IMMUNO

AKTIENGESELLSCHAFT FÜR CHEMISCH-MEDIZINISCHE PRODUKTE

PRODUKTIONSBETRIEBE:
ÖSTERREICHISCHES INSTITUT FÜR HAEMODERIVATE GES. M. B. H. IMMUNO DIAGNOSTIKA GES. M. B. H.

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A-1220 WIEN

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TELEGRAMME: IMMUNO WIEN
TELEX: 132722 imuno a
134865 imuno a

IMMUNO LTD.
Att. Mr. Berry

Arctic House
Rye Lane
Dunton Green, Nr. Sevenoaks
KENT TN14 5HB
G r e a t B r i t a i n

Vienna, 86 03 26
2122/Hi/MB

Re.: PPF 4.3 % / Product License Renewal

Dear Mr. Berry,

With reference to your telex no. 1527 of March 19, 1986 we are providing you with the following information:

1. We enclose an updated list of plasmapheresis stations supplying source material to IMMUNO Vienna.

2. Although the source material used for the manufacture of PPF is usually tested both for HB_s-Ag and HTLV-III-antibodies we do not intend to pledge ourselves to use only HTLV-III screened material.

   HBs-Ag is tested by RIA, anti-HTLV-III by ELISA.

3. - Specification of filters used during processing:

   Filtration

   Filter type: Cuno CPX 90 S
   Material: cellulose/kieselguhr
   Pore size: $\leq 1\mu m$

Reconstitution of Fraction Crude V

Filter type: Cuno CPX 50 S "Zeta Plus"
Material: cellulose/kieselguhr
Pore size: ≤ 1 µm

Sterilising Filtration

Filter type: Cuno CPX 90 S "Zeta Plus"
Material: cellulose/kieselguhr
Pore size: ≤ 1 µm

Filter type: GELMAN PREFLOW 100
Material: glass fibre
Pore size: ≤ 1 µm

Filter type: double membrane filter Pall SLX 7002 NFZP
Material: nylon 66
Pore size: 0.2 µm

- Integrity testing of sterilising filters

The continued integrity of the sterilising filter (PALL SLK 7002 NFZP) and filter unit is confirmed after use employing the forward-flow test method with an electronic filter integrity testing instrument. In accordance with the filter manufacturer's recommendation the pressure is raised to 2.7 bar and has to be held for a period of time which is also determined by the manufacturer of the filter. During this period a decrease of pressure can be observed which should not exceed a given limit as specified for each individual filter.

The test results are recorded automatically stating the type of filter, the testing pressure, the testing period and the pressure decrease observed.

If the pressure decrease exceeds this limit the filter and filter unit are considered non-effective and the filtering process has to be repeated.

Sincerely yours,
IMMUNO AG

GRO-C

Dipl.Dolm. I. Diernhofer
Head, Licensing Department

Encl.