

Certificate of Analysis

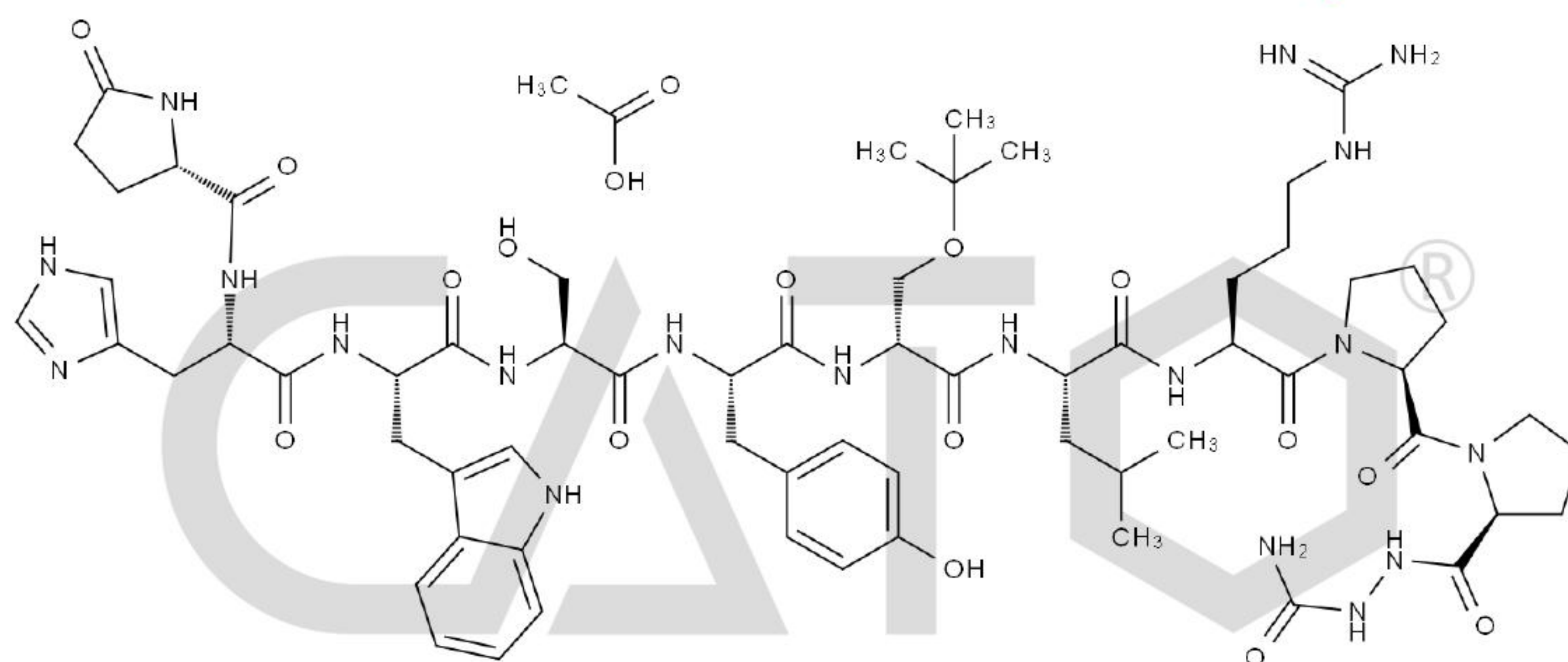
Reference Material & Standard

Product Name:	Goserelin EP Impurity J Acetate	Catalogue Number:	C4X-192010
Synonyms:	N/A	Lot Number:	0218-RC-0012
CAS Number:	N/A	Expiry Date:	Feb 28, 2025
Molecular Formula:	C ₆₄ H ₉₁ N ₁₉ O ₁₅ C ₂ H ₄ O ₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	1366.53 60.05	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Powder
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.9274%
Loss on Drying	TGA	9.13%
Assay		90.8%

Comment:

1. Acetic acid: 8.29%
2. The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$
 Loss on Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by: 冯思行

Reviewed by:

Debia

Approved by General Manager:

David

Date: Mar 01, 2021

Date: Mar 03, 2021

Date: Mar 03, 2021



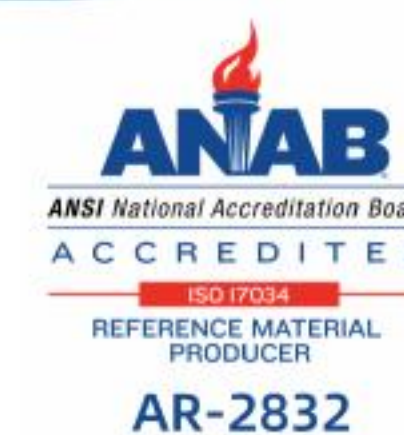
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