



विकिरण एवं आइसोटोप प्रौद्योगिकी बोर्ड
Board of Radiation & Isotope Technology
(BRIT/BARC Vashi Complex, Sector-20 Vashi, Navi Mumbai-400 705)



Manufacturers of medical products

Microbiological analytical services offered by BRIT for your medical products

According to pharmacopoeia requirements, in process control of the sterilization procedure is very much in use, which consists of testing and evaluating the efficacy of the sterilization process by using Biological Indicator. We offer you an effective quality control procedure by supplying biological indicator for a better 'in process control'. Yourself, as a manufacturer who actually deals with your product in the market, will thus, build up a confidence at their end.

As per the guidelines for the sterility testing of therapeutic goods, (British pharmacopoeia & European pharmacopoeia) experience in many countries over the years has confirmed that greater reliance must be placed on appropriate techniques & procedures throughout the manufacture of the product (including in process sterility testing at various stages) rather than simply depending on sterility test made on a number of samples of the final batch as the sole criterion of sterility. In view of this we are pleased to offer you the following services-

1. Biological indicators to be irradiated with your product at your end.
2. Certification & analysis of Biological Indicator.
3. Ready to use kit for Biological Indicator to be used as in process control, which includes its evaluation (this product will be released in market very soon).
4. The actual sterility testing of the final gamma irradiated products.

We supply herewith the free samples of Biological Indicator for your use & we require the feed back for the same. Our services offered will be at the very reasonable cost. We are also enclosing the technical information for carrying out in process control using Biological Indicator. A feedback form is enclosed herewith, please do fill up & send back to us at the earliest. We will be able to serve you better based on your feedback..

We are looking ahead to interact with you in this concern.

The cost of analysis of irradiated Biological Indicator will be Rs. 450/Batch of the product. For any queries please contact Ku. Pramila S Rao, Manager, Microbiology Group, contact Nos. 25594753/27887405.

To,
Director/manager,

Dr. Ramesh Chander
General Manager
Gamma Radiation Processing Services
Contact No. 022-25595374/27887405

**CERTIFICATE OF BIOLOGICAL IN PROCESS CONTROL OF GAMMA
IRRADIATION PROCESS**

NAME OF MANUFACTURER :
PRODUCT DESCRIPTION :
BATCH NO./LOT NO. :
DATE OF MANFG :
LOT/BATCH SIZE (No. OF CARTONS) :
LOCATION & NO.
OF BIOLOGICAL INDICATOR(BI) EXPOSED :
NAME OF IRRADIATION PLANT :
DATE OF IRRADIATION :
RADIATION DOSE DELIVERED ;
DATE OF TESTING :
NO. OF IRRADIATED BI TESTED :

THE CERTIFICATE

This is to certify that above gamma irradiation process was evaluated by biological indicator, *Bacillus pumilus ATCC 14884* as per the IP/USP requirement and is found to be satisfactory/non-satisfactory.

Microbiologist
Industrial Radiation Processing Group



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FEEDBACK FORM

1. Do you get your microbiological testing done at your end or from outside analytical laboratories? In house testing/analytical laboratories
2. Do you feel in process control will give you better confidence of sterility of your product? Yes/No
3. If yes would you like to purchase the Biological Indicators? Yes/No
* Give us your monthly requirement -----50/100/200
4. Would you like to get it analyzed by us? Yes/No
5. Alternatively would you like to use the ready to use kit for Biological Indicator which will be released soon for sale? Yes/No
6. Do you feel that the above in process control will help you in releasing the sterilized products before sterility test gets completed? Yes/No
7. Would you be interested in using our services being offered for sterility testing & reporting? Yes/No
 - If yes give us your monthly requirement -----5/10/50 samples

From:

Signature & Name of user :

Name of manufacturer :

Address :

Contact No.:

E mail :

Date:



Placement of BI

These are required to be placed at the geometric center of the box where the absorbed dose is minimum (25 kGy)

Procedure

1. A pair of spore disc should be placed along with your product for radiation sterilization at minimum dose position as indicated by sterilization agency.
2. After sterilization remove pair of spore disc and separately aseptically transfer to 10 ml sterile **SOYABEAN CASEIN DIGEST** broth in glass test tubes. This is **PRODUCT TEST**.
3. Repeat step 2 using unirradiated pair of spore disc as **POSITIVE CONTROL**.
4. Incubate the tubes at 37 °C for 7 days and observe for growth.
5. Record the observation in report sheet.

REPORT SHEET FOR BIOLOGICAL INDICATOR (BI)

1. Manufacturer :
2. Product :
3. BI : *Bacillus pumilus (ATCC 14884)*
4. Spores per disc : $10^6 - 10^7$
5. Batch No. of BI :
6. Irradiation details : GRPS/ISM/C- /PNI- /Date
7. Observations :

Sr No.	BI Disc	No. of BI disc remain sterile out of two			
		1 st Day	2 nd Day	3 rd Day	7 th day
1.	Irradiated				
2.	Unirradiated				

8. Remarks : Product passes/does not pass BI test
9. Name of the testing Lab :
10. Analyst (Name & signature) :

Note:

1. The term sterile means no turbidity visible & unsterile means visible turbidity
2. If turbidity is observed in irradiated BI broth, repeat the test to overcome cross contamination
3. The work should be carried out by person who has been trained thoroughly in aseptic techniques.