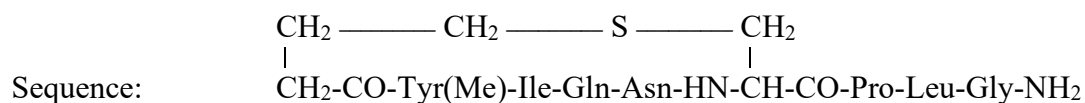


**CARBETOCIN  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 988

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Last update: 25 AUG 2021

Available registration documents (CTD format): DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
<b>CHARACTERISTICS</b>		
Appearance	White fluffy powder	Visual inspection
<b>IDENTIFICATION</b>		
Identification, HPLC	Retention time and peak shape of main peak corresponds to that of reference	In-house
Mass spectrometry	Monoisotopic mass $987.5 \pm 1.0$ u	Ph.Eur./USP
<b>ASSAY</b>		
Carbetocin content (HPLC) (% of total mass of substance)	$\geq 89\%$	In-house
Carbetocin content (% of the anhydrous and acetic acid free substance)	95 to 105%	Calculation
<b>PURITY</b>		
Related substances <sup>1</sup> :		In-house
Any unspecified impurity	$\leq 0.3\%$	
Sum of all impurities	$\leq 2.5\%$	

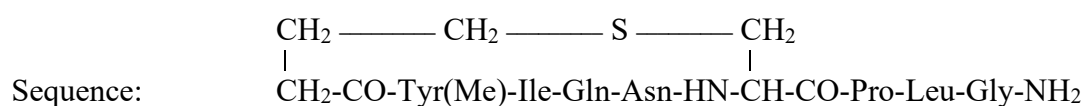
<sup>1</sup> Detailed impurity specification not provided

**CARBETOCIN**  
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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
<b>OTHER TESTS</b>		
Specific optical rotation $[\alpha]_D^{20}$ (c=0.2, 1% acetic acid)	-81° to -71°	Ph.Eur./USP
Acetic acid content	≤ 2%	In-house
Water content	≤ 6%	Ph.Eur./USP
<b>RESIDUAL SOLVENTS</b>		
Dimethylformamide	≤ 880 ppm	In-house
Acetonitrile	≤ 410 ppm	In-house
<b>MICROBIOLOGICAL CONTROL</b>		
Total aerobic microbial count	≤ 10 CFU/0.1 g	Ph.Eur./USP
Total combined yeasts and moulds count	≤ 10 CFU/0.1 g	Ph.Eur./USP
Bacterial endotoxins	≤ 500 IU/mg	Ph.Eur./USP