

IMPURITIES IN PEPTIDE APIs

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Impurities observed in peptide APIs can be process related impurities, which cannot be removed completely during purification of the crude peptide or product related impurities that are formed as degradation products during storage. Typically these impurities are byproducts resulting from side reactions occurring during the syntheses, such as racemization, deamidation, oxidation or aspartimide formation. Peptide APIs obtained by solid-phase synthesis may additionally contain analogs resulting from deletion or double insertion of amino acids. References of such compounds are needed for analytical method development and release testing, because fulfilling the specifications for byproducts is required by the relevant pharmacopeia and, most importantly, for ensuring the quality of the API.

Impurities of Atosiban

Atosiban (free acid)	4083914
Atosiban (1-8) lactam	4081127
(Orn(Ac) ⁸)-Atosiban	4081126
(Orn(Atosiban (free acid)) ⁸)-Atosiban	4083915
Atosiban	4065438

Impurities of the Buserelin Ph. Eur. Monograph

(Des-Gly ¹⁰ ,D-His ² ,D-Ser(tBu) ⁶ ,Pro-NHET ⁹)-LHRH ((D-His ²)-Buserelin) Impurity A	4018942
(Des-Gly ¹⁰ ,D-Ser(tBu) ⁶ ,Pro-NHET ⁹)-LHRH (Buserelin)	4028150

Impurities of Exenatide

(D-Asn ²⁸)-Exenatide	4084643
(Asp ²⁸)-Exenatide	4085312
(D-Asp ²⁸)-Exenatide	4085313
(β-Asp ²⁸)-Exenatide	4085314
(β-D-Asp ²⁸)-Exenatide	4085315

(D-His ¹)-Exenatide	4072224
Met(O) ¹⁴ -Exenatide	4082706
Acetyl-Exenatide	4072222
(Des-Gly ²)-Exenatide	4072221
Endo-38a-Pro-Exenatide	4072223
Exenatide	4019602

Impurities of Glucagon

(Asp ²⁸)-Glucagon (1-29) (human, rat, porcine)	4079056
(Glu ³)-Glucagon (1-29) (human, rat, porcine)	4079054
(Glu ²⁰)-Glucagon (1-29) (human, rat, porcine)	4079055
(Glu ²⁴)-Glucagon (1-29) (human, rat, porcine)	4071253
(Des-Thr ⁵)-Glucagon	4045345
(Des-Thr ⁷)-Glucagon	4045365



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(Met(O) ²⁷)-Glucagon (1-29) (human, rat, porcine)	4043506
Glucagon (1-29) (human, rat, porcine)	4033017

Impurities of Gonadorelin

LHRH (free acid) (Gonadorelin (free acid))	4009735
(D-His ²)-LHRH ((D-His ²)-Gonadorelin)	4035476
(D-Leu ⁷)-LHRH ((D-Leu ⁷)-Gonadorelin)	4041861
LHRH (1-5) (free acid) (Gonadorelin (1-5))	4028309
LHRH (acetate salt) Gonadorelin (acetate salt)	4033013

Impurities of the Goserelin Ph. Eur. Monograph

(D-Ser ⁴ ,D-Ser(tBu) ⁶ ,Azagly ¹⁰)-LHRH ((D-Ser ⁴)-Goserelin) Impurity A	4035304
(Ser(tBu) ⁶ ,Azagly ¹⁰)-LHRH ((Ser(tBu) ⁶)-Goserelin) Impurity B	4035307
(Des-Gly ¹⁰ ,D-Ser(tBu) ⁶ ,Pro-NHNH ₂ ⁹)-LHRH (Decarbamoylgoserelin) Impurity E	4039400
(D-Tyr ⁵ ,D-Ser(tBu) ⁶ ,Azagly ¹⁰)-LHRH ((D-Tyr ⁵)-Goserelin) Impurity F	4035302
(D-His ² ,D-Ser(tBu) ⁶ ,Azagly ¹⁰)-LHRH ((D-His ²)-Goserelin) Impurity G	4035303
(Ser(Ac) ⁴ ,D-Ser(tBu) ⁶ ,Azagly ¹⁰)-LHRH ((Ser(Ac) ⁴)-Goserelin) Impurity K	4054732

