

Certificate of Analysis

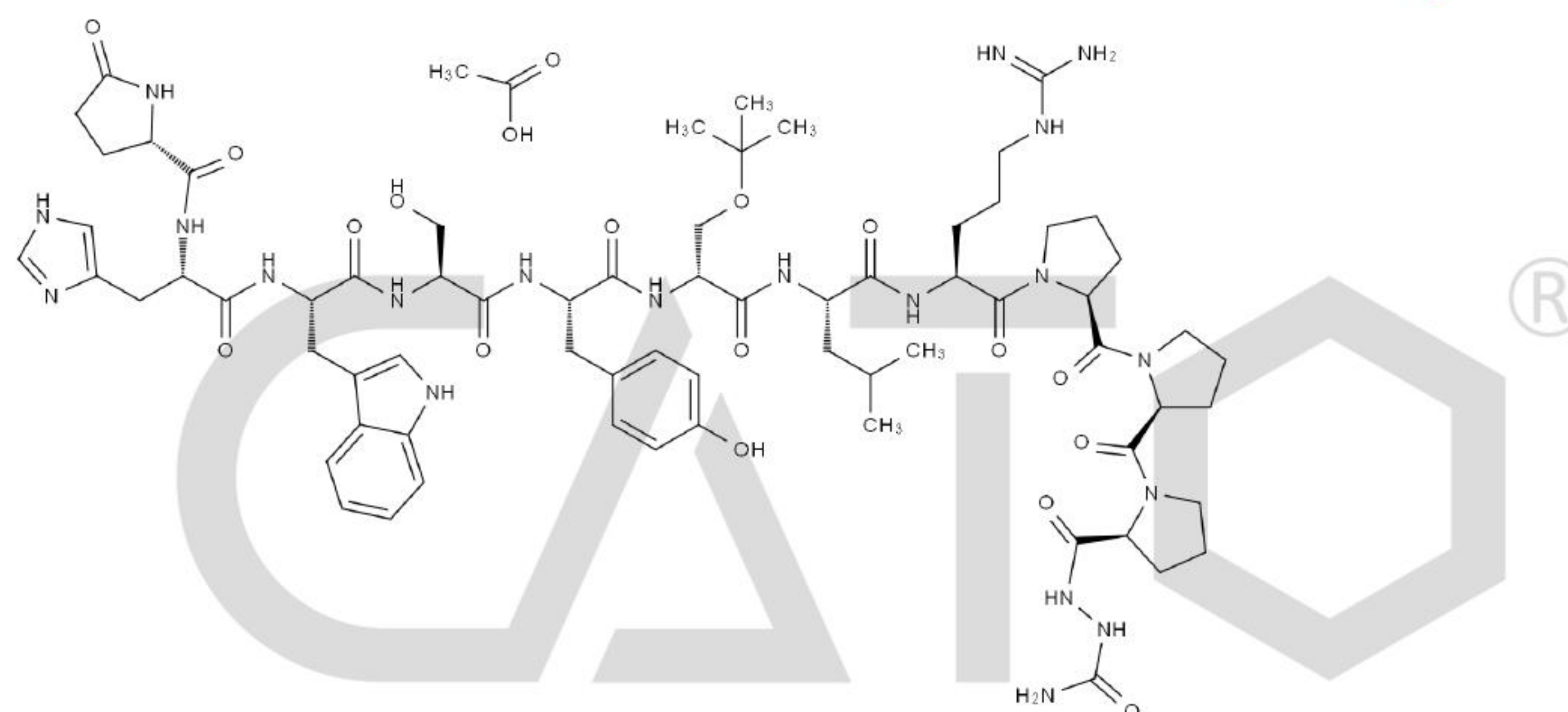
Reference Material & Standard

Product Name:	Goserelin EP Impurity I Acetate	Catalogue Number:	C4X-19209
Synonyms:	N/A	Lot Number:	0218-RC-0018
CAS Number:	N/A	Expiry Date:	Mar 08, 2025
Molecular Formula:	C ₆₉ H ₉₈ N ₂₀ O ₁₆ C ₂ H ₄ O ₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	1463.64 60.05	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Brown Powder
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.8569%
Loss on Drying	TGA	4.04%
Assay		95.8%

Comment:

1. Acetic acid:8.56%
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:

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Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Mar 09, 2021

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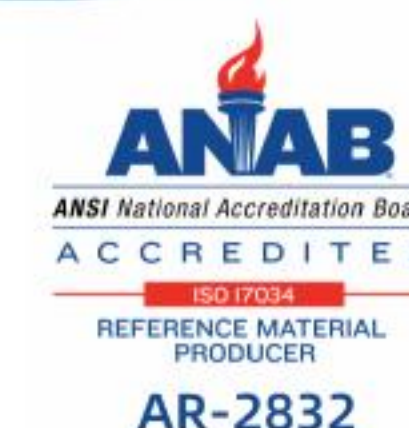
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