ATOSIBAN ACETATE
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 994.2

Sequence: Mpa-D-Tyr(Et)-Ile-Thr-Asn-Cys-Pro-Orn-Gly-NH_2 (acetate)

Last version: 27 AUG 2021

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
Appearance	White to off-white powder	Visual inspection
Identification, HPLC 1	Retention time of the main peak conforms to that of the reference	In-house
Identification, HPLC 2	Retention time of the main peak conforms to that of the reference	In-house
Identification, Mass spectrometry	994.5 ± 0.2	Ph. Eur.
Identification of acetic acid/acetate, HPLC	Retention time of the main peak conforms to that of the reference	In-house
Peptide content, HPLC		In-house
	95 to 105% of atosiban, calculated with reference to the anhydrous, acetic acid free and ethanol free substance	
	≥ 85% of atosiban, calculated with reference to the total mass of the substance	
Peptide related impurities, HPLC		In-house
Single impurity[1]		
Any unspecified impurity	≤ 0.1%	
Sum of unidentified impurities	≤ 0.4%	
Sum of impurities	≤ 3.0%	

[1] Detailed impurity specification not provided

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
Specific optical rotation $[\alpha]_D^{20}$ (c = 1.0, 1% acetic acid)	-54.5 to -46.5	Ph. Eur.
pH	4.9 to 6.9	Ph. Eur.
Acetic acid/acetate content, HPLC	5.0 to 8.0%	In-house
Water content, Karl Fischer	≤ 8.5%	Ph. Eur.
Ethanol content	≤ 1.5%	In-house
Sulphated ash	≤ 0.1%	Ph. Eur.
Microbiological tests		Ph. Eur.
TAMC	< 100 CFU/g	
TYMC	< 100 CFU/g	
Bacterial endotoxins	≤ 12.0 IU/mg	