PGE1-Alfadex (drug product)

Specification No DP0705/Vers01

Quality characteristic	Requirement	Test methods
1. Properties		
Description vial content	white lyophilisate cake, at the bottom of the vial	organoleptic test
Primary packaging material	colourless 6 ml glass-vial, hydrolytic class I crimped with a grey rubber septum and red aluminium caps	organoleptic test
2. Identity*		
a) Reaction with dinitrobenzene solution	Red-brown-violet colour	JP monograph Alprostadil-alfadex, identification (2)
b) HPLC	RT value for PGE1	EP 2.2.29
c) Reaction with iodine solution	dark blue precipitate	JP monograph, Alprostadil-alfadex, identification (3)
** either a) and b) **or** a) and c) has to be performed*		
3. Purity		
3.1. General parameters Solubility	< RS 1 (reference standard)	EP 2.2.1, in 5ml of isotonic sodium chloride solution
pH-value	4.0 to 6.5	Potentiometric method, EP 2.2.3
Water content	not more than 1.5%	Karl-Fisher, EP 2.5.12
3.2 Organic impurities		
PGA1 (impurity A) 15-keto-PGE1 (Impurity C)	NMT 2.0 %	HPLC method

Single unknown impurities Total impurity level	NMT 1.0 % NMT 0.1 % NMT 5.0 %	HPLC method HPLC method HPLC method

Specification: PGE –Alfadex-Drug Product (continued)

Quality characteristic	Requirement	Test methods
3.3. Particulate contamination:		
Visible particles	clear and practically free from particles.	EP 2.9.20 EP 2.9.19, Method 1
Sub - visible particles	NMT 6000 ≥ 10 µm NMT 600 ≥ 25 µm	
4. Assay		
Alprostadil	19.5 - 21.5 µg/vial (97.5 - 107.5 %)	HPLC method
Uniformity of content	17.0 - 23.0 µg/vial 85 - 115 % (n=10)	EP 2.9.6
5. Microbial Purity		
Sterility	Sterile	EP 2.6.1 (Membrane filtration)
Bacterial Endotoxins (LAL)	Maximum allowable endotoxin concentration (MAEC) 350 EU/vial (equivalent to 47 EU/ml when reconstituted in 7.5 ml)	EP 2.6.14, bacterial endotoxins

Vienna, 07.07.2005

Ewald H. Moser