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〈KOACH INFORMATION〉
広島大学病院薬剤部／日本医療薬学会発表
KOACHを利用して
非無菌室で無菌製剤の調整に成功
〈防災対策における呼吸保護〉
噴火災害への備えとして必要な
呼吸用保護具
興研株式会社
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KOACH Information

Department of Pharmaceutical Services
Hiroshima University Hospital

Conference Presentation at the Japanese Society of Pharmaceutical Health Care and Sciences

"Successful production of sterile drug products under non-aseptic conditions by using KOACH"

At the Department of Pharmaceutical Services, Hiroshima University Hospital, a study was conducted on the possibility of production of sterile drug products in a hospital ward under non-aseptic conditions. Sterile drug products are conventionally produced using a clean bench set in an aseptic room. The result of this study was presented at the 24th annual meeting of the Japanese Society of Pharmaceutical Health Care and Sciences. By using KOACH production possibilities of sterile drug products are expected to be widened in the future.

We interviewed Mr. Tetsuya Murase who made a presentation at the conference. He works at the Department of Pharmaceutical Services, Hiroshima University Hospital.

About a clean environment required for production of sterile drug products.

KOKEN: Could you give us examples of drug products produced in an aseptic room in a hospital ward?

MR. MURASE: Sterile drug products are produced in an aseptic room. A typical example is Total Parenteral Nutrition (TPN). TPN is a way of intravenously feeding a person who cannot eat by mouth. However, cautions are required for this method because a high calorie TPN may induce the quick growth of bacteria if contamination should occur.

KOKEN: What will happen if contamination occurs in sterile drug products?

MR. MURASE: Many patients who need TPN tend to show lower resistance to disease, which may lead to hospital-acquired infections.

Cases with TPN contamination by spore forming bacteria are reported at academic conferences. We are paying a full attention to prevent bacteria from entering TPN.

KOKEN: I see that a clean environment is required for handling sterile drug products.

MR. MURASE: Sterile drug products such as TPN are prepared to meet the need of an individual patient in a pharmaceutical department of a hospital.

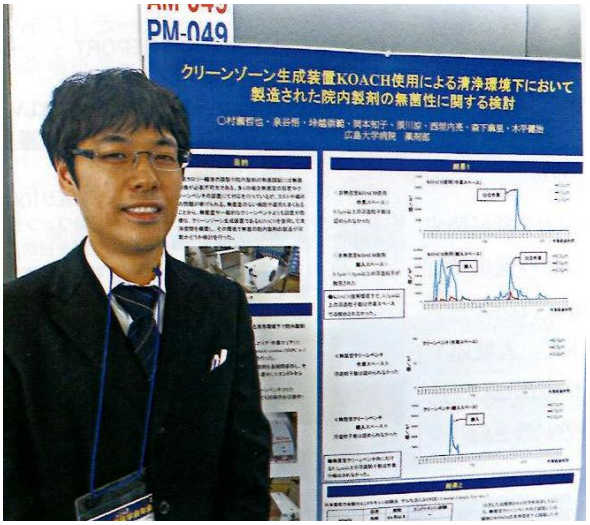
According to the Guideline for the handling injectable drug products produced by aseptic processing in a hospital made by the Japanese Society of Hospital Pharmacists, hospital pharmacists are recommended to prepare injectable drug products in a hospital ward under aseptic conditions in order to prevent bacteria from entering the drug products.

KOKEN: We hear that it is difficult to form and maintain a clean environment.

MR. MURASE: The clean space required by the Guideline can be formed by the combined use of an aseptic room and a clean bench. Because this requires a certain extent of space and cost, I think it is rather difficult for small-to-midsize medical facilities to install such equipment right away.

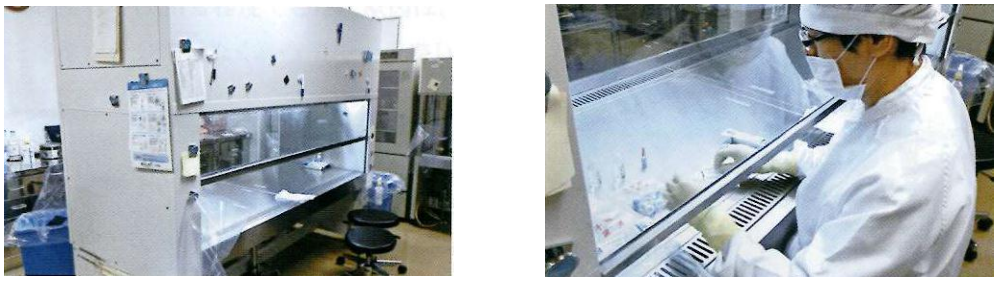
Even in the hospital that has already installed an aseptic room, a strict procedure for entry and exit must be followed to maintain a required level of cleanliness, such as changing into clean suits or receiving an air-shower.

When preparing sterile drug products in a clean bench, a front glass sliding viewscreen may restrict the hand movement of a worker or the reflection of light on the glass surface may disturb the workability.



Mr. Tetsuya Murase
Department of Pharmaceutical Services
Hiroshima University Hospital

An aseptic room is installed to prevent bacteria from entering sterile drug products during manufacturing process. Many steps of procedures must be followed to maintain the strict level of cleanliness in an aseptic room.