(D-Ser(tBu) ⁶ ,D-Leu ⁷ ,Azagly ¹⁰)-LHRH ((D-Leu ⁷)-Goserelin) Impurity L	4037082
(D-Ser(tBu) ⁶ ,Azagly ¹⁰)-LHRH (Goserelin)	4038252

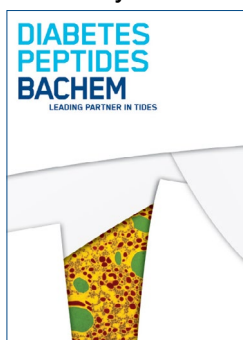
Impurities of Histrelin

(Des-Gly ¹⁰ ,D-His ² ,D-His(Bzl) ⁶ ,Pro-NHEt ⁹)- LHRH ((D-His ²)-Histrelin)	4028762
(Des-Gly ¹⁰ ,D-Ser ⁴ ,D-His(Bzl) ⁶ ,Pro-NHEt ⁹)- LHRH ((D-Ser ⁴)-Histrelin)	4025431
(Des-Gly ¹⁰ ,D-Tyr ⁵ ,D-His(Bzl) ⁶ ,Pro-NHEt ⁹)- LHRH ((D-Tyr ⁵)-Histrelin)	4028763
(Des-Gly ¹⁰ ,D-His(Bzl) ⁶ ,Pro-NHEt ⁹)-LHRH (Histrelin)	4035442

Impurities of the Leuprorelin Ph. Eur. Monograph

(Des-Gly ¹⁰ ,D-Ser ⁴ ,D-Leu ⁶ ,Pro-NHEt ⁹)-LHRH ((D-Ser ⁴)-Leuprorelin) Impurity A	4033803
(Des-Gly ¹⁰ ,D-His ² ,D-Leu ⁶ ,Pro-NHEt ⁹)-LHRH ((D-His ²)-Leuprorelin) Impurity B	4028311
(Des-Gly ¹⁰ ,Leu ⁶ ,Pro-NHEt ⁹)-LHRH ((Leu ⁶)-Leuprorelin) Impurity C	4033802
(Des-Gly ¹⁰ ,Ser(Ac) ⁴ ,D-Leu ⁶ ,Pro-NHEt ⁹)- LHRH (Ser(Ac) ⁴)-Leuprorelin) Impurity D	4034724
(Des-Gly ¹⁰ ,D-Trp ³ ,D-Leu ⁶ ,Pro-NHEt ⁹)-LHRH ((D-Trp ³)-Leuprorelin) Impurity E	4058815
(Des-Gly ¹⁰ ,D-His ² ,D-Ser ⁴ ,D-Leu ⁶ ,Pro- NHEt ⁹)-LHRH ((D-His ² ,D-Ser ⁴)-Leuprorelin) Impurity F	4048380
(Des-Gly ¹⁰ ,D-Tyr ⁵ ,D-Leu ⁶ ,Pro-NHEt ⁹)-LHRH ((D-Tyr ⁵)-Leuprorelin) Impurity G	4028312
(Des-Gly ¹⁰ ,D-Leu ⁶ ,D-Leu ⁷ ,Pro-NHEt ⁹)- LHRH ((D-Leu ⁷)-Leuprorelin) Impurity H	4028310
(Des-Gly ¹⁰ ,D-Pyr ¹ ,D-Leu ⁶ ,Pro-NHEt ⁹)-LHRH ((D-Pyr ¹)-Leuprorelin) Impurity I	4046113
(Des-Gly ¹⁰ ,D-Leu ⁶ ,Orn ⁸ ,Pro-NHEt ⁹)-LHRH ((Orn ⁸)-Leuprorelin)	4065128
(Des-Gly ¹⁰ ,D-Leu ⁶ ,Pro-NHEt ⁹)-LHRH (Leuprorelin, Leuprolide)	4033014

