

Sterile irradi. Isopropyl Myristate

Ordering number: 1.46628.0006

Isopropyl myristate (IPM) is a fatty acid ester which is used as solvent in water-in-oil emulsion, oils and fatty based ointments. The use of IPM is recommended in the Sterility Test chapter of the European, Japanese and United States Pharmacopoeia (EP, 2.6.13, JP, 4.06 and USP, 71) as diluent for oils and oily solutions, as well as for ointments and creams. Indeed, its solvent properties improve the filterability of these samples

Product Information

Our irradiated IPM comes in a 500 mL glass bottle with a filling volume of 360 mL, closed with a septum and red flip cap. One box contains 6 bottles.

The product is sterilized by gamma-irradiation within a dose range of 25 to 40 kGy.

Appearance

The appearance of the fluid is clear and colorless.
The clear glass bottle turns into an amber color due to the gamma-irradiation waves.

Application

According to EP, JP and USP, oils and oily solutions of high viscosity may be diluted if necessary with isopropyl myristate to facilitate membrane filtration. The oil should penetrate the membrane by its own weight followed by filtering by gradual application of pressure or suction. The membrane may be washed 3 times with 100 mL Fluid D afterwards. At least one or one half of the filter is incubated in Tryptic Soy Broth (e.g. article number 146317) and a second or the other half of the filter in Fluid Thioglycollate Medium (e.g. article number 146406) for not less than 14 days.

According to EP, JP and USP, ointments and creams can also be diluted up to 1% in IPM prior to filtration.

Note: In case of direct inoculation of microorganisms into IPM, addition of 9% NaCl Peptone Buffer ensures recovery rate above 50%.

Storage and Shelf Life

The product can be used for sterility testing until the expiry date if stored upright, protected from light and properly closed at +2 °C to +25 °C.

Disposal

Please mind the respective regulations for the disposal of chemicals. Waste material must be disposed of in accordance with the national and local regulations.

Literature

Tsuji K, Robertson JH. Microbial Toxicity of Isopropyl Myristate Used for Sterility Testing of Petrolatum-Based Ophthalmic Ointments. Applied Microbiology. 1973;25(1):139-145.

Tsuji K, Stapert EM, Robertson JH, Waiyaki PM. Sterility Test Method for Petrolatum-Based Ophthalmic Ointments. Applied Microbiology. 1970;20(5):798-801.

European Pharmacopeia 9.0 (2016) 2.6.1. Sterility

United States Pharmacopeia 41 (2018) <71> Sterility Tests

Japanese Pharmacopeia 17 (2016) 4.06. Sterility Test

European Pharmacopeia 9.0 (2016) Isopropylmyristate. 1047200. [110-27-0]

ISO 11137-2 Sterilization of health care products — Radiation Part 2: Establishing the sterilization dose

Ordering Information

Product	Cat. No.
Isopropylmyristate - irradiated	1.46628.0006
Steritest™ NEO filtration device for solvents, creams, ointments and veterinary injectables	TZHVSL210
NaCl Peptone Buffer 9.0 mL EP 1936r-100p	1.46196.0100
Tryptic Soy Broth acc EP+USP	1.46317.0010
Fluid D acc. USP	1.46397.0010
Fluid Thioglycollate Media acc EP+USP	1.46406.0010

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