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Review Article

Suggestions for the Development of Rapid Drug Testing

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Abstract

The definite results of rapid drug testing are not the definitive conclusions of drug quality, but it's the critical initial screening. It plays an important role in the work of drug technology against the counterfeiting drug. Rapid drug testing can improve the relevance and hit-rates of the Drug Administration sector to save the cost of the sample. So that it make testing truly to be "targeted sampling, target testing." In this paper, according to the status and prospects of rapid drug testing in China, we made a few suggestions for China drug fast testing management.

Key words: Rapid drug testing; suggestions

1. Resource sharing of rapid drug control:

In recent years, with the development of modern information and scientific technology, China government has taken much attention and investment for rapid drug testing. The information about rapid drug testing has been fast expanding [1]. Therefore, the resources about rapid drug testing must be shared, based on information technology.

We should establish a unified database which includes methods about rapid drug testing and counterfeit medicines as soon as possible, and build searching engine to facilitate primary units who have duty on collecting and testing samples in their daily work. They can search the information according to the drug names, manufacturers, and batches, so they could carry out an inspection immediately. The database should also include adverse record-files, testing

standards, non-standard approaches, literature resources which the drugs or substances were involved in. References should be connected with CNKI online database in order to obtain comprehensive and updated literature resources. Based on a unified database, scientific researcher may be able to find the species with more adverse records in order to determine which certain species would be rapidly tested. They can find the species that had completed the fast testing, so it wouldn't waste time and effort. It can also connect literature resources for further research.

It is necessary to establish the monitoring information network system, which has the functions of flow tracking, exception warning, program management, information transmission, statistical summary and system management functions required for the daily supervision of rapid drug testing. It could support convenient and accurate product information resources. Primary testing unit can also obtain the latest and fastest information based on this system. The information of monitoring information network system must unify with the above database and constantly update each other.

It is necessary to cooperate with foreign Drug Administration and research institutions as well, receiving the updated latest progress from each other in order to share the resources globally.

2. Improving methods:

Currently, for the higher frequency of counterfeit drugs, commonly used drugs, expensive drugs, importing drugs and new drugs on the market, it should develop a rapid testing method as soon as possible. With the continuous improvement of fabrication technologies, new technologies of forgery are also emerging, from the most primitive complete fake, to recent targeted counterfeit. For example, from 2004 to 2006, our institute had collected the counterfeit drugs, which had mostly none of or less treatment components, such as Beijing Lower Blood Pressure Zero, Di-Ao-Xin-Xue-Kang Capsule with very low composition of diosgenin, Throat Disease Capsules with no tannin reaction, Jing-Zhi-Niu-Huang-Jie-Du Tablet with big difference on the smell of borneol. We can detect these counterfeits from their characters, smell, and identification of the reaction. However, in the market there were some informal manufacturers making counterfeit drugs by changing the manufacturing process, reducing or even canceling the launch of some relatively expensive medicines to achieve cost reduction. For example, the whole extract of Ban-Lan-Gen Tablet and some other tablets, according to prescription, they should be the whole extract production, but some unscrupulous manufacturers, in order to reduce costs, utilized powders of herbs instead.

The methods of rapid drug testing should be turning to the intrinsic identification of drug quality. It is difficult to distinguish inferior drugs currently, but it has distinct effects to the counterfeit drugs with no drug-ingredients. So it requires the development of methods that focus on the intrinsic quality of medicines, especially the fast tasting method for efficacy components of precious medicinal herbs in traditional Chinese medicine.

Therefore, rapid testing should be based on the current trends and conditions, apply the new technologies and new ways to shift the intrinsic quality of identification, and make better improvement on the testing methods.

3. Rapid testing of Chinese medicines and keep-healthy products that illegally added chemical composition

In recent years it had been frequently mentioned that Chinese medicines and healthy products had added some illegal chemical compositions. It might have some unpredictable consequences. We must resolutely put an end to it. To solve this problem, researchers have learnt a lot on the methods for detecting illegally

added chemical composition in Chinese medicine. For example: Zheng Rong et al, [4] had established TLC method for detecting illegal antihypertensive chemicals added in traditional Chinese medicine. The method had used two kinds of preparation methods for the drug solution and two extending conditions. The method mentioned above can be used for the rapid screening of seven chemical compositions such as illegally added reserpine, nifedipine, clonidine hydrochloride, prazosin, atenolol, hydrochlorothiazide and captopril in traditional Chinese medicine. Li Li et al, [5] applied HPLC in studying four kinds of chemical testing methods about anti-asthmatic cough classes in traditional Chinese medicine illegally added ephedrine hydrochloride, prednisone acetate, codeine phosphate, dexamethasone acetate. Yao Yu et al.[6] established HPLC-DAD method for separation of samples to 10 kinds of chemicals commonly. They had found illegally added chemical components in the traditional Chinese medicine approved sedative. Cao Ling and others [7] established methods in qualitative and quantitative detection of health food diet illegally added chemical composition of sibutramine hydrochloride, using thin-layer chromatography, high performance liquid chromatography - diode array detection, LC / MS / MS-MS techniques for qualitative identification, using high performance liquid chromatography in which the content of sibutramine hydrochloride.

Although it has made some progress on the Chinese medicines and healthy products that illegally added chemical composition, but there are wide range among Chinese medicines, and it has been established the type of rapid testing methods for less. The researchers in this field also need to continue to improve the rapid testing methods and the expansion of types of Chinese medicines.

4. The improvement of the personnel quality:

It requires the operator must have a certain amount of chemical knowledge and experimental basis in the rapid drug testing. At present, a considerable portion of the grass-roots Drug Administration officials had neither pharmacy professional background, nor connection with experimental operation, master rapid testing technologies not well. It will directly affect the accuracy of rapid testing drugs. So the training focused on training potential staff, improving the professional skills and legal knowledge of the Drug Administration, continuously strengthening continuing education training technical supervision of professionals, and constantly update their knowledge and enhancement of standards. It ensures the technical supervision of professionals cuold closely follow the development of technology and administrative supervise requirements.

5. Others:

Throughout recent years, according to rapid testing methods for pharmaceutical literature, Lin Jui-Hung’s synthesis report "Analysis of Rapid Detection of Drugs" was analyzed comprehensively and fully right the course of China's rapid testing drugs, role, characteristics, defects, and rapid inspection of the current drug proposal. The article was mentioned the establishment of “rapid drug testing” works management mechanism; emphasis on training, the formation of an active hard working, skillful term to work creatively; exploring the unique patterns of rapid testing around the Institute of Drug Control, universities, research institutions, the development of new topics of practical advice [8-10].

In summary, drug rapid testing is needed continually to develop and mature in practice. This article put some proposals with sharing of resources, improving methods; rapid testing of Chinese medicines and healthy products that

illegally added chemical composition, the improvement of the personnel quality, etc.

It is hoped that it could provide reference to the development and in-depth study for rapid testing.

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