Annexure 'D'

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)
NOTIFICATION
New Delhi, the 20th December, 2001

G.S.R. 909(E) – Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in part – II, Section 3, Sub-section (i), of the Gazette of India, Extraordinary, dated the 22nd June, 2001, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number GSR 449(E), dated the 22nd June, 2001, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 23-6-2001.

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely :-

2. (1) These rules may be called the Drugs and Cosmetics (10th Amendment) Rules, 2001.

(2) They shall come into force on the date of their publication in the Official Gazette.

3. In the Drugs and Cosmetics Rules, 1945, in Schedule K, after serial number 5A and the entries related thereto, the following shall be inserted namely;

Class of Drugs	Extent and Conditions of Exemptions.
5B. Whole Human Blood I.P. and / or its components stored for transfusion by a First Referral Unit, Community Health Centre, Primary Health Centre and a Hospital.	The provisions of chapter IV of the Act and the rules made thereunder which require obtaining licence for operation of a blood bank or processing Whole Human Blood and / or its components, subject to the following conditions, namely. (1) The First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall be

approved by the State / Union Territory Licensing Authority after satisfying the conditions and facilities through inspection.

(2) The captive consumption of Whole Human Blood I.P. or its components in the First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall not be more than 2000 units annually.

(3) The Whole Human Blood and / or its components shall be procured only from the Government Blood Bank and/or Indian Red Cross Society Blood Bank and/or Regional Blood Transfusion Centre duly licensed.

(4) The approval shall be valid for a period of two years from the date of issue unless sooner suspended or cancelled and First Referral Unit, Community Health Centre, Primary Health Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval.

(5) The First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall have the following technical staff for storage of blood or its components :

(a) A trained Medical Officer for proper procurement, storage and cross matching of blood and/or its components. He/She shall also be responsible for identifying haemolysed blood and ensure non-supply of date expired blood or its components.

(b) A blood bank Technician with the qualification and experience as specified in Part XII B of Schedule F or an experienced laboratory technician trained in blood grouping and cross matching.

(6) The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall have an area of 10 sq. meters. It shall be well lighted, clean and preferably air-conditioned. Blood Bank refrigerator of appropriate capacity fitted with alarm device and temperature indicator with regular temperature monitoring shall be provided to store blood units between 2^0C to 8^0C and if the components are proposed to be stored, specialized equipments as specified in Part XII B of Schedule F shall also be provided.

(7) The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall maintain records and registers including details of procurements of Whole Human Blood I.P. and/or blood components, as required under Part XII B of Schedule F.

(8) The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall store samples of donors blood as well as patients sera for a period of seven days after transfusion."

[No. X-11014/3/2001-DMS & PFA]
Deepak Gupta, Jt. Secy.

Foot Note – The principal rules were published in the Official Gazette vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide G.S.R. 900(E) dated 12-12-2001.
The Drugs and Cosmetics Rules, 1945, as amended upto the 1st May, 1979 are contained in the publication of the Ministry of Health and Family Welfare (Department of Health) containing the Drugs and Cosmetics Act, 1940 (PDGHS-61).

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