

Full solution for irradiated products

- Measurement on bioburden acc. to ISO 11137
- Dosimetric validation / revalidation
(dose mappings)
- Validation / revalidation of microbiology
(dose audits)
- Physical and chemical tests of
product properties after irradiation



Irradiated dropper bottles

Gerresheimer Plastic Packaging specializes in the widely varied spectrum of pharmaceutical plastic packaging within solid, liquid and ophthalmic applications. Our products for ophthalmic and nasal applications include bottles and droppers in LDPE and nasal sprays with either nebulisers or pumps. They are produced in modern classified clean room class ISO 7.

Now Gerresheimer is offering a complete solution for irradiated products and validations in order to simplify the purchase of dropper bottles for our customers. Gamma radiation is the service provided using the method VDmax 17,5 kGy. Gamma validation is done in accordance with the relevant ISO standards 11137, 11737 and 13004.



FEATURES

- Validated process of irradiation using method VDmax 17,5
- Physical and chemical tests of product properties after irradiation
- Monitoring of bioburden level
- Standardization of products designed to being irradiated

ADVANTAGES

- Supervision of the irradiating company as the approved supplier
- Transport from Gerresheimer to sterilization company and then to the place designed by customer
- Managing validation process as well as revalidation
- Lower costs relate to validation process as well as irradiation service
- The dose of VDmax 17,5 has less physical impact on the packaging material

PROOF

We have passed the validation process of the gamma irradiation, which was based on:

- Dose substantiation of a irradiation dose of 17,5 kGy (Method VDmax 17,5)
- Bioburden estimation and performance of verification dose experiment (bioburden and sterility test)
- Dose mapping within established scope: Min. dose 17,5 kGy – max dose 50 kGy



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