SAFETY of JBP Placental Extract (Human)
Safety Scheme of JBP Placental Extract (Human)

1. 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

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

① With organic solvent
② With digestive enzyme+acid processing
③ With 121°C × 20 minute autoclave (final sterilization)

All sterilization methods and processes are validated by spiking.
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.