

Certificate of Analysis

Product:

Dexamethasone 2mg/5ml Oral Solution

Lot Number:

1014933

Licence:

4786/Nov 02

Chemistry Method Reference:

MFC-000093 V. 2.0

(DEXA002)

Test	Result	Comparative result (Units)
Colourless to Faint Yellow Liquid	Complies	Complies
Odour (Garden Mint)	Complies	Complies
рН	3.80	
Weight per millilitre	1.118	g/ml
Assay of Dexamethasone (from Dexamethsone Sodium Phosphate)	103.0	%
Free Dexamethasone	0	μg/5ml
Assay of Benzoic Acid	100.4	%
Impurities / Degradant Peaks	0.0	%
Total Impurities / Degradation Peaks	0.0	%

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: Sep/2024

Date of Expiry:

Sep/2026

Analyst(s):

H Mohammed

H Shah

Checked:

T Hussain

Sign and Date:

Approved for release:

H Pearson: QC Release and Compliance Officer

Date: 31-00-224