PolyPeptide GROUP

CERTIFICATE OF ANALYSIS

Product:	**Degarelix, Fmoc-SPPS**	**Product No.:**	**500104**
Batch No.:	**20-19-0077-01**	**Specification: Q-3.2.S.4.1-7645; Ver. 2.0**	
Manufacturing date:	**10 Apr 2019**	**Retest date:**	**10 Apr 2022**

TESTS/ANALYTICAL PROCEDURES	ACCEPTANCE CRITERIA	RESULTS
DESCRIPTION		
Visual inspection USP Curr. Ed	White to off-white powder	Complies
IDENTIFICATION		
Electrospray-MS Ph.Eur./USP Curr. Ed	Correct monoisotopic mass (1630.8 ± 0.4 u)	1630.8 u
LC/UV 3.2.S.4.2-7644	To give a single peak in the composite solution of sample and reference	Complies
DEGARELIX CONTENT		
LC/UV, 3.2.S.4.2-7644	≥ 83.0% (w/w)	89.6%
IMPURITIES		
FE 200699 ([4Aph^{5}(DHor)]degarelix) GC/MS, 3.2.S.4.2-105	≤ 0.7%	0.28%
FE 201605 ([D4Aph^{6}]degarelix)	≤ 0.5%	< 0.07%
FE 201140 ([Lys^{8}(iPr,Cbm)]degarelix)	≤ 0.5%	< 0.07%
Any unspecified impurity	≤ 0.10%	< 0.07%
Any unspecified degarelix related impurity LC/UV, 3.2.S.4.2-7644	≤ 0.3 %	0.14%
Sum of impurities 3.2.S.4.2-105, 3.2.S.4.2-7644	≤ 2.5%	1.0%
ACETATE		
LC/UV, Ph. Eur./USP Curr. Ed.	4.5 – 10.0% (w/w)	7.1%
TRIFLUOROACETATE		
IC, 3.2.S.4.2-133	≤ 500 ppm	< 100 ppm
WATER		
Karl Fischer Titration, Ph. Eur./USP Curr. Ed.	≤ 8.0 % (w/w)	2.7%
pH		
Potentiometric determination Ph. Eur./USP Curr. Ed.	3.6 – 4.6	4.3

PolyPeptide Laboratories (Sweden) AB

28 Oct 2019 / Carlos

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TESTS/ANALYTICAL PROCEDURES	ACCEPTANCE CRITERIA	RESULTS
BACTERIAL ENDOTOXINS Amoebocyte lysate test Ph. Eur./USP Curr. Ed.	≤ 0.9 EU/mg	< 0.2 EU/mg
TAMC **(TOTAL AEROBIC MICROBIAL COUNT)** Microbial Enumeration test Ph. Eur./USP Curr. Ed.	≤ 10^2 CFU/g	< 50 CFU/g
TYMC **(TOTAL COMBINED YEASTS/MOLDS COUNT)** Microbial Enumeration test Ph. Eur./USP Curr. Ed.	≤ 10^2 CFU/g	< 50 CFU/g

The batch listed above is manufactured and tested in accordance with cGMP at PolyPeptide Laboratories (Sweden) AB's manufacturing site in Limhamn, Sweden.

The batch above meets specification Q-3.2.S.4.1-7645; Ver. 2.0. Manufacturing documents for this batch have been reviewed and approved by the PolyPeptide Laboratories (Sweden) AB's Quality Assurance Department.

The batch complies with current Ph. Eur. general monograph 01/2008:1483 "Products with risk of transmitting agents of animal spongiform encephalopathies".

Certificate authorised by Quality Assurance

Prepared by: Carina Lundblad
Date: 28 Oct 2019 Sign: Carina Lundblad
Quality Assurance

Approved by: Mattias Norén
Date: 28 Oct 2019 Sign: Mattias Norén
Quality Assurance

PolyPeptide Laboratories (Sweden) AB
28 Oct 2019 /cahu