

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PPA0465/008/002B

Case No: 2043232

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

PCO Manufacturing Limited

Unit 222, Western Industrial Estate, Naas Road, Dublin 12, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Amoxil 500 mg Capsules

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **22/11/2007**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

4 CLINICAL PARTICULARS

5 PHARMACOLOGICAL PROPERTIES

6 PHARMACEUTICAL PARTICULARS