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The Global Threat of Counterfeit Drugs, Spurious Drugs, and Protection Measures by New Technology to Identify Them - A Review

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Abstract: ***The problem of the spurious, adulterated, counterfeit drugs had become a massive problem in the medical society and hampering the patients' health condition. The problem of counterfeit drugs has caused a global health crisis and financial hardship in several countries. The marketing, availability, and usage of counterfeit drugs can have major negative effects on patients, including death. The pharmaceutical industry, governments, and international organizations that deal with health, commerce, customs, and excise have not worked closely together to tackle the incidence of counterfeit drugs, which appear to be increasing. According to the WHO the 10.5% of medicines are substandard or falsified. The value of this counterfeit drugs could be estimated around $200 billion(globally). The Indian pharmaceutical market is estimated to worth INR 40,000 crore each year due to counterfeit medicines. The WHO has made several suggestions and taken all practical measures to prevent counterfeiting. Public health is in grave danger due to the persistent risk of counterfeit drugs on the Indian market. In this situation all the organizations are taking effective measure to prevent from this massive problem. In this study, as a pharmacist it's our responsibility to point out the fake medications and advising the general public to be aware. Here lastly, we will also discuss about some of the method which will be helpful to identify.***

Keywords: Medical society, Effective measure, Financial hardship, Responsibility, Pharmacists, Organizations, Massive problem, Data

1. Introduction

The global health is hampering because of the Counterfeit /Spurious /Adulterated /Not standard quality (NSQ). As there is a scarcity of particular medications, the Covid-19 epidemic has caused a global issue that has increased the trade in counterfeit medications. The manufacturing prices are 40% lower in developing nations than in developed ones, the **World Health Organization (WHO**) estimates that 25% of medications taken in these nations may be fake or substandard. It is believed that counterfeit and illegally sold medications control 40% of the pharmaceutical business. In addition to the health of the population, government inspectors suffer a significant loss as they are denied enormous sums of money due to sales tax & excise charge [3-4]. This issue may be addressed with the support of appropriate medication quality monitoring, legal and regulatory enforcement, an efficient and successful regulatory framework, and knowledge and vigilance on behalf of all stakeholders. The issue of substandard, suspicious, falsely-labelled, falsified, and counterfeit (SSFFC) medical items is especially serious in nations with unstable health infrastructures and poor health regulatory frameworks. These characteristics increase the likelihood that medical products that violate national and local health regulations may be manufactured and/or distributed, putting patients at risk. Prescription shortages, high and variable prices, and restricted access to reasonably priced pharmaceuticals are all factors that encourage the actions, activities, and behaviours that result in SSFFC medical products [4].

Drugs that are purposefully and fraudulently manufactured and/or mislabelled with regard to identity and/or source in order to give the impression that they are authentic are known as **counterfeit drugs.** Drugs that include contaminants, an inaccurate quantity of active pharmaceutical ingredient (API), a substandard API, an erroneous API, or repackaged expired medicines are examples of counterfeit pharmaceuticals. Some fake drugs could even be made under unsatisfactory circumstances and with erroneous formulations. The World Health Organization (WHO) has estimated that 10% of global pharmaceutical commerce, or $21 billion worth, involves counterfeit drugs.

Pharmaceutical items that do not satisfy official rules (such as those set forth by the FDA, USP, or other regulatory agencies) regarding quality, strength, purity, or composition are referred to as **adulterated medications**. Intentional or accidental adulteration may entail the following:

1) Being contaminated by dangerous materials (such as dirt, chemicals, or germs).
2) Substitution for various or inferior components not specified on the label.
3) Inaccurate formulation, including inaccurate active ingredient concentrations.
4) Poor storage, which might cause contamination or deterioration.

Ineffectiveness, toxicity, and even potentially fatal responses are just a few of the major health hazards associated with contaminated medications. In the United States, legislation such as the Food, Drug, and Cosmetic Act (FDCA) frequently govern this idea [7].

In contrast to adulterated drugs, which may be accidentally contaminated, spurious drugs are purposefully deceptive, often created to defraud consumers. They pose serious health risks, including toxicity, ineffective treatment, and even death. Spurious drugs are counterfeit or fake pharmaceutical products that are purposefully mislabelled with regard to their

identity, composition, or source. There are various detection method involved for counterfeit, spurious and adulterated drugs which will be beneficial and helpful for the patients in medical field [7-9].

2. Methodology-Detection Methods of Spurious and Counterfeit Drugs

Several techniques have been developed for testing counterfeit drugs due to the many negative effects of counterfeit drug products. The main prerequisite for these techniques is the ability to identify the Active Pharmaceutical Ingredient (API), substances other than the API, and excipients/additives present in the dosage form.

