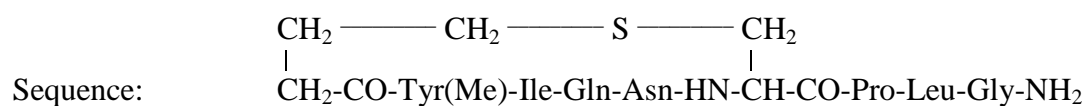


**CARBETOCIN**  
**DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 988

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Last update: 26 SEP 2014

Available registration documents (CTD format): DMF

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

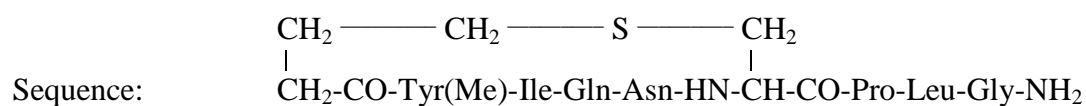
TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
<b>CHARACTERS</b>		
Appearance	White fluffy powder	Visual inspection
<b>IDENTIFICATION</b>		
Identification, HPLC	Complies with reference	In-house
Mass spectrometry	Monoisotopic mass $987.5 \pm 1.0$ u	Ph.Eur./USP
<b>PURITY</b>		
Related substances, HPLC:		In-house
[D-Cys <sup>6</sup> ]carbetocin	$\leq 0.5\%$	
[Des-Gln <sup>4</sup> ]carbetocin	$\leq 0.5\%$	
Any unspecified impurity	$\leq 0.3\%$	
Sum of all impurities	$\leq 2.5\%$	
<b>ASSAY</b>		
Carbetocin content	$\geq 89\%$	In-house
Carbetocin content (anhydrous and acetic acid free substance)	95 to 105%	In-house
<b>OTHER TESTS</b>		
Specific optical rotation $[\alpha]_D^{25}$	-81 to -71	Ph.Eur./USP
Acetic acid	$\leq 2\%$	In-house

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Water	≤ 6%	Ph.Eur./USP
RESIDUAL SOLVENTS		
DMF	≤ 880 ppm	In-house
Acetonitrile	≤ 410 ppm	
MICROBIOLOGICAL TESTS		
Total viable aerobic count	≤ 10 CFU/0.1 g	Ph.Eur./USP
Total combined yeast and moulds count	≤ 10 CFU/0.1 g	Ph.Eur./USP
Bacterial endotoxins	≤ 500 IU/mg	Ph.Eur./USP