

Safety Scheme of JBP Placental Extract (Human)

I. Donor Screening

- Negatives for all virus & bacteria tests
- Screening by Donor's overseas stay experience
- Consent by Donor

2. Acceptance Inspection Testing

3. Sterilization by 3 Different Methods

4. Product Specification Testing for Viruses

Donor Screening + Donor's Consent

Virus & Bacteria Testing

Donor must show "negative" for all of:

1 HBV 2 HCV 3 HIV 4 HTLV 5 Parvovirus-B19

in addition to: treponema pallidum, gonorrhea, TB, etc.

Donor's Overseas Stay Experience

To minimize probability of exposure to BSE, Donor must not have stayed in any of 7 European countries for 6 months+ (1 day+ for United Kingdom & France) since January 1980.

Acceptance Inspection Testing

1. Individual inspection by weight, colour, smell, etc.

2. NAT testing for HBV-DNA, HCV-RNA, HIV-1-RNA of all samples.

Virus testing methods are all validated accordingly.

Accepted

Sterilization Employing 3 Different Methods

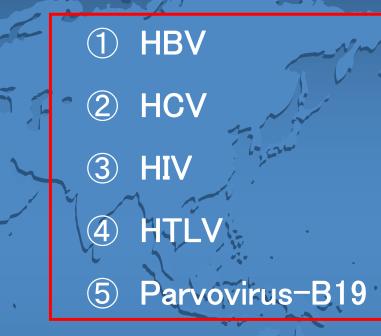
1With organic solvent

2 With digestive enzyme+acid processing

(3) With $121^{\circ}C \times 20$ minute autoclave (final sterilization)

All sterilization methods and processes are validated by spiking.

Product Specification Testing for Viruses



Product specification testing must show "negative" for all 5 viruses above, before approved for clearance.

Testing methods and procedures are all validated by spiking of respective viruses.