Manufacture

The manufacturing facilities and the manufacturing process for a substance or dosage form that is the subject of a monograph in the International Pharmacopoeia must meet the current WHO requirements of Good Manufacturing Practice[1]. Where applicable, substances must be manufactured in accordance with the WHO "Recommendations on Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" reproduced in the section Supplementary Information.

Statements under the heading manufacture draw attention to particular aspects of the manufacturing process but are not necessarily comprehensive. They may be in the form of mandatory instructions to manufacturers or, where clear from the form of wording used, they may provide guidance. In the general monographs for dosage forms, information is given that is intended to provide broad guidelines concerning the main steps to be followed during production, indicating those that are most important.

[1] For the current WHO recommendations, consult the WHO Medicines website (http://www.who.int/medicines).