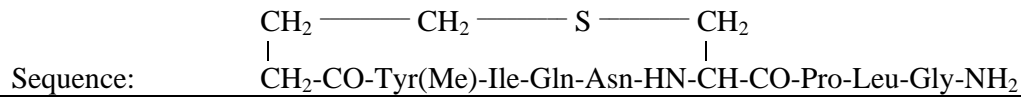


**CARBETOCIN
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 988

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Last update: 12 SEP 2007

Available registration documents (CTD format): Contact PolyPeptide Laboratories
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
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CHARACTERS

Appearance	White fluffy powder	Visual inspection
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IDENTIFICATION

Identification, HPLC	Complies with reference	In-house
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Amino acid analysis	Asp: 0.95 to 1.05 Glu: 0.95 to 1.05 Pro: 0.95 to 1.05 Gly: 0.95 to 1.05 Ile: 0.95 to 1.05 Leu: 0.95 to 1.05 Tyr: 0.95 to 1.05 Cys C3: Present	Ph.Eur.
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PURITY

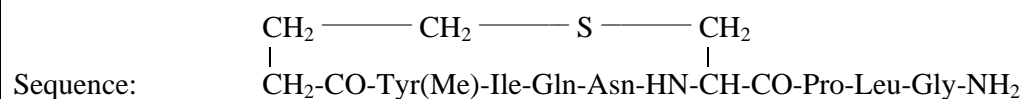
Related substances, HPLC:		In-house
[D-Cys ⁶]carbetocin	≤ 1.0%	
[D-Asn ⁵]carbetocin	≤ 1.0%	
Carbetocin sulfoxide I	≤ 0.3%	
Carbetocin sulfoxide II	≤ 0.4%	
[isoAsn ⁵]carbetocin	≤ 0.5%	
Any other individual impurity	≤ 0.3%	
Sum of other impurities	≤ 1.0%	
Total amount	≤ 3.5%	

**CARBETOCIN
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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
ASSAY		
Peptide content	≥ 85%	In-house
Mass balance	95 to 105%	In-house
OTHER TESTS		
Specific optical rotation $[\alpha]_D^{25}$	-81 to -71	In-house
Acetic acid	≤ 5%	In-house
Water	≤ 6%	Ph.Eur.
RESIDUAL SOLVENTS		
Methanol	≤ 0.3%	Ph.Eur.
MICROBIOLOGICAL TESTS		
Total viable aerobic count	≤ 100 CFU/g	USP/Ph.Eur.
Bacterial endotoxins	≤ 2000 IU/mg	USP/Ph.Eur.