

CLEANING AND STERILIZATION PROCEDURES FOR PHARMACEUTICAL HOSES

Introduction

The validation of the sterilization process for the pharmaceutical hoses and tubings is responsibility of the users. Tests should always be carried out prior to adopting specific cleaning procedures in order to verify whether the chosen cleaning process may alter the performance of the hose. In general terms, the IPL pharmaceutical line may be cleaned with the following processes:

Autoclave or Steam Sterilization IPL pharmaceutical hoses may be sterilized by steam in autoclave. The hoses can bear a standard cycle: 1) 30 minutes at +121°C, at a pressure of 1 bar* 2) 5-7 minutes at + 134°C, at a pressure of 2,1 bar (except Pharmapress and Pharmasteel)*

* Data refer to the hose without fittings

Gamma Radiation Sterilization Gamma radiations sterilization (up to 2,5 Mrad) do not adversely impact physical features of the hoses such as hardness, elongation, tear strength, nor performance capabilities; however repeated cycles of gamma sterilization and high levels of radiations may change the physical properties of the elastomer used.

Ethylene Oxide Sterilization The pharmaceutical hoses may be sterilized with Ethylene Oxide (ETO) with no degradation of physical properties. We recommend that sufficient time is allowed for a complete outgassing of residual ETO and ETO by-products.

Notes:

- We advise that repeated sterilization cycles could compromise the properties of the hose.
- Polyurethane hoses are not suitable for any sterilization method (steam).

