

## Certificate of Analysis

Product: **Tamoxifen Oral Solution 20mg/10ml**

Lot Number: **8JL0045**

Licence: **NDC 89141-123-01**

Chemistry Method Reference: **RPL\_MFC\_SOLB010\_8.0**

Test	Result	Comparative result (Units)
Clear Colourless Liquid		Complies
Liquorice and Aniseed		Complies
pH	4.7	---
Weight per millilitre	1.12	g/ml
Assay of (Z)-Tamoxifen	100	%
Assay of (E)-Tamoxifen	0.0	%
Assay of Ethanol	104	%
Individual Impurities	0.0	%
Tamoxifen N-oxide	0.0	%
Total Impurities	0.0	%
Identification of (Z)-Tamoxifen by RT & UV		Complies
Identification of (E)-Tamoxifen by RT		Complies
Identification of Ethanol		Complies

**Comments and other tests:**

Complies with Ph Eur chapter 5.1.4 - Microbiological Quality of Non-sterile Pharmaceutical Preparations & Substances for Pharmaceutical Use

**CONCLUSION:** The product **Complies** with respect to the stated specification

Date of Manufacture: Sep/2018

Date of Expiry: Aug/2020

Analyst(s): W Ali L Edwards

Check analyst: S Mistry

Approved for release:   
**B Ighayere M.Sc (Hons): Manager QC & Stability**

Date: 16 09 2018

