as determined by an appropriate neutralization test in animals or by a method shown to be equivalent.

- For hepatitis B immunoglobulin, at least 100 IU/ml of anti-hepatitis antibody.
- For varicella zoster immunoglobulin, at least 100 IU/ml of anti-varicella zoster antibody, as measured by a comparative enzyme-linked immunosorbent assay or by a method shown to be equivalent.
- For anti-D (anti-Rh_0) immunoglobulin, the estimated potency shall be expressed in International Units and shall be not less than 90% and not more than 120% of the stated potency, and the fiducial limits of error shall be within 80% and 125% of the estimated potency.

The national control authority shall specify the antibody limits for other immunoglobulins.

After the potency tests, a test for immunoglobulin subclass may be performed. Different manufacturing steps have been shown to reduce the concentration of specific immunoglobulin subclasses (e.g. IgG1, IgG2, IgG3 and IgG4) in immunoglobulin preparations. The distribution of the four subclasses of IgG may be a factor in the efficacy of intravenous immunoglobulin preparations, since specific antibodies belonging to particular subclasses have been identified as being important in several infectious diseases.

In some countries the distribution of IgG subclasses has been measured by radial immunodiffusion. Enzyme-linked immunosorbent assays have also been described, and may be used if properly validated. Assays should be calibrated against the appropriate international reference materials.

15.3 *Sterility and safety*

Each filling lot shall be tested for sterility. Part A, section 5, of the revised Requirements for Biological Substances No. 6 (General Requirements for the Sterility of Biological Substances) (*9*, p. 48) shall apply.

In some countries a general safety test may be required, whereby each filling lot is tested for extraneous toxic contaminants by appropriate tests involving injection into mice and guinea-pigs. The injection shall cause neither significant toxic reactions nor death within an observation period of seven days. The tests shall be approved by the national control authority.

The tests generally used are the intraperitoneal injection of 0.5 ml into each of at least two mice weighing approximately 20 g and the injection of 5.0 ml into each of at least two guinea-pigs weighing approximately 350 g. In some countries, if one of the animals dies or shows signs of ill-health, such as weight loss, during a specified period, the test is repeated. The substance passes the test if none of the animals of the second group dies or shows signs of ill-health, such as weight loss, during that period.

15.4 *Identity test*

An identity test shall be performed on at least one labelled container from each filling lot to verify that the preparation is of human origin. The test shall be one approved by the national control authority.

Additional tests shall be made to determine that the protein is predominantly immunoglobulin.

The methods in most common use are radial immunodiffusion and electrophoresis.

15.5 *Freedom from pyrogenicity*

Each filling lot shall be tested for pyrogenicity by the intravenous injection of the test dose into three or more rabbits that have not previously received blood products. In general, the dose shall be at least equivalent proportionally, on a rabbit body-weight basis, to the maximum single human dose recommended, but not more than 10 ml/kg of body weight. The recommended test doses are 1 ml/kg and 10 ml/kg of body weight for intramuscular and intravenous preparations, respectively.

A filling lot shall pass the test if it satisfies the requirements specified by the national control authority.

15.6 *Moisture content*

The residual moisture content of a sample from each filling lot shall, where appropriate, be determined by a method approved by the national control authority.

The methods in use are: (a) drying over phosphorus pentoxide for at least 24 h at a pressure not exceeding 2.7 Pa (0.02 mmHg); and (b) the Karl Fischer method.

The acceptable moisture content shall be determined by the national control authority.

15.7 *Hydrogen ion concentration*

The final product, reconstituted if necessary and diluted with 0.15 mol/l sodium chloride to give a protein concentration of 10 g/l, should, when measured at a temperature of 20–27 °C, have a pH of 6.9 ± 0.5.

In some countries, a different range of pH values is permitted for intravenous immunoglobulins.

15.8 *Stability*

For immunoglobulin solutions, a stability test shall be performed on each filling lot by heating an adequate sample at 37 °C for four weeks. No gelation or flocculation shall occur.

Alternatively (or in addition), the molecular size distribution of the immunoglobulin or assays of enzymes such as plasmin (fibrinolysin) may be used, when shown to predict stability reliably and when approved by the national control authority.

15.9 *Records*

The requirements of Good Manufacturing Practices for Biological Products (*8*, pages 27–28) shall apply.

15.10 *Samples*

The requirements of Good Manufacturing Practices for Biological Products (*8*, page 29, paragraph 9.5) shall apply.

15.11 *Labelling*

The requirements of Good Manufacturing Practices for Biological Products (*8*, pages 26–27) shall apply.

In addition, the label on the container shall state:

- the type of source material;
- the protein concentration;
- the concentration of preservative, if any;
- "For intramuscular use only" (if the immunoglobulins are not specially prepared for intravenous use);
- "For intravenous use", when appropriate;
- for specific immunoglobulin, the content of specific antibody expressed in International Units or equivalent national units;
- for freeze-dried preparations, the name and volume of reconstituting liquid to be added.