World Health Organization (WHO) basic tests for pharmaceutical dosage forms

One of the several screening methods for confirming the identification of pharmaceutical dosage forms is the WHO basic test. According to WHO, these tests were created to:

- Provide a practical way to confirm a drug's identity in the absence of a well-equipped laboratory facility;
- Indicate whether significant degradation has taken place in certain compounds that are known to decompose readily under unfavourable conditions; and
- Provide a straightforward and easily applicable method for confirming the identity of drug substances when the labelling and physical characteristics give rise to doubt, using a limited range of readily available reagents.

These tests are not meant to take the place of international pharmacopoeia or other pharmacopeial monographs that provide quality assurance because they merely verify the identity of drug compounds or the presence of contaminants. WHO basic tests consist of:

Visual Inspection:

With this approach, the dosage forms and packaging system are carefully inspected prior to, during, and following purchase, as well as in advance of administration. Even without knowledge of a medicine product's physical attributes, this technique may be used as a guide to spot counterfeit medicines.

Visual inspection of the package:

- Check the package to see whether it looks strange or different from what you've seen before.
- Examine the sealing tape and seals for cracks or rips to determine whether the security seal has been tampered with.
- Check for spelling mistakes, odd typefaces, font sizes, and print colors.
- Verify that the data on the primary and secondary packages is readable.
- Verify that the manufacturer's address, batch number, and expiration date on the secondary package match those on the original package.
- Verify whether the manufacturer's address can be traced, meaning it includes the precise location of the business rather than just the national address.
- Verify if the registration number—or, in the case of goods marketed or sold in Nigeria, the NAFDAC number—is correctly printed or whether it seems altered.

Visual inspection of the dosage form:

Look for variations in the drug's physical attributes, such as consistency, size, shape, and color homogeneity. According to WHO, the following physical flaws in tablets should be watched out for:

- Too much powder and/or tablet fragments at the bottom of the container (from crushed, broken, or abraded tablets);
- Chips or cracks in the tablets, as well as swelling, mottling, discoloration, and tablet fusion;
- The crystal's appearance on the tablet or the container walls [7].
- The capsule shell should also be checked for signs of hardening or softening, cracking, swelling, mottling, or discoloration.

Figure 1: Visual inspection of the dosage form

Test Tube Colour Reactions:

When the physical characteristics of the dosage form or the packaging system raise questions, the test-tube color response, a WHO basic test, offers a quick and easy way to confirm the authenticity of pharmaceutical dosage forms. A predetermined quantity of the medicinal product sample is combined with reagents for these tests, and any color changes that may result from the reaction are monitored. This technique can only detect the presence of a drug substance; it cannot determine whether the levels are different from those reported [5,6].

Figure 2: Test tube colour reactions

Melting Point Determination:
This is an additional method of confirming the authenticity of a pharmaceutical product. Finding the melting range entails calculating the temperature range between the drug sample's initial melting point and the temperature at which the solid disappears, signifying that the drug sample has melted entirely. Unless otherwise indicated, the permissible melting point is typically within ± 4 o C of the specified value [3].

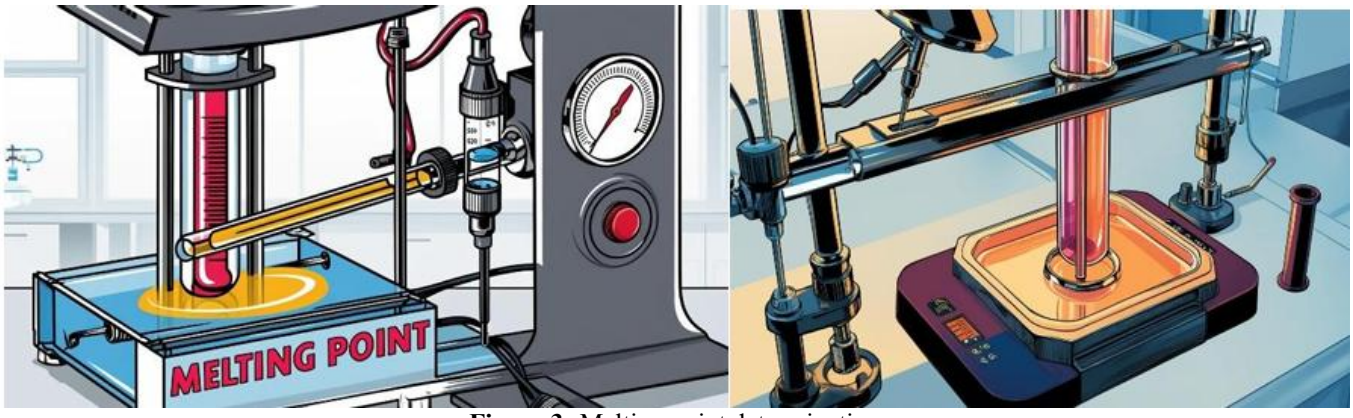

Figure 3: Melting point determination

Thin Layer Chromatography (TLC):
This technique is used to determine if a drug sample contains contaminants or the quantity of the drug component. The specific affinity of test materials for the static or mobile phase is the foundation of the TLC technique for drug substance identification. Because of its sensitivity and selectivity, TLC techniques are preferred over WHO basic tests for assessing medication items with inadequate active components. Additionally, there is less excipient interference with this approach [5-6].

