



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

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

- 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 for Viruses

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

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.