

ASSURING FEED SAFETY BY FOLLOWING WHO HUMAN BLOOD PROCESSING GUIDELINES FOR THE COLLECTION AND PROCESSING OF SPRAY-DRIED ANIMAL PLASMA

APC follows strict manufacturing guidelines that mirror the World Health Organization (WHO) guidelines* for safety of human blood products. This assures that spray-dried plasma is safe for use in livestock feeds. Below is a schematic outlining the processing guidelines.

*WHO Technical Report, Series No. 924, 2004
www.who.int/bloodsafety/en/

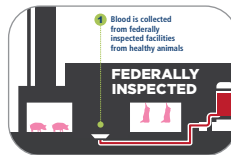
WHO Guidelines for Human Blood Collection	APC Guidelines for Production of Spray-Dried Plasma
Donor Selection	Healthy Animals from Federally Inspected Abattoirs
Testing of Plasma Pools	Pooling, Testing and Analysis of Product
Robust Processing	Spray-Drying and Post-Drying Heat Treatment

DONOR SELECTION

The first step in reducing the risk of transmission of infectious diseases through human blood is to select voluntary donors from low-risk populations. Donations from such individuals are at a lower risk for transfusion-transmissible infections.



Blood is collected at federally inspected abattoirs from animals that have been examined and passed as fit for slaughter for human consumption.



This precludes collecting blood from a clinically sick animal or animals from regions where OIE List diseases have been reported.

TESTING OF PLASMA POOLS

WHO recommends that all blood donations be screened for evidence of infection prior to the release of the blood and its components for clinical or manufacturing use.



All lots of plasma are tested post-production, prior to finished product release.

Additional testing may be performed as requested by customers.

VIRAL INACTIVATION & REMOVAL PROCEDURES

A robust, effective and reliable process step will be able to remove or inactivate substantial amounts of virus, typically 4 logs or more.

A production process should include one robust processing step able to inactivate enveloped viruses.

OR

A production process should include two robust processing steps able to inactivate non-enveloped viruses.



Robust Step: Spray-drying

80°C throughout substance is a validated inactivation step and has been shown to inactivate > 4 logs of both enveloped and non-enveloped viruses. Spray-drying is computer controlled and continuously monitored. Published research demonstrates spray-drying inactivates PRRS, PRV, SVD, PEDV and ASFV and other viruses.



Additional Step: Post-drying Heat Treatment Plasma is held for a minimum of 14 days at 20° C, which has been validated to inactivate viruses such as PEDV and other potential pathogens.