

大阪府立公衆衛生研究所薬事指導部 平成10年度行政試験実施品目一覧表 (理化学試験)

成分名	試験項目	測定方法	剤型
ピタミン主薬製剤	有効成分の定量 重量偏差試験 崩壊試験	HPLC (ODS) 滴定 (直接滴定) HPLC (Phenyl)	フィルムコーティング錠 糖衣錠 素錠 軟カプセル剤 顆粒剤 硬カプセル剤
H <sub>2</sub> 遮断薬	有効成分の定量 重量偏差試験 崩壊試験	HPLC (CN) HPLC (ODS)	硬カプセル剤 フィルムコーティング錠 細粒剤
局方製剤	有効成分の定量 重量偏差試験 崩壊試験 溶出試験	吸光度	素錠 糖衣錠
菌科用医薬品 (消毒剤)	有効成分の定量	滴定 (直接滴定) 吸光度 HPLC (ODS) GC	液剤
解熱鎮痛消炎剤	有効成分の定量 重量偏差試験 崩壊試験	HPLC (ODS) 吸光度 滴定 (直接滴定)	硬カプセル剤 散剤 軟カプセル剤

溶出試験	HPLC (phenyl)	細粒剤 フィルムコーティング錠 素錠
フェナセチン マレイン酸プログルゲルメタシン スルピリン インドメタシン アンフェナクナトリウム アセメタシン 塩酸プロムヘキシン 塩酸アンブプロキソール L-カルボシステイン イブプロフェン メシル酸カモスタット 塩酸アマンタジン	有効成分の定量 重量偏差試験 崩壊試験 有効成分の定量 重量偏差試験 崩壊試験 有効成分の定量 崩壊試験 精油含量	素錠 硬カプセル剤 細粒剤 素錠 フィルムコーティング錠 細粒剤 生薬
ケイヒ サイシン ビヤクジュツ ソウジュツ ウイキョウ リン酸ピリドキサル メコバミン コバマミド ヒドロキソコバラミン シアノコバラミン	有効成分の定量	注射剤
ビタミン含有注射薬	吸光度 HPLC (ODS)	
その他の医療用医薬品 抱水クロラール 塩酸プロムヘキシン 硫酸サルブタモール アテノロール 酒石酸メトプロロール 酢酸トコフェロール セチルアルコロール ステアリアルコロール トコフェロール パラベン類 ホルムアルデヒド	有効成分の定量 経時変化試験 含量均一性試験 配合上限成分の確認 表示指定成分の確認 表示指定成分の確認 配合禁止成分の確認 溶出物試験 強熱残分試験	化粧水
化粧品	HPLC (ODS)	
化粧品 医療用具	HPLC (ODS) 吸光度	香水

内用固形製剤	成分	溶出試験	吸光度 HPLC (ODS)	硬カプセル剤 糖衣錠 素錠
インドメタシン 塩酸クロルプロマジン メチルドパ プレドニゾロン イソニアジド 塩酸プロカインアミド クロルジアゼボキシド ノルゲストレル エチニルエストラジオール ビベシズ酸チペピジン タウリン	確認・定量	紫外吸収スペクトル 赤外吸収スペクトル HPLC (ODS)	液剤	

The study of structuring mutual network of pharmaceutical affairs among national institutes and local institutes.

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The purpose of the institutes : There are national institutes (National Institute of Health and National Institute of Infectious Disease), which test the quality of medicine at the request of the Ministry of Health and Welfare, and 59 district institutes, which do the same test at the request of local government in Japan. Then we studied for structuring mutual information trade network between national institute and district institute or among the district institutes. This study aimed to unify information from these institutes, and to secure the quality of medicine more organically, more rapidly, more efficiency and without regional differences.

Method : 49 institutes (National Institutes and so on) participated in structuring the network.

We studied the management of network, availability of information should be provided. And we also studied the usefulness of network concerning the detection of the case against pharmaceutical affairs low, maintenance of secret, and care for the ethics and so on.

Results : The network were utilized these network for supplying the method of analysis, standard of spectrum analysis. Then we could confirm the usefulness of mutual network to ensure the quality of medicine. And intercommunity of information could decrease the area gap in the matter of testing the quality of medicine. As the result of the sharing the knowledge on network, the effect of decreasing the public healthy injury by defective or injurious medicine was confirmed. Furthermore sharing information decrease dissatisfaction and insufficiency people had in national or public institutes. After this in view of these outcome, we promote the more available usage of network. We would like to accelerate the value of network and use it to restrain people from the damage of defective or injurious by interchanging more frequently and up grading the data base moreover.

