, spurious, falsely labeled, falsified drugs)), while they do not know that these drugs are actually invalid, especially in rural places and developing countries^{1, 2, 3, 4}. The risks and threats of taking or using of the invalid drugs are many and wide vary and can affect on drug therapy and patient safety as infections, headache, vomiting, or death, as well as, waste of money, too^{2, 5, 8}.

In this research I found a lot of public people are not- fully trusted on the validity of the drugs, and the regulatory institutions efforts are not enough to prevent these risks and threats completely, as well as the recorded expire date on the drug container, too. Because it can be cheated and not accurate way, too. As it can be affected by many environmental effects as light and temperature as in bad storage conditions^{9, 11}.

I tried in this research to find an additional, more accurate, simple way to differentiate between the real valid drugs the invalid drugs, to be suitable for public people, *i.e.* I tried in this research to determine the actual validity period (is the real period at which the drug will be valid, actually), while the expected validity period: is the expected time at which the drug will be valid, and can be determined by the manufacturers (as by the recorded expire date on drug containers)⁵.

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I developed a new suitable way to differentiate between the valid and invalid drugs that suitable for public people, the idea of this way depends on the change on chemical constituents of the drug that may cause changes in the pH degree of the drug media, which can be detected by suitable pH indicator which will sharply change in color to indicate simply the actual validity of the drug.

MATERIALS AND METHODS: In this research and through about 2 years (1996 - 1997 and 2015 - 2016), I used a simple Questionnaires Design (face to face and computerized)^{13, 14}, and I got the most needed answers as (YES or NO) nominal data that can be analyzed (by calculating the percent of each answers Yes or No) simply and rapidly from random adult people aged 21-60 years old^{16, 17}, and I used and tested some facts of Chemical and Physical nature of some drugs' substances and pH indicators in my simple Laboratory. *e.g.* Lo-Ion test kit, short range: pH 6-8. Each 0.5 unit of pH change is distinctly colored. Readings estimated to 0.25 PH unites¹⁸, and I got some information and references from the Internet, too.

The Risks and the Threats of the Invalid Drugs and the Need of an additional Methods to Determine the Drug Validity: Threats of the invalid drugs are many and dominated all over the world, especially in developing countries, as in China, India, Egypt, Brazil. And it has a direct and indirect effect on peoples' health, society and economy^{2, 3, 7}. For example: Worldwide sales of counterfeit medicines could top US\$ 75 billion on 2009, a 90% rise in five years, according to an estimate published by the Center for Medicine in the Public Interest in the United States of America (USA)².

The risks of taking or use the invalid drugs are various and related to drug and patient safety, they may be not harmed or harmful, as they may cause nausea, vomiting, infection, liver hurt, kidney toxicity, and may lead to death^{2, 3, 5, 6}. All efforts at international or the regulatory institution's efforts, education and recorded expire date are not enough to prevent these problems completely⁵, as the recorded expected to expire date in drug container is not an accurate way (and can be cheated, too.), because it depends on the assumption that drug may be valid till this date if the drug is

manufactured and transferred and stored in an ideal manner, but in the real conditions the drugs may expose to different conditions that may effect on its actual - real- validity and on its actual -real- expire date, As harmful environmental conditions (especially during storing and transferring to different places) that may decrease the drug warrant period *e.g.* air, dust, light and temperature^{9, 10, 11}.

I made surveys by the simple Face-to-Face Questionnaires and computerized (as by Facebook, net, WhatsApp and emails) Questionnaires, too,^{14, 15}, and asked 276 random adult persons simple questions and to get most of the answers as (Yes or No) nominal data that can be analyzed (by calculating the percent of each answers Yes or No)¹⁶, as follow:

First Question: Do you think or know that some drugs in the pharmacies may be actually cheated in spite of good recorded expire date that recorded on the drug container?

Second Question: Do you need a new, additional, accurate and simple way to differentiate between the valid and invalid drugs to make you more comfortable and trusted about the drug?

First Question's Answers: I found 210 from 276 (about 76 %), think or know that some drugs in the pharmacies may be actually cheated in spite of good recorded expire date that recorded on the drug container, because they know the fact that the cheated drugs are found and in most countries in the world.

Second Question's Answers: And I found 195 from 276 (about 71%), hope to found a new, additional, more accurate and simple method to differentiate easily between the actual valid drugs from the invalid drugs, because that makes them more trusted and more comfortable about drug validity and effectivity. And we can summarize the results as in the following **Table 1**.

TABLE 1: RESULTS SUMMSRY

	Answer's Yes	Answer's No	Total
First Question's Answers:	210 (about 76 %)	66 (about 24%)	276
Second Question's Answers:	195 (about 71%)	81 (about 29%)	276

But the others 30 from 66 persons (who did not know about cheated or invalid drug probability after they know the fact of the invalid drug's presence in all the world) three of them had changed their mind and said as the other persons said in a second question, as above. So, the final second result becomes 240 from 276 about (about 87%).

A New Additional Way for Drug Validity Determination Using pH Indicators: The idea of this method depends on the difference between the pH between valid drug media and invalid one, as when the drug become invalid, pH of its chemical constituents may change too, and that may cause changes in pH degree of the drug media and this pH can be detected by suitable pH indicator, and this pH indicator will sharply changes in colour, if only the pH of the drug changes to the pH in which the drug will start to be invalid, to indicate simply the actual validity of the drug.

