

**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: 08 JUN 2018

Available registration documents: CMC technical package (CTD format)

<b>ITEST</b>	<b>ACCEPTANCE CRITERION</b>	<b>ANALYTICAL PROCEDURE</b>																														
Appearance	White powder or flakes	Visual inspection																														
Identity, AAA (relative ratios)	<table border="0"> <tr><td>Asx</td><td>1.8 - 2.2</td></tr> <tr><td>Ser</td><td>1.6 - 2.2</td></tr> <tr><td>Glx</td><td>4.5 - 5.5</td></tr> <tr><td>Pro</td><td>3.6 - 4.4</td></tr> <tr><td>Gly</td><td>2.7 - 3.3</td></tr> <tr><td>Ala</td><td>2.7 - 3.3</td></tr> <tr><td>Val</td><td>2.7 - 3.3</td></tr> <tr><td>Met</td><td>0.9 - 1.1</td></tr> <tr><td>Leu</td><td>1.8 - 2.2</td></tr> <tr><td>Tyr</td><td>1.8 - 2.2</td></tr> <tr><td>Phe</td><td>2.7 - 3.3</td></tr> <tr><td>His</td><td>0.9 - 1.1</td></tr> <tr><td>Lys</td><td>3.6 - 4.4</td></tr> <tr><td>Trp</td><td>present</td></tr> <tr><td>Arg</td><td>2.7 - 3.3</td></tr> </table>	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	In-house
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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																														
Water content, Karl Fischer titration	≤ 7% (w/w)	Ph. Eur./USP																														

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<b>ITEST</b>	<b>ACCEPTANCE CRITERION</b>	<b>ANALYTICAL PROCEDURE</b>
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