REAGENTS AND SOLUTIONS, Page 883,

Buffer solutions, Page 888,

Insert before – Palladium Chloride Solution, Buffered

Imidazole buffer solution pH 7.3 for Thrombin Assay*: Dissolve 0.34g of imidazole salt; 0.58g of Sodium Chloride;* ***0.37g of Calcium Chloride;*** *1.86ml of 1M HCl in 40ml of distilled water and make upto 100ml and adjust pH 7.3.*

Adsorbed Diphtheria, Tetanus and Hepatitis B (rDNA) Vaccine. Page 3570

FINAL LOT

Tests

Pyrogens (2.2.8).

Change **from:** Complies .....If used, the content should be within the limits approved by the National Regulatory authority.

to: Complies.....If used, the content should be less than 100EU per Single Human Dose.

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and *Haemophilus influenzae* Type b Conjugate Vaccine. Page 3572

FINAL LOT

Tests

Pyrogens (2.2.8).

Change **from:** Complies .....If used, the content should be within the limits approved by the National Regulatory authority for the haemphilus component of the particular product. If any component of the vaccine prevents the determination of the endotoxin, a test for Pyrogen should be carried out.

to: Complies.....If used, the content should be Less than 100 EU per Single Human Dose; for haemphilus component less than 25 IU per mcg of PRP. If any component of the vaccine prevents the determination of the endotoxin, a test for Pyrogen should be carried out.

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Hepatitis B (rDNA) Vaccine. Page 3574

FINAL LOT

Tests

Pyrogens (2.2.8).

Change **from:** Complies.....If used, the content should be within the limits approved by the National Regulatory authority.

to: Complies.....If used, the content should be less than 100EU per Single Human Dose.

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component), Inactivated poliomyelitis Vaccine and *Haemophilus influenzae* Type b Conjugate Vaccine. Page 3576

FINAL LOT

Tests

Pyrogens (2.2.8).

Change **from:** Complies .....If used, the content should be within the limits approved by the National Regulatory authority for the haemphilus component of the particular product. If any component of the vaccine prevents the determination of the endotoxin, a test for Pyrogen should be carried out.

to: Complies.....If used, the content should be Less than 100 EU per Single Human Dose; for haemphilus component less than 25 IU per mcg of PRP. If any component of the vaccine prevents the determination of the endotoxin, a test for pyrogens should be carried out.

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated poliomyelitis Vaccine. Page 3580

FINAL LOT

Tests

Insert following before Assay

Pyrogens (2.2.8). Complies with the test for pyrogens. Inject the equivalent of 1 human dose into each rabbit or a validated test for bacterial endotoxin (2.2.3) may be used instead of the test for pyrogens. If used, the content should be less than 100EU per Single Human Dose.

Adsorbed Pertussis (Acellular Component) Vaccine. Page 3587

FINAL LOT

Tests

Insert following before Assay:

Pyrogens (2.2.8). Complies with the test for pyrogens. Inject the equivalent of 1 human dose into each rabbit or a validated test for bacterial endotoxin (2.2.3) may be used instead of the test for pyrogens. If used, the content should be less than 100EU per Single Human Dose.

Adsorbed Pertussis (Acellular; Co-purified) Vaccine. Page 3590

FINAL LOT

Tests

Insert following before Assay:

Pyrogens (2.2.8). Complies with the test for pyrogens. Inject the equivalent of 1 human dose into each rabbit or a validated test for bacterial endotoxin (2.2.3) may be used instead of the test for pyrogens. If used, the content should be less than 100EU per Single Human Dose.

Hepatitis B Vaccine (rDNA). Page 3625

FINAL LOT

Tests

Insert following before Assay:

Pyrogens (2.2.8). Complies with the test for pyrogens. Inject the equivalent of 1 human dose into each rabbit or a validated test for bacterial endotoxin (2.2.3) may be used instead of the test for pyrogens. If used, the content should be less than 30EU per Single Human Dose.

Pneumococcal Polysaccharide Vaccine (Liquid/Adsorbed). Page 3669

FINAL LOT

Tests

Pyrogens (2.2.8).

Delete following:

"or a validated test for bacterial endotoxins (2.2.3) may be used instead of the test for pyrogens. If used, the content should be within the limits approved by the National Regulatory authority."

Fibrin Sealant Kit. Page 3917

Component 2 (Thrombin Preparation)

Tests

Assay

Thrombin

Line 5,

Change **from.** *imidazole buffer solution pH 7.3*

to: *Imidazole buffer solution pH 7.3 for Thrombin Assay.*

Human Prothrombin Complex. Page 3938

Definition

Change **from: Definition**. Human Prothrombin complex is a plasma protein fraction containing blood coagulation factor IX together with variable amounts of coagulation factors II, VII and X, the presence and proportion of these additional factors depends on the method of fractionation. It is obtained from human plasma that complies with the monograph on Human Plasma for Fractionation.

The potency of the preparation, reconstituted as stated on the label, is not less than 20IU of factor IX per ml.

to: Definition. Sterile plasma protein fraction containing human coagulation factor IX together with variable amounts of human coagulation factors II, VII and X; the presence and proportion of these additional factors depends on the method of fractionation. It is obtained from human plasma that complies with the monograph on Human plasma for fractionation. The preparation may contain excipients such as stabilisers, heparin and antithrombin. The potency of the preparation, reconstituted as stated on the label, is not less than 20 IU of human coagulation factor IX per millilitre. If the content of any of the factors is stated as a single value, the estimated potency is not less than 80 per cent and not more than 125 per cent of the stated potency; if the content of any of the factors is stated as a range, the estimated potency is not less than the lower limit and not greater than the upper limit of the stated range.

Labelling

Change **from: Labelling.** The label states (1) the number of International Units of factor IX, factor II and factor X per container; (2) where applicable, the number of International Units of factor VII per container

to: Labelling.

- The number of International Units of human coagulation factor IX, and the number or range of International Units of human coagulation factor II per container
- Where applicable, the number or range of International Units of human coagulation factor VII and human coagulation factor X. per container

Recombinant Streptokinase bulk solution. Page 4043

Identification

E. determine by isoelectric focussing polyacrylamide gel electric focussing (PAGE) (2.4.33) under non-reducing condition.
Para 3,
Change **from**: .....The sample should have single main band at R_f position pI 5.5 - 6.1 is observed
to: .....The sample should have single main band at R_f position pI 5.0 -5.3 is observed