I designed and tested a design I called it Validity Investigator Spot (VIS) as the (Fig.1). To identify and distinguish the invalid drugs and valid drugs by only identifying the color of this small spot that put in a suitable place on the drugs containers, such as Capsules, tablet, syrup.

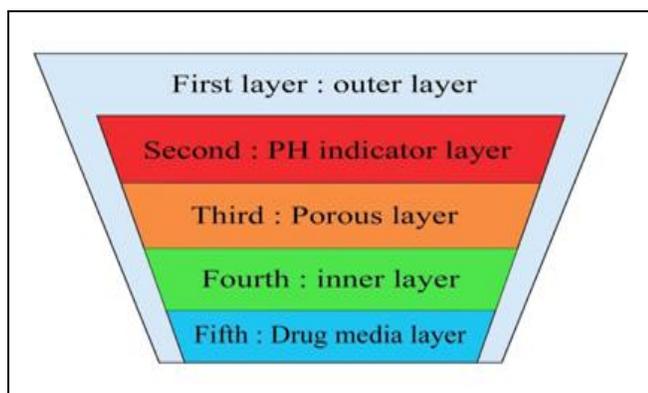


FIG. 1: VALIDITY INVESTIGATOR SPOT (VIS)

The design is simply contains 3 layers, as follow:

First Layer: Is the outer layer is usually one visible inert non-reactive layer, with suitable strength, and it may be: As a part of the wall of the drug container, as in the glass wall of the bottle of syrup drugs. Or just plastic visible layer as the outer covered plastic layer in tablets strips or capsules strips. Or may be strong, visible layer that appeared and fixed on the wall of the metal or the

plastic invisible containers as in inhaler bottles, and it may designed to contain and hold the other layers, each other's as one piece, too.

Second Layer: Is the pH indicator layer that contains about 1 mm diameter a piece of suitable pH indicator strip. That pH indicator should be nontoxic, incompatible with the drug components, cheap, sharp change in color in an exact desire pH of the drug, as Lo-Ion test kit, short range: pH 6 - 8. Each 0.5 unit of pH change is distinctly colored. Readings estimated to 0.25 PH unites¹⁸.

Last Layer (Fifth Layer): Is the drug media layer or thin covered drug layer according to drug media types, as a solution, or solid etc. that may directly attach to the other inner layers.

But in some types of drugs we may need another 2 layers, between a second layer (pH indicator strip layer) and the last layer (drug media layer) according to the drug nature and the pH indicator nature, as follows:

Third Layer: Is somewhat permeable layer to permit transfer of the drug media molecules into pH indicator layer to give the desired effect, but prevent transfer of the pH indicator's substance molecules into the drug media. As silica solid layer, or alumina layer¹².

Fourth Layer: Is the inner layer is inert, non - reactive, perforated layer, as plastic or glass or glass, perforated layer, may need to hold the other layers each other's. For example: Drug X (as I tested: Vitamin C tablets, Augmentin vials and paracetamol syrups) their pH changed when become expired, then we will need a specific pH indicator strip that only changes in color in this specific pH only. And we can use Validity Investigator Spot (VIS) as follows:

In Glass Bottle as in a Glass Syrup Container: The outer layer may be a part of the glass wall of the bottle of syrup drugs.

In Solid Container as Tablets or Capsules Strips: The outer layer is just a plastic visible layer, as the outer covered plastic layer in tablets strips or capsules strips.

In Invisible Plastic or Metal Container Drugs as in Inhaler Containers: The outer layer may be strong and visible glass layer and fixed in the wall of metal or plastic invisible container to be appeared by optic.

RESULTS AND DISCUSSION: Most of the people are not - fully trusted in the drug validity and the recorded expire date in the drug containers, and they hoped to find a new, additional, more accurate and simple method to differentiate easily between the actual valid drugs from the invalid drugs. All existed efforts as international or the regulatory institutions efforts, education and recorded expire date (as well as, I failed to find another studies that can treat these international issues, dynamically) are not enough to prevent these problems completely^{1,5}.

So, we will need an additional way (besides all regulatory efforts) to determine the actual - real validity of the drugs for public people, and most of people are hope to found a new, additional, more accurate and simple method to differentiate and distinguish easily between the actual valid drugs from the invalid drugs as this (VIS) method, because it is more accurate, simple for anyone to understand and recognize it by using only optic eye, cheap, can determine the actual - real validity of the drugs, decrease the risks and threats of the invalid drug, increase drug safety, makes the people more trusted and more comfortable about the drug validity, safety and activity That effect on their psychological and general health, too^{18,19}. As well as suitable for most drugs, most ingredients, most pharmaceutical forms of drugs, suitable for some types of food and canned food, too and I recommend this method to be applied by drugs manufactured companies for all drugs as possible.

It is a good step for drug manufacturing and development, but it needs some desired information accurately from the manufacturing companies, as the information about the exact pH at which the drug will start to become actually expired or actually invalid. And the manufacture may need (in some types of drugs) to design the drug components in which pH of the valid drug should differ enough from the pH of the invalid drugs, to get the exact and the suitable pH indicator type and

to get the suitable design of Validity Investigator Spot (VIS) easily and accurately.

CONCLUSION: The study in this research revealed that development of a new additional way (like Validity Investigator Spot method) to differentiate the invalid drugs, the valid drugs and detect the drug validity is necessary for decreasing the invalid drugs threats and risks, and to increase drug safety.

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