Safeguarding public health

Certificate No: UK GMP 22500 Insp GMP/IMP 22500/1125023-0002

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	ANDERSEN CALEDONIA LIMITED
Site address	CALEDONIAN HOUSE PHOENIX CRESCENT STRATHCLYDE BUSINESS PARK BELLSHILL ML4 3NJ UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with Art. 111(1) of Directive 2001/83/EC (or Article 80(1) of Directive 2001/82/EC) transposed in the following national legislation: For human medicines 'The Medicines Act 1968 as amended'; for veterinary medicines 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 30/04/2012, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road London SW1W 9SZ
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1.5	**Packaging only**		
	1.5.1	*Primary packaging*	
		1.5.1.1 Capsules, hard shell	Not Authorised
		1.5.1.2 Capsules, soft shell	Not Authorised
		1.5.1.3 Chewing gums	Not Authorised
		1.5.1.4 Impregnated matrices	Not Authorised
		1.5.1.5 Liquids for external use	Not Authorised
		1.5.1.6 Liquids for internal use	Not Authorised
		1.5.1.7 Medicinal gases	Not Authorised
		1.5.1.8 Other solid dosage forms	Not Authorised
		1.5.1.9 Pressurised preparations	Not Authorised
		1.5.1.10 Radionuclide generators	Not Authorised
		1.5.1.11 Semi-solids	Not Authorised
		1.5.1.12 Suppositories	Not Authorised
		1.5.1.13 Tablets	Not Authorised
		1.5.1.14 Transdermal patches	Not Authorised
		1.5.1.15 Intraruminal devices	Not Authorised
		1.5.1.16 Veterinary premixes	Not Authorised
		1.5.1.17 Other non-sterile medicinal products *Not Authorised*	Not Authorised
	1.5.2	Secondary packaging	Not Authorised
1.6	**Quality control testing**		
	1.6.1	Microbiological: sterility	Not Authorised
	1.6.2	Microbiological: non-sterility	Authorised
	1.6.3	Chemical/Physical	Not Authorised
	1.6.4	Biological	Not Authorised