

IS 3829 (Part 1) : 1999
Plastics collapsible containers for human blood and blood components
Part 1 Conventional containers

Comprehensive guide about Blood bag used in Transfusion Centre

Blood bag is a medical device that is used to **collect, store, process, transport, separate and administer blood and blood components for transfusions.**

It is important that the **material of the blood bag does not interact with blood** and cause unwanted reactions like inflammation and coagulation. So, the Blood bags are tested for **biocompatibility requirements** like **cytotoxicity, haemolytic, pyrogenicity and impermeability of microorganisms.** It is also crucial to consider the **leachable chemical constituents** from the material of the bag. The **permissible limit of each constituent and ignition residue** are also mentioned.

The **tubing of the bag** are tested for transparency, non-collapsibility and leakproof. The **blood collection needle** covered by a tamper evident protective cap, are tested for leakproof and ability to maintain sterility.

Air entered in a blood bag can be fatal and can cause **vascular air embolism (VAE)**, and cause blockage in the blood vessels. So it is important that the bag shall be capable of **filling blood without air being introduced**, the **permissible ratio of the air in the blood bag to the number of containers in the bag shall be less 15 ml.** The bags shall be **filled and emptied** in less than 8 mins and 2 mins respectively.

Sterility of the bag is ensured to **prevent contamination of the blood.** The test method to evaluate the effectiveness of the sterilization process is mentioned.

Packaging of the bag is important to **resist the damage of the bag and maintain the mentioned shelf life** of the blood bag, as per the stability studies.

Labelling requirements provide **vital information, traceability** and help ensure the safety of patients and donors.

The quality requirements of the **anticoagulant and preservative solution** are ensured.

This standard IS 3829 (Part 1) ensures the **safety, quality and effectiveness of the blood collected in the bag.**