# **The Study of Structuring Mutual Network of Pharmaceutical Affairs Among National Institutes and Local Institutes**

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## **A : Purpose of the study**

This study aimed at prevention of the distribution of unjust or defective drugs more quickly and minimization of the healthy damage of people to receive from unjust or defective drugs in Japan.

## **B : Achievement method for the purpose**

In Japan, there are national research institutes(3 institutes) examining quality of drugs by a request of the Ministry of Health and Welfare and district institutes(about 70 instutes) to examine similar quality research by a request of a local government.

Then we build a mutual information exchange network between these national research institutes and district research institutes or a district research institute and district research institutes. And we attain the purpose by unifying the information that these institutes have.

## **C : The formal course of information releases between public offices**

Information releases about the detection of unjust or defective drugs in Japan are done like next by dispatch of documents.

District institute for health A → prefectural office A(Pharmaceutical Affairs Div.) → Ministry of Health and Welfare (Pharmaceutical safety bureau)→  
→→→→→→→→→→

→ prefectural office B → district institute for health B

→ National institute for health

→ prefectural office C → district institute for health C

## **D : The establishment of informal information release course**

We utilize a network and install release course of informal information. By this we exchange information quickly and do quick exclusion of unjust or defective drugs.

- The district institute for health A (researcher)
- district institute for health B ( researcher)
  - district institute for health C ( researcher)
  - district institute for health D (researcher)
  - National institute for health (researcher)
  - Ministry of Health and Welfare (medicine security bureau)
  - prefectural office A (pharmaceutical affairs dev.) (official)
- The following is not affiliated to the network.
- prefectural office B (pharmaceutical affairs dev.) (official)
  - prefectural office C (pharmaceutical affairs dev.) (official)

**E : Precondition of establishment of informal information release course**

- 1: The network is administered with closed and a home page is protected by a password.
- 2: A researcher belonging to the network communicates information to other researchers with e-mails when they detected unjust or defective drugs and doubted drugs.
- 3: It is assumed that contents of information are informal. We use formal information releases course between formal government offices as a formal release of information .
- 4: Contents of information are based on the result of early examination. Thus because contents of information may be lacking in accuracy, we protect obligation of keeping secrecy of a public employee strictly.
- 5: When release of information became necessary, we cope mainly on a sender of information adequately.
- 6: The others, we change information such as examination technology, information exchange about reference standard and registration of the results of examination necessary for drug application regulation.

**F : The problems that occurred on the occasion of network administration**

- Resistance of local government for informal information offering and information exchange
- Lack of budget for a network(LAN) in district institute for health and lack of understanding of a local government for it
- Difference of level and recognition exist in district institute for health about information management (a habit of secret and so on)
- A burden of network manager with work to be related to a network
- Information release procedure

## **G : The results of network access**

◎ The following information exchange that utilized a mailing list

○ Information exchange about the test method, reference standard and the result of test

○ Exchange of know-how about the procedure of GMP inspection

○ Submitting of problems that people in charge of examination has, and answers to them from the practitioners experienced examination

○ Information providing about an test method of Pharmacopeia from national research institute

○ An opinion of district institute for health about the official test method

○ Exchange of test result of market product that accumulated at each district institute for health

◎ The following information exchange by notice board

○ Among information changed in the above, the information with the significance that should be carried is laid on a notice board.

(writing is impossible from the outside on the notice board)

○ Writing up the matter to think that participants want to present on a notice board

(members write on it freely)

## **H : Net rate and a mailing list of national research institute and district institute for health**

Net rate: It is 63 institutes among national and district research 73 institutes.  
(non-engage institutes are during preparation of their LAN)

A mailing list: About 250 people

## **I : Effect for exclusion from a market of unjust or defective drugs got by Net**

○ By information exchange, we specified chemical compounds( include drugs) mixed falsely in traditional drugs and healthy food more quickly and removed them more quickly from the market.

○ By detection information of defective drugs from one district institute for health, other district institute for health could remove the similar defective drugs without area disparity from the market quickly.

○ By virtue of exchange of information about the test method, the know-how of the test method and reference standard, it became more