

ISOMED : Beginning of the Radiation Sterilization Technology Era in India

Radiation sterilization is the process of destruction of micro-organisms, by exposing the material to ionizing radiation such as gamma ray from radioisotopic sources. With the aim to improving the quality of locally made healthcare products and devices and practical demonstration of radiation sterilization of healthcare supplies on an industrial scale, DAE, with assistance from United Nations Development Programme (UNDP) and International Atomic Energy Agency (IAEA), had set up the ISOMED plant at Trombay, which was commissioned on January 1, 1974. With this, India ushered in the “Radiation Sterilization Technology Era”.

This method of sterilization has many advantages over the conventional methods of sterilization based on heat or ethylene oxide (ETO). The materials can be effectively sterilized by radiation in their final packages, that provides considerable flexibility in packaging for sterilization and allows the product to be retained in the sterile form until the package is opened or damaged.

The operating experience of ISOMED, for over three decades, has not only demonstrated the technology of radiation sterilization, but also has firmly established this technology as an industrial process for sterilization of healthcare products. The process is now widely accepted in the country.

The plant is designed to irradiate medical/healthcare products of bulk density ranging from 0.1 to 0.2 g/cc.

The products to be treated are packed in a standard cardboard cartons of volume approx. 90 litres, with the gross weight not exceeding 14.5 kg each.

The source rack is designed to house 90 composite source units with a maximum activity of 1 Mci (million curies). The products processed are released to the customer based on product dosimetric results. ISOMED has adopted a highly precise and accurate dosimetric systems.

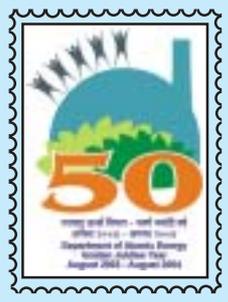
The minimum radiation dose imparted to the product for sterilization is 25 kGy (energy equivalent to 6.2 calories of heat) conforming to International standards. Such a dose offers a sterility assurance level (SAL) of the order of 10^{-6} provided the initial bioburden is not excessively high and the primary packaging of the product is adequate to maintain post-irradiation sterility of the products. Microbiological dosimeters (Biological indicators) are

also employed, as additional measure, in the facility

Thus quality assurance of the process and products is achieved by strict adherence to Good Irradiation Practice (GIP) and Good Manufacturing Practices (GMP).

A broad classification of the products which are regularly processed at ISOMED are outlined in the table below.

Radiation sterilization of medical products being done at ISOMED Plant, Trombay



- Antibiotic Powders
- Ayurvedic Products
- Containers And Closures
- Contraceptives (Family Welfare)
- Dai Kits (Rural Healthcare Programme)
- Eye / Ear Droppers
- Herbal Products (Export)
- Latex Gloves
- Ointments
- Orthopaedic Implants
- Perfusion Sets
- Pharmaceutical Raw Materials (Export)
- Surgical Blades, Sutures, Dressings
- Veterinary Products
- Miscellaneous

Gamma sterilization charges constitute only a fraction of the cost of finished product (around 3%). Moreover, in the energy starved world, gamma radiation sterilization requires only one fifth of the energy input required for ETO sterilization.

ISOMED, presently under the Board of Radiation and Isotope Technology (BRIT) has been offering radiation sterilization services to the healthcare sector in the country for the past three decades. Users of ISOMED services have increased from around 12 in the year 1974 to well over 1600 by the year 2003, thus demonstrating the acceptance of radiation sterilization technology by the healthcare profession and industry in our country.

ISOMED facility is considered to be a centre of excellence in the field of gamma radiation sterilization of healthcare products, in the Asia Pacific region, by many national and international agencies. In fact, ISOMED had conducted around 10 training courses, each of 2 weeks duration, sponsored by IAEA/RCA, on relevant aspects of radiation sterilization. The participants for the above courses were from countries such as Bangladesh, China, Korea, Malaysia, Pakistan, Philippine, Singapore, Sri Lanka, Thailand, Vietnam etc. Apart from the above, ISOMED used to get short term trainees sponsored by IAEA from many overseas countries.

ISOMED obtained ISO-9002 accreditation in the year 2000.

ISOMED had been bestowed with many prestigious awards and commendations for excellence in customer service from a host of its user organizations on several occasions.

ISOMED has developed a number of sterile surgical and medical aids, which have been playing significant roles in the quality of the medical care, particularly in the rural areas, where infrastructural facilities are inadequate. One such product developed and promoted by ISOMED is the radiation sterilized Dai Kit.

Dai kit is a radiation sterilized packet containing the necessary basic items normally required for delivery procedures in rural home. The usage of such kits is reported to have significantly reduced the infant morbidity and mortality rates in India. The successful usage of such kits has encouraged many small scale entrepreneurs to take up manufacturing of such kits on a larger scale. The International Institute of Population Studies (IIPS) in its study has found that the infant mortality rate has fallen by 25-30 % in Rajasthan, Madhya Pradesh, Maharashtra and Uttar Pradesh as a result of distribution of the kits in these areas.

Hydrogel, another product developed at ISOMED, jointly by BRIT & BARC, is found to be very effective for faster healing especially for burns and other wounds. This product has been patented. The technology has been transferred by DAE to a private entrepreneur.

Gamma sterilization technology has greatly helped to improve the quality of healthcare products and thereby the quality of healthcare in the country. The introduction of this technology in our country, three decades ago, has provided an impetus to the growth of indigenous manufacturers of many sterile medical and healthcare products and devices.

Realizing the future potential of this technology, many private entrepreneurs have shown keen interest and have come forward to setup gamma radiation sterilization plants at different parts of the country.

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