



**Specification for Estradiol, Hemihydrate, (Non Micronized),
USP, bioCERTIFIED (TM) (EH901)**

Item Number	EH901
Item	Estradiol, Hemihydrate, (Non Micronized), USP, bioCERTIFIED (TM)
CAS Number	35380-71-3
Molecular Formula	$C_{18}H_{24}O_2 \cdot 1/2 H_2O$
Molecular Weight	281.39
MDL Number	
Synonyms	Oestradiol ; 17-β-Estradiol ; Estra-1,3,5(10)-triene-3,17β-diol

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	97.0	103.0 %
MELTING RANGE	173°	179°C
SPECIFIC ROTATION	+76° TO +83°	
PARTICLE SIZE (d90)	150 μm	
WATER DETERMINATION		3.5 %
CHROMATOGRAPHIC PURITY:		
INDIVIDUAL IMPURITIES		0.5 %
TOTAL IMPURITIES		1.0 %
MICROBIAL LIMITS:		
TAMC		1000 cfu/g
TYMC		100 cfu/g
BET		10 IU/g
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE AND ABSORPTIVITIES DO NOT DIFFER BY MORE THAN 3.0 %	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS		AS REPORTED

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