

ANTI D WORKING GROUP

Specifications of Anti D plasma for production of Anti D IgG

KEDRION
B I O P H A R M A

Keep Life *Flowing*

September 18th, 2023

AGENDA

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- What is an Immunoglobulin Anti-D
- Anti-D production flow
- Key factors in product manufacturing
- Take home messages

WHAT IS AN IMMUNOGLOBULIN ANTI D

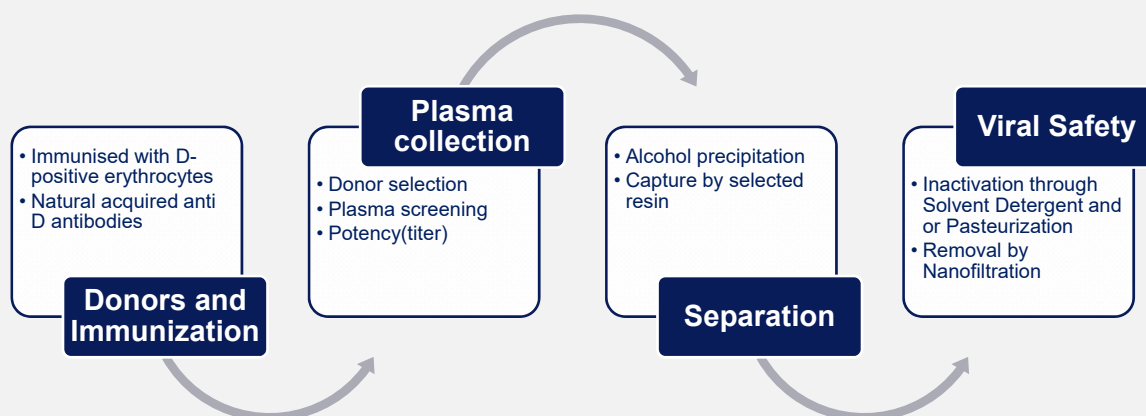
It is an injectible solution ready to use in a prefilled syringe or freeze dried powder to be reconstituted.

The drug is manufactured by Human plasma and contains immunoglobulins (antibodies) which prevents the factor Rhesus D alloimmunisation in pregnant women.

It is manufactured from high titer Anti D plasma obtained through immunisation of Rh negative donors.

Manufacturing technologies, donor immunisation strategy and plasma titer play a role in Anti D production efficiency.

ANTI D PRODUCTION FLOW



KEY FACTORS IN PRODUCT MANUFACTURING

- 1 Scalability**
 - Limited by anti D plasma availability
- 2 Efficiency**
 - > 1000 L plasma economic lot
- 3 Quality**
 - Plasma titer always above a given potency
- 4 Safety**
 - NAT for parvo mandatory (abortion risk)

TAKE HOME MESSAGE

Rh prophylaxis reach less than 50% of women in need worldwide.

Availability of plasma remains a main bottleneck for increasing access to their essential medication.

Expanding donor pool envisages two solutions:

- immunise donors outside US.
- collect plasma from naturally immunised donors (titre variability, boosting?).

Production can be scalable but measure to collect enough volumes of high titre plasma must be implemented.