



Agenzia Italiana del Farmaco

Certificate No: IT/173-1/H/2008

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of Italy confirms the following:

The manufacturer CHELAB S.R.L.

Site address VIA FRATTA,25 - RESANA (TV)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 40/2008 dated 03/12/2008 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D.Lvo 219/2006 art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/12/2007 it is considered that it complies with the Good Manufacturing Practice requirements referred to in 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.

AIFA Italian Medicines Agency
Manufacturing Authorization Unit
Via della Sierra Nevada, n° 60 - 00144 ROMA (ITALY)
Tel. +390659784470 Fax +390659784312
website: www.agenziafarmaco.it

PC
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Agenzia Italiana del Farmaco

Part 2

Name and address of the site: CHELAB S.R.L. - VIA FRATTA,25 , RESANA(TV)

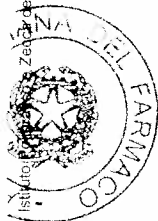
Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological





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Name and address of the site: CHELAB S.R.L. - VIA FRATTA,25 , RESANA(TV)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.6	Quality control testing
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

Rome, 07/09/2008

Name and signature of the authorised person of the Competent Authority of Republic of Italy



Dott.ssa Anna Rosa Marra
AIFA – Manufacturing Authorization Unit

Roma - Istituto Grafico e Zecca dello Stato S.p.A. - P.V.



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