

ANNEX

SUPPRESSION OF THE RABBIT PYROGEN TEST:

LIST OF TEXTS ADOPTED AT THE 179th PH. EUR. COMMISSION SESSION

Text number	Title	Type of text	Group of experts / Working Party
REVISED TEXTS OMITTING THE RABBIT PYROGEN TEST			
2034	<i>Substances for pharmaceutical use</i>	General monograph	BET (Bacterial Endotoxin Test)
1290	<i>Amikacin sulfate</i>	Individual monograph	7 (Antibiotics)
0709	<i>Chloramphenicol sodium succinate</i>	Individual monograph	7 (Antibiotics)
0319	<i>Colistimethate sodium</i>	Individual monograph	7 (Antibiotics)
0663	<i>Dicloxacillin sodium</i>	Individual monograph	7 (Antibiotics)
0668	<i>Flucloxacillin sodium</i>	Individual monograph	7 (Antibiotics)
0033	<i>Kanamycin acid sulfate</i>	Individual monograph	7 (Antibiotics)
0032	<i>Kanamycin monosulfate</i>	Individual monograph	7 (Antibiotics)
0203	<i>Polymyxin B sulfate</i>	Individual monograph	7 (Antibiotics)
1296	<i>Calcium levulinate dihydrate</i>	Individual monograph	10D (Organic chemistry – synthetic and semi-synthetic products)
0412	<i>Sodium citrate</i>	Individual monograph	9 (Inorganic Chemistry)
0177	<i>Glucose</i>	Individual monograph	CRB (Carbohydrates)
0178	<i>Glucose monohydrate</i>	Individual monograph	CRB (Carbohydrates)
2811	<i>Intravesical preparations</i>	Dosage form monograph	12 (Dosage forms and pharmaceutical technical procedures)
0520	<i>Parenteral preparations</i>	Dosage form monograph	12 (Dosage forms and pharmaceutical technical procedures)
1116	<i>Preparations for irrigation</i>	Dosage form monograph	12 (Dosage forms and pharmaceutical technical procedures)
1264	<i>Solutions for organ preservation</i>	Individual monograph	12 (Dosage forms and pharmaceutical technical procedures)
0125	<i>Radiopharmaceutical preparations</i>	General monograph	14 (Radiopharmaceutical Preparations)
0084	<i>Immunosera for human use, animal</i>	General monograph	15 (Human Vaccines and Sera)
0153	<i>Vaccines for human use</i>	General monograph	15 (Human Vaccines and Sera)
1932	<i>Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed)</i>	Individual monograph	15 (Human Vaccines and Sera)

2067	<i>Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)</i>	Individual monograph	15 (Human Vaccines and Sera)
2065	<i>Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)</i>	Individual monograph	15 (Human Vaccines and Sera)
2622	<i>Haemophilus type b and meningococcal group C conjugate vaccine</i>	Individual monograph	15 (Human Vaccines and Sera)
1219	<i>Haemophilus type b conjugate vaccine</i>	Individual monograph	15 (Human Vaccines and Sera)
1056	<i>Hepatitis B vaccine (rDNA)</i>	Individual monograph	15 (Human Vaccines and Sera)
3066	<i>Meningococcal group A, C, W135 and Y conjugate vaccine</i>	Individual monograph	15 (Human Vaccines and Sera)
2112	<i>Meningococcal group C conjugate vaccine</i>	Individual monograph	15 (Human Vaccines and Sera)
0250	<i>Meningococcal polysaccharide vaccine</i>	Individual monograph	15 (Human Vaccines and Sera)
2150	<i>Pneumococcal polysaccharide conjugate vaccine (adsorbed)</i>	Individual monograph	15 (Human Vaccines and Sera)
0966	<i>Pneumococcal polysaccharide vaccine</i>	Individual monograph	15 (Human Vaccines and Sera)
0216	<i>Rabies vaccine for human use prepared in cell cultures</i>	Individual monograph	15 (Human Vaccines and Sera)
1375	<i>Tick-borne encephalitis vaccine (inactivated)</i>	Individual monograph	15 (Human Vaccines and Sera)
2537	<i>3-O-Desacyl-4'-monophosphoryl lipid A</i>	Individual monograph	15 (Human Vaccines and Sera)
5.2.11.	<i>Carrier proteins for the production of conjugated polysaccharide vaccines for human use</i>	General chapter	15 (Human Vaccines and Sera)
3.3.4.	<i>Sterile plastic containers for human blood and blood components</i>	General chapter	16 (Plastic materials, plastic containers and closures)
3.3.7.	<i>Sets for the transfusion of blood and blood components</i>	General chapter	16 (Plastic materials, plastic containers and closures)
0024	<i>Human fibrinogen</i>	Individual monograph	6B (Human Plasma and Plasma Products)
0209	<i>Anticoagulant and preservative solutions for human blood</i>	Individual monograph (MP)	6B (Human Plasma and Plasma Products)
0255	<i>Human albumin solution</i>	Individual monograph	6B (Human Plasma and Plasma Products)
0275	<i>Human coagulation factor VIII</i>	Individual monograph	6B (Human Plasma and Plasma Products)

0338	<i>Human normal immunoglobulin for intramuscular administration</i>	Individual monograph	6B (Human Plasma and Plasma Products)
0554	<i>Human prothrombin complex</i>	Individual monograph	6B (Human Plasma and Plasma Products)
0878	<i>Human antithrombin III concentrate</i>	Individual monograph	6B (Human Plasma and Plasma Products)
0918	<i>Human normal immunoglobulin for intravenous administration</i>	Individual monograph	6B (Human Plasma and Plasma Products)
1223	<i>Human coagulation factor IX</i>	Individual monograph	6B (Human Plasma and Plasma Products)
1224	<i>Human coagulation factor VII</i>	Individual monograph	6B (Human Plasma and Plasma Products)
1644	<i>Human coagulation factor XI</i>	Individual monograph	6B (Human Plasma and Plasma Products)
1646	<i>Human plasma (pooled and treated for virus inactivation)</i>	Individual monograph	6B (Human Plasma and Plasma Products)
1928	<i>Anti-T lymphocyte immunoglobulin for human use, animal</i>	Individual monograph	6B (Human Plasma and Plasma Products)
2298	<i>Human von Willebrand factor</i>	Individual monograph	6B (Human Plasma and Plasma Products)
2387	<i>Human α-1-proteinase inhibitor</i>	Individual monograph	6B (Human Plasma and Plasma Products)
2788	<i>Human normal immunoglobulin for subcutaneous administration</i>	Individual monograph	6B (Human Plasma and Plasma Products)
2818	<i>Human C1-esterase inhibitor</i>	Individual monograph	6B (Human Plasma and Plasma Products)
0128	<i>Haemodialysis, solutions for</i>	Individual monograph	DIA (Dialysis)
0861	<i>Haemofiltration and haemodiafiltration, solutions for</i>	Individual monograph	DIA (Dialysis)
0862	<i>Peritoneal dialysis, solutions for</i>	Individual monograph	DIA (Dialysis)
NEW TEXT			
5.1.13	<i>Pyrogenicity</i>	General chapter	BET (Bacterial Endotoxin Test)