

Certificate of Analysis

Product: **Captopril 25mg/5ml Oral Solution**

Lot Number: **016840**

Licence: **Special 00427/01**

Chemistry Method Reference: **RPL_MFC_CAPB025_3.0**

Test	Result	Comparative result (Units)
Clear colourless liquid		Complies
pH	3.1	---
Weight per millilitre	1.253	g
Assay of Captopril	99.5	%
Assay of Captopril Disulphide	0.2	%
Any single degradant/ impurity (greatest)	0.0	%
Total impurities (including captopril disulphide)	0.2	%
Assay of Benzoic Acid	99.8	%
ID: Captopril (by UV and retention time)		Complies
ID: Benzoic Acid (by UV and retention time)		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: Apr/2012

Date of expiry: Oct/2012

Analyst(s): S Rose H Pearson

Check analyst: J Lawton

Approved for release


N Dosanjh B.Sc(Hons): Manager Quality Control

Date: 03 May 2012