PROPOSED AMENDMENT FOR BLOOD AND BLOOD RELATED PRODUCTS IN IP 2014/2018 FOR STAKEHOLDER COMMENTS

Human Normal Immunoglobulin for intravenous use Page No. 3935

Anti-A and anti-B haemagglutinins

Change **from:** Carry out the tests for anti-A and anti-B haemagglutinins as stated under monograph for Dried human haemophilic fraction. If the preparation to be examined contains more than 3.0 per cent of immunoglobulin, dilute to this concentration before preparing the dilution to be used in the test. The 1 to 64 dilutions do not show agglutination.

to: Carry out the tests for anti-A and anti-B haemagglutinins as stated under monograph for Dried human haemophilic fraction. If the preparation to be examined contains more than 3.0 per cent of immunoglobulin, dilute to this concentration before preparing the dilution to be used in the test. The 1 to 64 dilutions do not show agglutination and haemolysis should not be observed in any of the tubes.

Dried Human Antihaemophilic fraction Page No. 3913

Haemagglutinins, anti-A and anti-B.

Para 2

Change **from**: Prepare in duplicate serial dilution of the under examination in saline solution. To each dilution of one series add an equal volume of a 5 per cent v/v suspension of group A1 red blood cells previously washed 3 times with saline solution. To each dilution of the other series add an equal volume of a 5 per cent v/v suspension of group B red blood cells previously washed 3 times with saline solution. Incubate the suspension at 37º for 30 minutes and then wash the cells 3 times with saline solution. Leave the cells in contact with a polyvalent antihuman globulin reagent for 30 minutes. Without centrifuging, examine each suspension for agglutination under a microscope. The 1 in 64 dilutions do not show agglutination.

to: Prepare in duplicate serial dilution of the under examination in saline solution. To each dilution of one series add an equal volume of a 5 per cent v/v suspension of group A1 red blood cells previously washed 3 times with saline solution. To each dilution of the other series add an equal volume of a 5 per cent v/v suspension of group B red blood cells previously washed 3 times with saline solution. Incubate the suspension at 37º for 30 minutes and then wash the cells 3 times with saline solution. Leave the cells in contact with a polyvalent antihuman globulin reagent for 30 minutes. Without centrifuging, examine each suspension for agglutination under a microscope. The 1 in 64 dilutions do not show agglutination and haemolysis should not be observed in any of the tubes.