

UN/SCETDG/24/INF.62/Rev.1

Related document : ST/SG/AC.10/C.3/2003/36 (United Kingdom)
Aerosols for medical purposes

6. Proposal

Add a new 6.2.4.3 as follows:

- "6.2.4.3 With the approval of the competent authority, aerosols and receptacles, small, containing pharmaceutical products and non flammable gases that are required to be sterile, but may be adversely affected by water bath testing, are not subject to 6.2.4.1 if:
- (a) are manufactured under the authority of a national health administration and, if required by the competent authority, follow the principles of good manufacturing practice established by the World Health Organization (WHO), and
 - (b) an equivalent level of safety is achieved by the manufacturer's use of alternative methods for leak detection and pressure resistance, such as helium detection and water bathing a statistical sample of at least 1 in 2000 from each production batch."