

**CORTICOTROPIN (ACTH)  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 4567.2 (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: 12 AUG 2020

Available registration documents: CMC technical package (CTD format)

<b>TEST</b>	<b>ACCEPTANCE CRITERION</b>	<b>ANALYTICAL PROCEDURE</b>
Appearance	White powder or flakes	Visual inspection
Identity, AAA (relative ratios)		In-house
	Asx 1.8 - 2.2	
	Ser 1.6 - 2.2	
	Glx 4.5 - 5.5	
	Pro 3.6 - 4.4	
	Gly 2.7 - 3.3	
	Ala 2.7 - 3.3	
	Val 2.7 - 3.3	
	Met 0.9 - 1.1	
	Leu 1.8 - 2.2	
	Tyr 1.8 - 2.2	
	Phe 2.7 - 3.3	
	His 0.9 - 1.1	
	Lys 3.6 - 4.4	
	Trp present	
	Arg 2.7 - 3.3	
Identity, LC-UV	Retention time of the main peak conforms to reference	In-house
Potency	≥ 70 IU/mg	In-house
Peptide purity, HPLC-UV	≥ 95%	In-house
Peptide related impurities <sup>1</sup>		

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

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<b>TEST</b>	<b>ACCEPTANCE CRITERION</b>	<b>ANALYTICAL PROCEDURE</b>
Water content, Karl Fischer titration	≤ 7% (w/w)	Ph. Eur./USP
Acetic content, IC	< 15% (w/w)	In-house
Trifluoroacetic acid, IC	< 0.05%	In-house
Residual solvents, GC		
Acetonitrile	≤ 410 ppm (w/w)	In-house
Ethanol	≤ 5000 ppm (w/w)	In-house
Methyl-t-butyl ether	≤ 5000 ppm (w/w)	In-house
Microbial enumeration tests		
TAMC	< 2000 CFU/g	Ph. Eur./USP
TYMC	≤ 200 CFU/g	Ph. Eur./USP
Bacterial endotoxins	< 318 IU/mg	Ph. Eur./USP