

Item Number	P1679
Item	Alprostadil, USP
CAS Number	745-65-3
Molecular Formula	C <sub>20</sub> H <sub>34</sub> O <sub>5</sub>
Molecular Weight	354.48
MDL Number	
Synonyms	(1R,2R,3R)-3-Hydroxy-2-[(E)-(3S)-3-hydroxy-1-octenyl]-5-oxocyclopentaneheptanoic Acid ; Prostaglandin E ; (11?,13E,15S)-11,15-Dihydroxy-9-oxoprost-13-en-1-oic Acid ; 3-Hydroxy-2-(3-hydroxy-1-octenyl)-5-oxo-cyclopentaneheptanoic Acid

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	95.0	105.0 %
WATER DETERMINATION		0.5 %
RESIDUE ON IGNITION		0.5 %
FOREIGN PROSTAGLANDINS, TEST 1		
PROSTAGLANDIN A?		1.5 %
PROSTAGLANDIN B?		0.1 %
ANY FOREIGN PROSTAGLANDIN IMPURITY ELUTING BEFORE PROSTAGLANDIN A?		0.9 %
IMPURITY AT RELATIVE RETENTION TIME 0.6, RELATIVE TO PROSTAGLANDIN A?		0.9 %
FOREIGN PROSTAGLANDINS, TEST 2		
SUM OF THE IMPURITIES AT RELATIVE RETENTION TIME 2.0 AND 2.3		0.6 %
ANY OTHER FOREIGN PROSTAGLANDIN IMPURITY ELUDING AFTER PROSTAGLANDIN A?		0.9 %
TOTAL IMPURITIES: the sum of the impurities test 1 and test 2		2.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE	
RETEST DATE		
DATE OF MANUFACTURE		

Test	Specification	
	Min	Max
MONOGRAPH EDITION		
RESIDUAL SOLVENTS:	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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