

Certificate of Analysis

Product: **Dexamethasone Oral Solution 2mg/5ml**

Lot Number: **7ML0039**

Licence: **51714/1-7-2013**

Chemistry Method Reference: **RPL_MFC_DEXA002_5.0**

Test	Result	Comparative result (Units)
Colourless to Faint Yellow Liquid		Complies
Odour (Garden Mint)		Complies
pH	3.64	---
Refractive Index	33	%
Weight per millilitre	1.118	g/ml
Assay of Dexamethasone (from Dexamethasone Sodium Phosphate)	102.9	%
Free Dexamethasone	0	µg/5ml
Assay of Benzoic Acid	100.3	%
Impurities / Degradant Peaks	0.1	%
Total Impurities / Degradation Peaks	0.2	%

Comments and other tests:

Complies with Ph Eur chapter 5.1.4 – Microbiological Quality on Non- Sterile Pharmaceutical Preparations & Substances for Pharmaceutical Use

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

Date of Manufacture: Dec/2017

Date of expiry: Nov/2019

Analyst(s): D Doku N Hussain

Check analyst: L Edwards

Approved for release:


B Ighayere M.Sc. (Hons): Manager QC & Stability

Date: 05 Jan 2018