

***INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde,
I.P.***

CERTIFICATE NUMBER: *Promed Exports Private Limited 001/2009*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:

The manufacturer: ***Promed Exports Private Limited***

Site address: ***KheranNihla, Tehsil: Nalagarh, Solan, Himachal Pradesh, 174 101, India***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:

Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2009-04-23*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

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.

Part 2

Human Medicinal Products

1 Manufacturing Operations

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potential hazardous active ingredients this should be stated under the relevant produce type and dosage form;



1.1	Sterile Products	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
	1.1.1 <i>Aseptically prepared (list of dosage forms)</i> 1.1.1.4 Small volume liquids	
1.6	Quality control testing	
	1.6.1 Microbiological: sterility 1.6.3 Chemical/Physical	

Any restrictions related to the scope of this certificate :

1.1.1.4 Eye drops, solution

2009-07-28

Name and signature of the authorised person of the
Competent Authority of Portugal

Ms Fernanda Ralha

Inspeção e Licenciamento

**INFARMED - Autoridade Nacional do Medicamento e
Produtos de Saúde, I.P.**

Tel: +351 21 7987278

Fax: +351 21 7987257