A clean bench is set in an aseptic room. A front glass sliding viewscreen is opened only slightly to prevent contamination.

Sterile drug products can be prepared in a clean space formed by the portable KOACH T500-F in a non-aseptic general room.

KOACH will make aseptic processing easier dramatically.

KOKEN: Then, you came up with the idea of using the Table KOACH for aseptic processing, didn't you?

MR. MURASE: To prepare sterile drug products, a conventional method was that an aseptic room is constructed and a clean bench is set in it. In contrast, the Table KOACH can form a high level of cleanliness in a space without surrounding walls. Therefore, I thought it can be used when we prepare intravenous infusion or injectable drugs without using an aseptic room.

My intuition told me that with the use of the Table KOACH that is portable, aseptic processing can be administered in a hospital ward where the installation of an aseptic room is difficult. Aseptic processing may be changed completely in a way previously unthinkable in the future.

KOKEN: Could you tell me the outline of your presentation at the conference?

MR. MURASE: We examined if sterile drug products can be prepared in atmospheric environment using the Table KOACH. In a clean space formed by the Table KOACH set in a non-aseptic room, we subdivided the large quantity of eye drops into smaller containers and verified if they maintained in a disinfected condition after 6 months. For comparison, we did the same experiment using a clean bench with ISO Class 5 cleanliness set in an aseptic room and verified the condition after 6 months.

For both experiments, we did not identify the growth of bacteria.

Based on these experiments, we confirmed that the KOACH is a system that can make aseptic processing possible in a non-aseptic environment. We presented this result at the 24th annual meeting of the Japanese Society of Pharmaceutical Health Care and Sciences held in September, 2014.

KOKEN: What possibilities do you consider from the Table KOACH?

MR. MURASE: We confirmed in the latest experiments that the Table KOACH is capable of forming a clean environment even under non-aseptic conditions. This means that aseptic processing can be administered anywhere in an individual hospital ward without considering space and cost for installation of both an aseptic room and a clean bench.

Furthermore, a much bigger advantage is that by installing the KOACH in an individual hospital ward, mixing of injectable medications, which is currently performed in atmospheric conditions, can be performed more safely.

The concept of the Table KOACH “Create super clean anytime, anywhere” is closely linked to the establishment of a hospital system that should quickly respond to the requirements demanded by frontline staff. On top of that, we will be able to achieve a higher level of safety and security in medical services to provide patients with better services.

Even in a dispensing pharmacy who is engaged in home medical care the Table KOACH can form a clean environment without difficulty, which, I expect, will lead to the possibility to prepare sterile drug products on the spot.

Poster presentation by
Department of Pharmaceutical Services
Hiroshima University Hospital

Many participants who showed interest in the poster presentation also came to the Koken display booth.

Excerpts from the conference presentation by the Department of Pharmaceutical Services, Hiroshima University Hospital at the 24th Annual Meeting of the Japanese Society of Pharmaceutical Health Care and Sciences

Aseptic Condition of sterile drug products produced in a hospital ward which is specifically purified by the KOACH, a clean zone creator of KOKEN LTD.

By Tetsuya Murase and others
Department of Pharmaceutical Services, Hiroshima University Hospital

[Purpose]

To produce sterile drug products which do not allow contamination at all in a hospital's pharmacy, it is indispensable to form an aseptic environment in the first place.

In many hospitals, aseptic rooms and clean benches are installed to form an aseptic environment. However, there are many hospitals and pharmacies who are facing difficulty to cope with the space and cost for installment of such facility.

A study was conducted on the possibility of production of sterile drug products in a hospital ward that is specifically purified by the Koken's Table KOACH, a clean zone creator, which is easy to install compared with the conventional aseptic room and clean bench.

[Methods]

In a clean space formed by the Table KOACH set in atmospheric environment, we subdivided the large quantity of eye drops into smaller containers.

For comparison, we did the same experiment using a clean bench with ISO Class 5 (US FED standards Class 100) cleanliness set in an aseptic room.

- The number of airborne particulates were measured by a particle counter during mixing injection.
- The eye drops produced under both environmental conditions were stored for 6 months and verified if they remained in a bacteria-free condition.

[Results]

- Airborne particulates larger than 0.5μm were not found in a workspace formed by the KOACH.
- After storing the subdivided eye drops for 6 months in a cold place, both those which were prepared in a clean bench within an aseptic room and those which were prepared in a clean zone formed by the KOACH under atmospheric conditions were confirmed to be bacteria-free.

[Discussion]

It was concluded that a variety of tasks including production of sterile drug products in a hospital ward can be performed in a clean zone formed by the KOACH now that we found that the KOACH can achieve the same effect as in a clean bench within an aseptic room. The problem to cope with difficult installation conditions for installing an aseptic room or a clean bench may be solved by using the KOACH.

	Stored in	Period	Endotoxin test
KOACH under atmospheric conditions	A cold place	More than 6 months	－(negative)
Clean bench within an aseptic room	A cold place	More than 6 months	－(negative)

Endotoxin test positive: ＋

Endotoxin test negative: －