

Certificate of Analysis

Product: **Gabapentin Oral Solution 250mg/5ml**

Lot Number: **8GL0021**

Licence: **PL 00427/0155**

Chemistry Method Reference: **RPL_MFC_GABD250_1.0**

Test	Result	Comparative result (Units)
Clear Colourless liquid		Complies
pH	7.0	-
Weight per millilitre	1.023	g/ml
Assay of Gabapentin	100.0	%
Assay of Methyl hydroxybenzoate	99.4	%
Assay of Ethyl hydroxybenzoate	99.0	%
Related Compound A	0.0	%
Unknown impurities (Each)	0.0	%
Total Impurities (inc Related Compound A)	0.0	%
Uniformity of mass of delivered dose		Complies
Identification of Gabapentin (by Retention & UV)		Complies
Identification of Methyl & Ethyl Hydroxybenzoate (by Retention)		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/2019

Analyst(s): L Edwards L Wainwright

Check analyst: H Pearson

Approved for release


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

Date: 04 Oct 2018