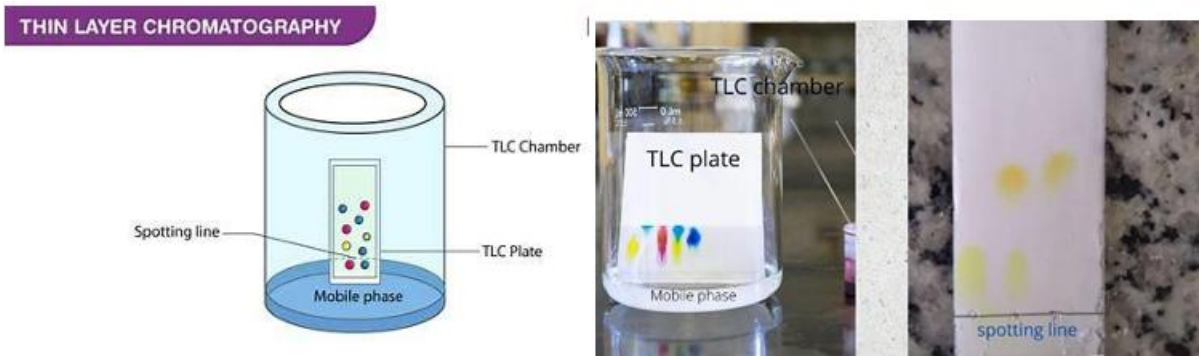

Figure 4: Thin Layer Chromatography

Analytical Techniques for Sophisticated Counterfeits:
The sophistication and organization of product faking have increased with technological advancements. This has resulted in the production of counterfeit medications that are nearly impossible to tell apart from the real thing through simple visual inspection or basic testing. When drug compounds are identified, separated, or quantified using analytical techniques like mass spectroscopy, High-Performance Liquid Chromatography (HPLC), etc., the likelihood of receiving a "false positive" or "false negative" result from test drug samples under examination has significantly decreased.

Figure 5: Analytical Techniques for Sophisticated Counterfeits

Use of Cutting Edge Technologies:
This entails identifying and semi-quantifying the active chemicals found in pharmaceutical goods using high-tech equipment. With the use of computerized control, these portable gadgets can identify medication goods in just a matter of minutes and only require a minimal bit of sample. Among the examples are:

- **TruScan:**

TruScan is an innovation of the US military. Rahrnan's spectroscopy is used in this portable, non-destructive point-and-shoot sample tool to detect fake medications instantly. This tool may be used to confirm a wide variety of chemical compounds and is used to do field-based screening of medicinal goods [8].

Figure 6: Image of TruScan

- **Mobile Authentication Service:**

One technique for testing counterfeit pharmaceuticals that has enabled many mobile phone users to identify phony drugs is the Mobile Authentication Service (MAS). Using the SMS platform, it is the first anti-counterfeiting gadget in the world. This technique for spotting counterfeit medications is very easy to use and produces fast findings on the integrity of medicinal goods [7].

Figure 7: Image of Mobile Authentication Service

- **The Black Eye:**

Israel created the benchtop gadget known as the "Black eye." It is a gadget that detects counterfeit medications using an active thermography (Infra-Red technology) concept. Because it represents a non-destructive procedure, this gadget has several benefits. Multiple drug samples can be screened simultaneously by the Black Eye. The Black Eye may also provide information on the individual chemicals in a medicinal dosage form, in addition to determining if a medicine product is authentic or not [5].

Figure 8: Image of the Black Eye

The Radio Frequency Identification System (RFID)
Using electromagnetic fields, this system can continuously track and trace regulated goods and medications from manufacture to the user, eliminating sensitive document forgeries.

Figure 9: Image of the RFID

3. Conclusion

It is concluded that different methods are involved for the identification of the spurious ,counterfeit drugs and to help the public health globally .These methods will be helpful in identifying and stop the supply of this false drugs to the public .These drugs will cause death of the patient .The methods involves like visual inspection, the dosage forms and packaging system are carefully inspected prior to, during, and following purchase, as well as in advance of administration. Even without knowledge of a medicine product's physical attributes, this technique may be used as a guide to spot counterfeit medicines. Test tube colour reactions, When the physical characteristics of the dosage form or the packaging system raise questions, the test-tube color response, a WHO basic test, offers a quick and easy way to confirm the authenticity of pharmaceutical dosage forms. TLC is a chromatographic method and others like black eye, Radio frequency identification system (RFID). In addition, it is advised to develop a hand -on instrument to easily identify the counterfeit or not standard quality drugs.

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