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Lilly

19 June 2019

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## Certificate of Analysis

To whom it may concern,

The analysis of this material was conducted according to GMP's and the results demonstrate conformance to the specification for this material.

**Material:** QA454F

**Material Name:** Olanzapine Parenteral

**Batch Number:** C848148

Note: This lot is derived from Olanzapine Final QA402E Parent Lot C764381

<u>Component</u>	<u>Result</u>	<u>Unit</u>	<u>Acceptance Criteria</u>
<b>Parent Lot QA402E Test Results:</b>			
Ethyl Acetate (Residual Solvents)	0.12	Percent	Ethyl Acetate (Residual Solvents) <=0.50
Fineness 106 Micron Particle Size	96	Percent Passing	Fineness 106 Micron Particle Size >=90
Fineness 20 Micron Particle Size	36	Percent Passing	Fineness 20 Micron Particle Size >=20 AND Fineness 20 Micron Particle Size <=60
Heavy Metals	PASS - NOT MORE THAN 10PPM		Heavy Metals = "PASS - NOT MORE THAN 10PPM"
Identity (Crystallinity)	PASS - THE X-RAY DIFFRACTION PATTERN MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS.		Identity (Crystallinity) = "PASS - THE X-RAY DIFFRACTION PATTERN MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS."
Identity (HPLC)	PASS - THE HPLC RETENTION TIME MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS.		Identity (HPLC) = "PASS - THE HPLC RETENTION TIME MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS."
Identity (IR)	PASS - THE IR SPECTRUM MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS.		Identity (IR) = "PASS - THE IR SPECTRUM MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS."
Largest Individual Related Substance	0.00	Percent	Largest Individual Related Substance[Average]<=0.10
Olanzapine (LSN 170053) Assay	100.0	Percent Volatiles Free	Olanzapine (LSN 170053) Assay >=98.0 AND Olanzapine (LSN 170053) Assay <=102.0
Olanzapine (LSN 170053) Assay	99.8	Percent as is	Olanzapine (LSN 170053) Assay >=98.0 AND Olanzapine (LSN 170053) Assay <=102.0
Physical Appearance (Description)	PASS - IT IS A YELLOW CRYSTALLINE SOLID		Physical Appearance (Description) = "PASS - IT IS A YELLOW CRYSTALLINE SOLID"
Residue On Ignition	0.0	Percent	Residue On Ignition <=0.1
Tin	0	ppm	Tin<=100
Total Related Substances	0.0	Percent	Total related Substances[Average] <=0.2
Water	0.1	Percent	Water[Average] <=1.0

### **Microbiological Test Results: Olanzapine Parenteral (QA454F)**

Description	Conforms		It is a yellow crystalline solid.
Bacterial Endotoxin	<2.0	E.U./mg	Not more than 8.0
Total Aerobic Microbial Count	<10	CFU/G	Not more than 200
Moulds & Yeasts	<10	CFU/G	Not more than 100

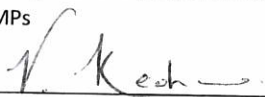
**Date of Manufacture:** 07-May-2017

**Release Date:** 16-Jan-2018

**Retest Date:** 06-May-2020


The data contained herein are results obtained by Eli Lilly and Company from tests performed on this product. The Batch was manufactured in compliance with applicable GMPs

Preparer: Valerie Keohane  
Printed Name:

  
Signature

Date: 19 Jun 2019  
DD-MMM-YYYY

Quality Approver: Caroline O'Driscoll  
Printed Name :

  
Signature

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DD-MMM-YYYY

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