Table 1

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Sindbis</th>
<th>VSV</th>
<th>HIV-1</th>
<th>HIV-2</th>
<th>Parv**</th>
<th>EMC</th>
<th>Reo</th>
<th>HAV</th>
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</thead>
<tbody>
<tr>
<td>DEAE Chromatography</td>
<td>1.4</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>1.5*</td>
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<tr>
<td>Solvent- Detergent</td>
<td>NTL 0.3</td>
<td>NT</td>
<td>NT</td>
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<td>Dual Affinity Chromatography</td>
<td>4.7</td>
<td>NT</td>
<td>NT</td>
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<tr>
<td>Nanofiltration</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>NT</td>
<td>3.6</td>
<td>3.4</td>
<td>4.1</td>
</tr>
</tbody>
</table>

**Porcine        NT=Not tested        NLT=Not less than        *Lower 95% confidence interval

Coagulation Factor IX (Human) AlphaNine® SD

Solvent Detergent Treated and Virus Filtered

DESCRIPTION

Coagulation Factor IX (Human) AlphaNine® SD is a purified solvent treated, virus filtered preparation of Factor IX derived from human plasma. It contains a minimum of 150 IU of Factor IX per mL. Levels of Factor IX (FVIIIc), Factor X (prothrombin) and Factor V (Def) measured at PFA-100® are below the limit of detection (less than 0.04 pF unit/mL), less than 0.09 Factor V unit/mL, and less than 0.2 Factor X (prothrombin) units/mL. AlphaNine® SD is a sterile, lyophilized preparation intended for intravenous administration only. Each vial is a single dose container.

AlphaNine® SD contains not more than 500 IU/mL of Factor VIIa, 0.5 unit of heparin, 0.07 mg of dextran, 11.0 mg of polysorbate 80 and 0.01 mg of tributylphosphosphate of Factor IX.

CLINICAL PHARMACOLOGY

AlphaNine® SD is a purified formulation of Factor IX containing not less than 150 IU of Factor IX activity of the total protein. AlphaNine® SD contains non-therapeutic levels of Factor XII, Factor X, and Factor III. Thromboplastin reagent in 1.2% sodium chloride injected into the rabbit's abdominal vein produced a mean rise of 7.6% (SD: 1.8) in the prothrombin time. The mean concentration of FVIII activity in the plasma samples was 95% (SD: 1.5) of normal controls.

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The ability of the AlphaNine® SD process to eliminate viruses, by physically partitioning virus from product, was evaluated at no less than six years of manufacturing process. Studies were performed using a virus-inactivated enviro-rodent virus (Sinbis) and one-cell model virus (pseudotyped enveloped, envepolysial glycoprotein, and virus). Focused harvests of multiple times, followed by the AlphaNine® SD process. The amount of virus removed at each subsequent purification step was then determined by plaque assay.

Addition of Sinbis is supplied in sterile, lyophilized form in single dose vials accompanied by 10 mL diluent administration. Reconstituted product should be inspected visually for particulate matter and discoloration prior to the solution should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits. After reconstitution with the Water for Injections solvent provided, the product should be used immediately. STORAGE

In clinical practice there is variability between patients and their clinical response. Therefore, the Factor IX level of each patient should be monitored frequently during replacement therapy.

Treatment Guidelines for Hemorrhagic Levels and Surgery in Patients Diagnosed with Hemophilia B

For adult usage:

Dosing Guidelines

Dosing requirements and frequency of dosing is calculated on the basis of an initial response of 1% FIX increase achieved per IU of Factor IX infused per kg body weight and an average half-life for FIX of 18 hours. If dosing studies have revealed that a particular patient exhibits a lower response, the dose should be adjusted accordingly.

Pediatric usage: See PRECAUTIONS.

Intraocular Use: See PRECAUTIONS.

Intravenous Use: See PRECAUTIONS.

Intrathecal Use: See PRECAUTIONS.

Intraperitoneal Use: See PRECAUTIONS.

Intramuscular Use: See PRECAUTIONS.

Intracutaneous Use: See PRECAUTIONS.

Intravenous Administration: See PRECAUTIONS.

Intramuscular Administration: See PRECAUTIONS.

Intraperitoneal Administration: See PRECAUTIONS.

Intracutaneous Administration: See PRECAUTIONS.

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