**Model SOP**

**Standard Operating Procedure**

**Name of the facility / activity : Quality control of Blood Components**

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| **SOP no.**  | **Effective Date** | **Pages** | **Prepared by**  | **Authorised by**  |
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| **LOCATION** : Blood Component Preparation Laboratory & Serology Lab. |
| **SUBJECT** : Quality control of Blood components  |
| **FUNCTION** : Ensure maximum safety and efficacy of blood components.  |
| **DISTRIBUTION**: Supervisor Incharge Red Cell Serology Laboratory & incharge component  laboratory. Master File |

1. **SCOPE & APPLICATION:**

Quality control of blood components ensures maximum safety and efficacy of blood
components. Blood should be properly collected, components adequately prepared and stored to minimise physical changes red cells and to prevent bacterial contamination. Good quality control measures help to attain minimal limits of viable, safe and potent blood products.

1. **RESPONSIBILITY:**

It is the responsibility of technical staff associated with blood component laboratory and red cell serology laboratory to ensure the quality control is done for all components as per the guidelines of drugs and cosmetic act.

1. **PROCEDURE:**

**COLLECTION OF BLOOD: QUALITY CONTROL:**

1- Adequate aseptic precautions adopted

2- Bacteriological examination of disinfectants used for preparation of venepuncture site.

3- Culture of venepuncture site

4- Blood bag inspection before collection

1. Anticoagulant clear
2. No leaks, breaks, turbidity or changes in colour of anticoagulant
3. Check for any fungal growth over the bag or under the label
4. Check for sealed needle with intact lock
5. Bactcriological $ biochemical examination of auticongulant

1. Ensure proper mixing during collection so that no clots are formed
2. Time of collection should not exceed 10 minutes
3. Quality control of whole blood volume.

Vol (ml) = weight of bag + blood (g) - weight of empty bag (g)
1.05

**BLOOD COMPONENTS - QUALITY CONTROL**

**Packed Red Blood Cells (PRBC):**

PRBC is the residue of cells that remains in the blood bag after plasma is expressed out.

**TO CHECK:**

1. Volume 280 ml (10% when processed from 450 m1 bag.
2. Free of contamination (Bacterial or particular)
3. Hematocrit 60-70%
4. Specific gravity 1.09
5. Storage temperature 2-80C (avoid freezing causes hemolysis bacterial contamination
6. Frequency of check- weekly
7. Indication of HIV, HbsAg, HCV status blood group type and Rh on label
8. Mention expiry date.

**Platelet concentrates:**

To ensure adequate hemostatis as a low count is associated with bleeding.

**TO CHECK:**

1. Volume -50-60ml
2. Free of contamination
3. PH-6 ( ensure viability)
4. Platelet count - 50 x 1010unit

75% units checked should give this count.

1. Swirling present till last day
2. Storage at 220C in a platelet shaker
3. On the label check date of expiry and infectious disease status.

**FRESH FROZEN PLASMA (FFP):**

Plasma separated from whole blood and frozen within 6 hrs of blood collections called FFP. Freezing is important to maintain activity of clotting factors.

 **To check:**

1. Volume I50-200ml
2. Mention blood group, unit no. and disease screening test results on the bag.
3. Stable coagulation factors - 200ml
4. Factor 0.6 IU/ml
5. Fibrinogen - 250 – 400mg.
6. Store at-20oC or low
7. Store in such a manner that bags do not add here.
8. Protect attached tubing as it breaks easily.
9. Check weekly

**CRYO PRECIPITATE: -**

Snap freezing of FFP bags is needed to maintain yield of factor 8 in cryo precipitate.

**To check:**

1. Volume I5-20ml
2. F8-( 80-120gm)
3. VWF - 40 -70% of original
4. Fibrinogen 150 -250gms
5. F212 - 20-30% of original
6. F2,5,9- small amount
7. Febronectin - 55mg
8. Store at -20oC or lower
9. Assay done on 4 bags /months OR I bag / week.
10. **DOCUMENTATION:**

All results and records to be maintained in Quality Control file and register.

1. **REFERENCES:**
2. Technical Manual of the American Association of Blood Banks – 15th edition 2005.
3. Introduction to Transfusion Medicine – Zarin Bharucha and D.M. Chouhan; 1st Edition, 1990.
4. Training module for laboratory technologists. National AIDS Control Organization, Ministry of Health and Family Welfare, Govt. of India publication, 1995.

**7. END OF DOCUMENT**