

PFC PRODUCT LICENCES : UPDATE AUGUST 1992

| PRODUCT | DOSE | LICENCE NO. | DATE GRANTED | DATE RENEWED | DATE FOR RENEWAL | COMMENTS |
|---|--------|--------------|--------------|--------------|------------------|---|
| 1. CLOTTING FACTORS | | | | | | |
| Human Anti-haemophilic Factor : Factor VIII Lyophilised | 200 iu | PL 3473/0007 | 26 Sept 1978 | 26 Sept 1983 | | Licence To Be Allowed To Lapse From 31 December 1992. |
| Human Factor IX Concentrate DEFIX | 300 iu | PL 3473/0008 | 16 July 1979 | 19 July 1989 | | Substitution Licence Application Made August 1992 including Variation For Heat Treatment. |
| 2. IMMUNOGLOBULINS | | | | | | |
| <u>IV Use</u> | | | | | | |
| Human Immunoglobulin | 3g | PL 3473/0011 | 16 Dec 1985 | 29 Dec 1985 | 29 Aug 1990 | Substitution Licence Application Made July 1992. |

SIGNED: _____

GRO-C

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| <u>IM IgG</u> | | | | | | |
| Human Normal Immunoglobulin | 750/250 mg | PL 3473/0014 | May 1990 | 18 July 1991 | 18 July 1996* | * Substitution Licence Applications Submitted June 1992. |
| Human Hepatitis B Immunoglobulin | 1000 iu | PL 3473/0016 | October 1990 | 27 Aug 1991 | 27 Aug 1996* | |
| Human Tetanus Immunoglobulin | 250 iu | PL 3473/0020 | Feb 1991 | 23 Oct 1991 | 23 Aug 1996* | |
| Human Rabies Immunoglobulin | 800 iu | PL 3473/0019 | Feb 1991 | N/A | N/A + | + SPC's Submitted April 1992. Licences Will Be Progressed When Manufacturing Method Updated August 1992. |
| Human Varicella-Zoster Immunoglobulin | 500 mg | PL 3473/0017 | Nov 1990 | N/A | N/A + | |
| Human Rubella Immunoglobulin | 25,000 iu | PL 3473/0018 | Nov 1990 | N/A | N/A + | |
| Human Anti-D Immunoglobulin | 250 iu | PL 3474/0015 | Dec 1990 | N/A | N/A + | |
| | 500 iu | PL 3473/0022 | Dec 1990 | N/A | N/A + | |
| | 5000 iu | PL 3473/0023 | Dec 1990 | N/A | N/A + | |

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| 3. ALBUMIN PRODUCTS | | | | | | |
| SPPS | 100ml + 400ml | PL 3473/0013 | March 1990 | 27 Feb 1992 | 27 Feb 1992 | |
| Human Albumin (203) | 5ml + 50ml | PL 3473/0021 | March 1991 | N/A | N/A | Data Sheets For Human Albumin And SPPS Submitted 2 June 1992. |

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| 4. OTHER SOLUTIONS FOR CLINICAL USE | | | | | | |
| Anticoagulant Citrate Dextrose Solution (Ph. Eur. 1A) | 150ml Pack 500ml Pack | PL 3473/0006 | 23 Sept 1980 | 23 Sept 1990 | 25 Sept 1995 | |
| Anticoagulant Citrate Dextrose Solution (Ph. Eur. 1B) | 500ml Pack | PL 3473/0009 | 15 Jan 1981 | 15 Jan 1991 | 15 Jan 1996 | |
| Anticoagulant Citrate Phosphate Soln. (CPD 50) | 150ml Pack | PL 3473/0010 | 15 Sept 1983 | 2 March 1989 | 2 March 1994 | |
| Anticoagulant Sodium Citrate Concentrate | 32ml in 65ml Vial | PL 3473/0012 | 1 May 1991 | N/A | 1 May 1996 | |
| Water for Injection (Ph. Eur.) | 20ml Vial 70ml Vial | PL 3473/0001 | 4 March 1977 | 4 March 1992 | 4 March 1997 | |
| Cryoprotective Solution | 250ml Pack | PL 3473/0005 | 3 Aug 1977 | 3 Aug 1992 | 3 Aug 1996 | |
| Frozen Blood Wash Solution | 250ml Pack | PL 3473/0004 | 14 Dec 1978 | 13 June 1989 | 13 June 1994 | |
| Hypertonic Saline Solution | 1000ml Pack | PL 3473/0003 | 4 March 1982 | 9 Dec 1988 | 9 Dec 1993 | |

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