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Impurities of Octreotide

Acetyl-Octreotide	4071290
(Cys(S) ²)-Octreotide	4071291
(D-Cys ⁷ ,des-L-threoninol ⁸)-Octreotide	4099464
(Des-L-threoninol ⁸)-Octreotide amide	4099462
(L-Threoninol(Ac) ⁸)-Octreotide	4099463
(Lys(Ac) ⁵)-Octreotide	4099465
Octreotide	4042822
Octreotide (Dimer, Antiparallel)	4080984
Octreotide (Dimer, Parallel)	4080983

Impurities of Teriparatide

pTH (2-34) (human)	4069253
pTH (1-34) (human) (Teriparatide)	4011474

Impurities of Tetracosactide (Cosyntropin)

(D-Lys ¹⁶)-ACTH (1-24) (human, bovine, rat) ((D-Lys ¹⁶)-Tetracosactide)	4033149
(D-Ser ¹)-ACTH (1-24) (human, bovine, rat) ((D-Ser ¹)-Tetracosactide)	4029278
(Des-Glu ⁵)-ACTH (1-24) (human, bovine, rat) ((Des-Glu ⁵)-Tetracosactide)	4063587
(Des-His ⁶)-ACTH (1-24) (human, bovine, rat) ((Des-His ⁶)-Tetracosactide)	4063586
(Des-Ser ³)-ACTH (1-24) (human, bovine, rat) ((Des-Ser ³)-Tetracosactide)	4059984
Endo-4a-Glu-ACTH (1-24) (human, bovine, rat) (Endo-4a-Glu-Tetracosactide)	4063588
ACTH (2-24) (human, bovine, rat) (Tetracosactide (2-24))	4059983
Acetyl-ACTH (3-24) (human, bovine, rat)	4059986
Acetyl-ACTH (7-24) (human, bovine, rat)	4062898
ACTH (1-24) (human, bovine, rat) (Tetracosactide, Cosyntropin)	4011958

Impurities of Triptorelin

(D-Trp ⁶)-LHRH (free acid) (Triptorelin (free acid))	4026526
(D-Trp ⁶ ,D-Leu ⁷)-LHRH ((D-Leu ⁷)-Triptorelin)	4025366

(D-Ser ⁴ ,D-Trp ⁶)-LHRH ((D-Ser ⁴)-Triptorelin)	4025363
(D-Tyr ⁵ ,D-Trp ⁶)-LHRH ((D-Tyr ⁵)-Triptorelin)	4025365
(D-Trp ⁶)-LHRH (acetate salt) (Triptorelin (acetate salt))	4033016
(D-Trp ⁶)-LHRH (pamoate salt) (Triptorelin (pamoate salt))	4039648

Impurities of Antazoline

N-(2-Aminoethyl)-2-(benzylphenylamino) acetamide · maleate Impurity A of Antazoline Hydrochloride Ph. Eur.	4028954
2-(N-Phenyl-N-benzyl-aminomethyl)- imidazole	4052755
Antazoline · HCl	4041456
Antazoline · 0.5 H ₂ SO ₄	4041457

Impurities of L-Alanyl-L-Glutamine for Parenteral Nutrition

H-Ala-D-Gln-OH	4011868
H-D-Ala-Gln-OH	4011870
H-Ala-Glu-OH	4002318
H-Ala-Ala-Gln-OH	4026080
Cyclo(-Ala-Gln)	4035535
Cyclo(-Ala-Glu)	4035536
H-Ala-Gln-OH	4003766

Impurities of the Aspartame Ph. Eur. Monograph

Cyclo(-Asp-Phe) Impurity A	4016611
H-Asp-Phe-OH Impurity B	4001477
H-Phe-OH Impurity C	4031148
Aspartame	4000411

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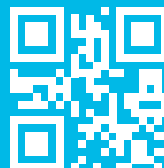
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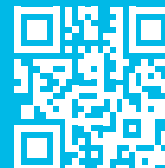
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