The label on the package or the package insert shall show:

- the approximate concentration of electrolytes and excipients and, for intravenous preparations, the approximate osmolality;
- the buffering capacity when the pH of the diluted product is lower than that specified in section 15.7;
- the concentration of preservative, if any;
- the recommended dose for each particular disease or condition;
- the warning "Do not use if turbid";
- the sodium and potassium concentrations (if the immunoglobulin is intended for intravenous use).

15.12 *Distribution and shipping*

The requirements of Good Manufacturing Practices for Biological Products (*8*) shall apply.

15.13 *Storage and shelf-life*

The requirements of Good Manufacturing Practices for Biological Products (*8*, pages 26–27) shall apply.

Liquid immunoglobulin shall be stored at 5 ± 3 °C and shall have a shelf-life of not more than three years. Freeze-dried preparations shall be stored below 25 °C and shall have a shelf-life of not more than five years.

Other storage conditions and shelf-lives may be approved by the national control authority.

16. Control of preparations of coagulation-factor concentrates (factor VIII, factor IX and fibrinogen)

Factor VIII preparations are available as both frozen products and freeze-dried concentrates. The frozen products are usually derived from a single donation and consist of the cryoprecipitated factor VIII from the donor concerned prepared in a closed separation system. The control of this product and the freeze-dried product from fewer than 10 plasma donations is covered in Part B, section 7.8.1.

Generally, the small-pool product undergoes little or no purification and is handled and subdivided in such a way that many control tests are inappropriate. However, freeze-dried factor VIII concentrates prepared from more than 10 donations may be purified.

Source material for factor VIII preparations shall meet the general criteria for donor selection and testing for disease markers as specified in Parts A and B. It shall preferably be plasma frozen within 8 h of collection or frozen cryoprecipitate. Such material shall be kept frozen at such a temperature that the activity of the factor VIII is maintained.

16.1 *Tests on final containers*

16.1.1 *Sterility and safety*

Each filling lot shall be tested for sterility. Part A, section 5, of the revised Requirements for Biological Substances No. 6 (General Requirements for the Sterility of Biological Substances) (*9*, p. 48) shall apply.

In some countries a general safety test may be required, whereby each filling lot is tested for extraneous toxic contaminants by appropriate tests involving injection into mice and guinea-pigs. The injection shall cause neither significant toxic reactions nor death within an observation period of seven days. The tests shall be approved by the national control authority.

> The tests generally used are the intraperitoneal injection of 0.5 ml into each of at least two mice weighing approximately 20 g and the injection of 5.0 ml into each of at least two guinea-pigs weighing approximately 350 g. In some countries, if one of the animals dies or shows signs of ill-health, such as weight loss, during a specified period, the test is repeated. The substance passes the test if none of the animals of the second group dies or shows signs of ill-health, such as weight loss, during that period. For factor VIII and factor IX concentrates, the test dose should not exceed 500 IU of the coagulation factor per kg of body weight of the test animal.

16.1.2 *Freedom from pyrogenicity*

Each filling lot shall be tested for pyrogenicity by the intravenous injection of the test dose into three or more rabbits that have not previously received blood products. In general, the dose shall be at least equivalent

proportionally, on a rabbit body-weight basis, to the maximum single human dose recommended, but not more than 10 ml/kg of body weight.

The following test doses are suggested: factor VIII, 10 IU/kg of body weight; factor IX, 50 IU/kg of body weight; and fibrinogen, 30 mg/kg of body weight.

16.1.3 *Solubility and clarity*

Factor VIII preparations shall dissolve in the solvent recommended by the manufacturer within 30 min when held at a temperature not exceeding 37 °C. Factor IX preparations shall dissolve in the solvent recommended by the manufacturer within 15 min when held at 20–25 °C. The solutions, when kept at room temperature, shall not show any sign of precipitation or gel formation within 3 h of dissolution of the coagulation factors.

16.1.4 *Protein content*

The amount of protein in a final container shall be determined by a method approved by the national control authority.

16.1.5 *Additives*

Tests to determine the concentration of additives (such as heparin, polyethylene glycol, sodium citrate and glycine) used during production shall be carried out if required by the national control authority.

16.1.6 *Moisture content*

The residual moisture content shall be determined by a method approved by the national control authority. The acceptable moisture content shall be determined by the national control authority.

> The methods available are: (a) drying over phosphorus pentoxide for 24 h at a pressure not exceeding 2.7 Pa (0.02 mmHg); and (b) the Karl Fischer method.

