

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						
IV Use						
Human Immunoglobulin	3g	PL 3473/0011	16 Dec 1985	29 Dec 1985	29 Aug 1990	Substitution Licence Application Made July 1992.

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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 (20g)	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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