

**CORTICOTROPIN (ACTH)  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 4567.6 (free peptide)

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Sequence: H-Ser-Tyr-Ser-Met-Glu-His-Phe-Arg-Trp-Gly-Lys-Pro-Val-Gly-Lys-Lys-Arg-Arg-Pro-Val-Lys-Val-Tyr-Pro-Asn-Gly-Ala-Glu-Asp-Glu-Leu-Ala-Glu-Ala-Phe-Pro-Leu-Glu-Phe-OH

Last update: 30 AUG 2007

Available registration documents (CTD format): None, the substance is sold based on its CoA  
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>CHARACTERS</b>		
Appearance	White or almost white amorphous powder of low density	Visual inspection
<b>IDENTIFICATION</b>		
Amino acid analysis	Asp: 1.8 to 2.2 Glu: 4.5 to 5.5 Pro: 3.6 to 4.4 Gly: 2.7 to 3.3 Val: 2.7 to 3.3 Leu: 1.8 to 2.2 His: 0.9 to 1.1 Arg: 2.7 to 3.3 Lys: 3.6 to 4.4 Ser: 1.8 to 2.2 Met: 0.9 to 1.1 Tyr: 1.8 to 2.2 Phe: 2.7 to 3.3 Ala: 2.7 to 3.3 Trp: 0.9 to 1.1	In-house
Identification, HPLC	Conforms to reference standard	In-house
<b>PURITY</b>		
Peptide purity, HPLC:	≥ 95%	In-house

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<b>TEST</b>	<b>ACCEPTANCE CRITERIA</b>	<b>ANALYTICAL PROCEDURE</b>
<b>ASSAY</b>		
Potency, HPLC	≥ 70 IU/mg	In-house
<b>OTHER TESTS</b>		
Acetic acid	< 15%	In-house
Water	≤ 7%	USP/Ph.Eur.
Trifluoroacetic acid	≤ 0.05%	In-house
<b>RESIDUAL SOLVENTS</b>		
N,N-Dimethylformamide	≤ 880 ppm	In-house
Methanol	≤ 0.3%	In-house
Diethyl ether	≤ 0.5%	In-house
<b>MICROBIOLOGICAL TESTS</b>		
Total viable aerobic count	< 10 <sup>2</sup> CFU/g	Ph.Eur.
Bacterial endotoxins	≤ 318 IU/mg	USP/Ph.Eur.