16.1.7 *Hydrogen ion concentration*

When the product is dissolved in a volume of water equal to the volume stated on the label, the pH of the resulting solution shall be 7.2 ± 0.4.

> In some countries, different pH values are approved.

16.2 ***Test applicable to factor VIII concentrates***

Each filling lot shall be assayed for factor VIII activity by a test approved by the national control authority, using a standard calibrated against the International Standard for Blood Coagulation Factor VIII: Concentrate.

> The national standard and the manufacturer's house standard should be a concentrate rather than a plasma because the former has better long-term stability and provides more homogeneous assay results.

The specific activity shall be at least 500 IU/g of protein. The estimated potency shall be not less than 80% and not more than 125% of the stated potency. The confidence limits of error shall be not less than 64% and not more than 156% of the estimated potency.

16.3 *Tests applicable to factor IX concentrates*

16.3.1 *Potency*

Each filling lot shall be assayed for factor IX activity by a test approved by the national control authority, using a standard calibrated against the International Standard for Human Blood Coagulation Factors II, IX, and X in Concentrates.

Other coagulation factors may also be present in the final product, depending on the method of production, and products shall be assayed for all coagulation factors claimed to be present at a therapeutic level, including factors II, VII and X. The assay methods used for these factors shall be approved by the national control authority.

16.3.2 *Presence of activated coagulation factors*

A test for the presence of activated coagulation factors shall be carried out by a method approved by the national control authority.

In some countries, the non-activated partial thromboplastin times of normal plasma are measured after the addition of an equal volume of a number of different dilutions of the product under test.

In some countries, a test for the presence of thrombin is carried out by mixing equal volumes of the product under test and fibrinogen solution. The mixture is held at 37 °C and should not coagulate within 6 h. The usual range of concentrations of fibrinogen solution is 3–10 g/l.

16.3.3 *Alloantibodies*

A test shall be made for the presence of alloantibodies A and B by a method approved by the national control authority.

It is not possible to be specific about the tests for alloantibodies or to specify an upper limit for the titre.

16.4 *Test applicable to fibrinogen*

Each filling lot shall be assayed for clottable protein by a test approved by the national control authority.

Not less than 70% of the total protein should be clottable by thrombin.

16.5 *Identity test*

An identity test shall be performed on at least one labelled container from each filling lot of coagulation-factor concentrate to verify that the preparation is of human origin. The test shall be one approved by the national control authority.

For albumin and plasma protein fraction, additional tests shall be made to determine that the protein is predominantly albumin.

The methods in most common use are radial immunodiffusion and electrophoresis.

16.6 ***Records***

The requirements of Good Manufacturing Practices for Biological Products (*8*, pages 27–28) shall apply.

16.7 ***Samples***

The requirements of Good Manufacturing Practices for Biological Products (*8*, page 29, paragraph 9.5) shall apply.

16.8 ***Labelling***

The requirements of Good Manufacturing Practices for Biological Products (*8*, pages 26–27) shall apply.

In addition, the label on the container shall state:

- the content of the coagulation factor expressed in International Units, where they exist;
- the amount of protein in the container;
- the volume of diluent needed for reconstitution;
- a reference to a package insert giving instructions for use, warnings about the possible transmission of infectious agents and precautions.

16.9 ***Distribution and shipping***

The requirements of Good Manufacturing Practices for Biological Products (*8*) shall apply.

16.10 ***Storage and shelf-life***

The requirements of Good Manufacturing Practices for Biological Products (*8*, pages 26–27) shall apply.

Final containers of freeze-dried preparations of factor VIII and factor IX shall have a maximum shelf-life of two years if they are stored at 5 ± 3 °C. Final containers of fibrinogen shall have a maximum shelf-life of five years if they are stored at 5 ± 3 °C.

Other storage conditions and shelf-lives may be approved by the national control authority provided that they are consistent with the data on the stability of the products.

Part D. National control requirements

17. General

The general requirements for control laboratories in the Guidelines for National Authorities on Quality Assurance for Biological Products (*6*) shall apply.

The national control authority shall provide the standards and reference preparations necessary for the quality control of human blood and blood

products. Where appropriate, these standards should be calibrated against the relevant International Standard.

The national control authority shall have authority to approve the production and control methods used and settle all matters left for its decision or approval in Parts A, B and C.

The national control authority shall also have authority to approve the use of materials that carry potential risk and shall approve any new method of production and the preparation of any new product.

> New products or products prepared by new production methods may be monitored to confirm their efficacy and safety.

18. Release and certification

Human blood and blood products shall be released only if they satisfy the requirements of Parts A, B and C, wherever applicable.

A certificate signed by the appropriate official of the national control authority shall be provided at the request of the manufacturing establishment and shall state whether the product in question meets all national requirements as well as Parts A, B and C (whichever is relevant) of the present Requirements. The certificate shall also state the date of the last satisfactory potency test performed by the manufacturer, if applicable, the number under which the lot is released, and the number appearing on the labels of the containers. In addition, a copy of the official national release document shall be attached.

