IPC develops & introduces quality standards for 22 blood components to ensure safe blood transfusion

The Indian Pharmacopoeia Commission (IPC) has developed general requirements and monographs or quality standards for blood and blood components from human source to ensure safe blood transfusion for patients in the country. These quality standards will prevent the occurrence of blood transfusion transmitted infections.

These quality standards are aligned with the Directorate General of Health Services (DGHS) manual and other international guidelines. A general requirement on irradiation of blood components has also been introduced. Pan India experts from reputed institutions and blood centres have also contributed towards the development of these standards.

These quality standards shall be published in the upcoming edition of Indian Pharmacopoeia (IP 2026), ensuring the quality and safety of blood and blood components used in transfusion medicine. The IP will be the first and only pharmacopoeia globally to include such comprehensive quality standards for blood and blood components used in transfusion medicine.

Blood transfusion is a procedure in which whole blood or parts of blood are put into a patient's bloodstream through a vein. The blood may be donated by another person or it may have been taken from the patient and stored as per regulatory requirements. People need safe blood transfusions to replace lost blood or specific blood components due to injury, surgery, or illness. Transfusions are vital for conditions like severe anaemia, major surgery, accidents, cancer treatment, childbirth complications, and inherited blood disorders.

IP standards are authoritative, legally acceptable in courts of law, and enforced by regulatory authorities for quality control in India.

The newly developed monographs for blood and blood components and general requirements integrate harmonized testing into a public standard, maintaining quality throughout the shelf-life of the product. By promoting the use of quality drugs and mitigating the risk of sub-standard medicines and practices, these quality standards directly contribute to the reduction of adverse effects and are the most crucial measure to safeguard patient well-being against public health catastrophes.

IPC, an autonomous institution under the ministry of health and family welfare, Government of India (GoI), serves as the standard-setting organization for drugs and pharmaceuticals across the country. In compliance with the Drugs and Cosmetics Act, 1940 and the Rules 1945 thereunder, IPC is dedicated to ensuring the quality, safety, and efficacy of medicines by continuously updating and expanding the IP.

As per ‘The Drugs Rules, 1945, ‘Blood Component’ is defined as a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor, thereby legally designating both blood and blood components from a human source as drugs.

The IPC standards are essential to public health as they provide an independent assessment of the identity, quality, strength, and purity of drugs and pharmaceuticals, ensuring quality at par with international standards.

Total 22 monographs or quality standards include 02 revised monographs and 20 new monographs. It also includes general requirements for blood and blood components from human source and general requirements for irradiation of blood and blood components.

Monographs for whole blood include whole blood, whole blood: irradiated. monographs for red cell components include packed red blood cells, red blood cells in additive solution, leucodepleted red blood cells, red blood cells: Buffy coat removed in additive solution, red blood cells: cryopreserved, red blood cells: Washed.

Monographs for plasma components include fresh frozen plasma (FFP): whole blood, fresh frozen plasma (FFP): Apheresis method, cryoprecipitate, cryo-poor plasma (CPP).

Monographs for platelets components include platelet rich plasma (PRP), pooled random donor platelets, pooled platelet concentrate: Buffy coat method, random donor platelet concentrate: PRP method, random donor platelet concentrate: Buffy coat method, single donor platelets (SDP): Apheresis method, single donor platelets in additive solution (SDP-PAS), double single donor platelets: apheresis method and monographs for granulocyte components include granulocytes: Apheresis method and pooled granulocytes: Buffy coat method.

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