

ANNEX I

DEFINITIONS

(as referred to in Article 1)

1. 'Autologous donation' means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual.
2. 'Allogeneic donation' means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material/raw material for manufacturing into medicinal products.
3. 'Validation' means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
4. 'Whole blood' means a single blood donation.
5. 'Cryopreservation' means prolongation of the storage life of blood components by freezing.
6. 'Plasma' means the liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leucocyte-depleted platelets. It may also be used for re-suspension of red cell preparations for exchange transfusion or perinatal transfusion.
7. 'Cryoprecipitate' means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma.
8. 'Washed' means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times.
9. 'Red cells' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed.
10. 'Red cells, buffy coat removed' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed.
11. 'Red cells, leucocyte-depleted' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed.
12. 'Red cells in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. A nutrient/preservative solution is added.

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13. 'Additive solution' means a solution specifically formulated to maintain beneficial properties of cellular components during storage.
14. 'Red cells, buffy coat removed, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed. A nutrient/preservative solution is added.
15. 'Buffy coat' means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets.
16. 'Red cells, leucocyte-depleted, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed. A nutrient/preservative solution is added.
17. 'Red cells, apheresis' means the red cells from an apheresis red cell donation.
18. 'Apheresis' means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.
19. 'Platelets, apheresis' means a concentrated suspension of blood platelets obtained by apheresis.
20. 'Platelets, apheresis, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed.
21. 'Platelets, recovered, pooled' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation.
22. 'Platelets, recovered, pooled, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leucocytes are removed.
23. 'Platelets, recovered, single unit' means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.
24. 'Platelets, recovered, single unit, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed.
25. 'Plasma, fresh-frozen' means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored.
26. 'Plasma, cryoprecipitate-depleted for transfusion' means a plasma component prepared from a unit of plasma, fresh-frozen. It comprises the residual portion after the cryoprecipitate has been removed.
27. 'Granulocytes, apheresis' means a concentrated suspension of granulocytes obtained by apheresis.
28. 'Statistical process control' means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.