> The purpose of this certificate is to facilitate the exchange of human blood and blood products between countries.

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Acknowledgements

Acknowledgements are due to the following experts for their comments and advice on the draft of these Requirements: Professor S. M. Ballester, Director Institute of Haematology and Immunology, Havana, Cuba; Ms M. Cone, Vice-President for Scientific Affairs, International Federation of Pharmaceutical Manufacturers Associations, Geneva, Switzerland; Dr I. Di Tommaso, Tuscan Institute for Serotherapy and Vaccine Production (SCLAVO), Siena, Italy; Dr J. Furesz, formerly Director, Bureau of Biologics, Ottawa, Ontario, Canada; Dr G. Fürst, German Association for the Establishment, Coordination and Working Method of Plasmapheresis Centres, Bonn, Germany; Dr W. N. Gibbs, Chief, Health Laboratory Technology and Blood Safety, WHO, Geneva, Switzerland; Dr A. Gonzaga, Chief, Brazilian Red Cross Blood Programme, Rio de Janeiro, Brazil; Mr J. Guley, Director, Regulatory Affairs, Alpha Therapeutic Corporation, CA, USA; Dr C. Guthrie, General Manager, Blood Products Division, CSL Ltd, Parkville, Victoria, Australia; Dr B. Habibi, National Blood Transfusion Centre, Paris, France; Dr K. Hannegren, National Bacteriological Laboratory, Stockholm, Sweden; Professor S. R. Hollán, National Institute of Haematology and Blood Transfusion, Budapest, Hungary; Dr F. C. Kothe, Head, Blood Programme, International Federation of Red Cross and Red Crescent Societies, Geneva, Switzerland; Mr B. Kubanck, Medical Director, Department of Transfusion Medicine, University of Ulm, Germany; Mrs S. F. Langlois, Director, Regulatory Affairs, Connaught Laboratories Ltd, Ontario, Canada; Mr P. Lemoine, Brussels, Belgium; Dr R. M. Lequin, Manager, Evaluation and Training Group, Organon Teknika, Turnhout, Belgium; Dr T. Matuhasi, Professor Emeritus, Okinaka Memorial Institute for Medical Research, University of Tokyo, Tokyo, Japan; Professor N. V. Medunitsin, Director, Tarasevich State Institute for the Standardization and Control of Medical Biological

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Appendix

Summary protocol for collection of source material

1. Name and address of collecting centre _____

   _____

2. Source material _____

3. Details of single donations, where applicable:
   (a) Donor identification _____
   (b) Date of collection _____
   (c) Volume in container _____
   (d) Results of tests for HBsAg _____
   (e) Results of tests for anti-HIV _____
   (f) Results of tests for anti-HCV _____
   (g) If applicable, results of tests for antibody to hepatitis B core antigen _____
   (h) If applicable, results of tests for alanine aminotransferase _____

4. Special information:
   (a) Anticoagulant used _____
   (b) Was the material collected for special purposes (e.g. as a source of specific antibodies)? _____
   (c) Precautions to be taken when using the material _____

5. Conditions of storage _____

6. Does the donation comply with existing agreements between the supplier and manufacturer? _____

7. Does the donation comply with the Requirements for the Collection, Processing and Quality Control of Blood, Blood Components and Plasma Derivatives published by WHO? _____

Name and signature of responsible person _____

Date _____

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

Number	Effective Date	Pages	Author	Authorised by
SP 001		3		
Version	**Review Period**	**No. of Copies**	**Approved by**	**Date**
1	1 Year			

LOCATION	SUBJECT
Donor Room	Criteria for Donor Selection
FUNCTION	**DISTRIBUTION**
Assessing suitability of donor for blood donation	- Medical Officer in charge of Donor Area - Master File

1. SCOPE & APPLICATION

This SOP describes the criteria for a donor to be accepted for blood donation, for ensuring safety of donor as well as recipient. The purpose of donor selection is to identify any factors that might make an individual unsuitable as a donor, either temporarily or permanently.

2. RESPONSIBILITY

The Medical Officer is responsible for determining the suitability of donor for blood donation. He/She should confirm that the criteria are fulfilled after evaluation of health history questionnaire and medical examination including the results of pre donation screening tests.

3. REFERENCES

Technical Manual of American Association of Blood Banks- 13th edition, 1999 pgs 90-97, 103-110.

4. MATERIAL REQUIRED

- Donor Questionnaire
- Donor Card

5. PROCEDURE

CRITERIA FOR SELECTION OF BLOOD DONORS

A. Accept only voluntary/replacement non-remunerated blood donors if following criteria are fulfilled.