Agenzia Italiana del Farmaco

Certificate No: IT/11-1/H/2011

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 MONTERESEARCH S.R.L.
Site address VIA IV NOVEMBRE n.92 - 20021 BOLLATE (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 118/2010 dated 08/31/2010 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 05/20/2010 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 Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1349

VI
GMP

Part 2 *Agenzia Italiana del Farmaco*

Name and address of the site: MONTERESEARCH S.R.L. - VIA IV NOVEMBRE n.92, 20021 BOLLATE(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell Special Requirements: Hormones or substances with hormonal activity Immuno-suppresives Other : Beta 2 adrenergic agonists
		1.2.1.2	Capsules, soft shell Special Requirements: Immuno-suppresives Other : Beta 2 adrenergic agonists
		1.2.1.5	Liquids for external use
		1.2.1.6	Liquids for internal use Special Requirements: Immuno-suppresives
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids
		1.2.1.12	Suppositories
		1.2.1.13	Tablets Special Requirements: Hormones or substances with hormonal activity Immuno-suppresives

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1349

VI
GMP

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

Quality control testing, no microbiological tests, and batch certification;
1.2.1.1 Capsules, hard shell: Hormones or substanceswith hormonal activity: corticosteroid hormones;
1.2.1.8 Other solid dosage forms: Powders and granules.;
1.2.1.13 Tablets: Hormones or substances with hormonal activity: sexual hormones;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS		
2.1	**Quality control testing of imported medical products**	
	2.1.3	*Chemical/Physical*
2.2	**Batch certification only (list of product types)**	
	2.2.2	*Non-sterile products*

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1349

VI
GMP

Name and address of the site: MONTERESEARCH S.R.L. - VIA IV NOVEMBRE n.92, 20021 BOLLATE(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.2	**Non-sterile investigational medical products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell Special Requirements: Hormones or substances with hormonal activity Immuno-suppresives Other : Beta 2 adrenergic agonists
		1.2.1.5	Liquids for external use
		1.2.1.6	Liquids for internal use
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids
		1.2.1.12	Suppositories
		1.2.1.13	Tablets
1.5	**Packaging only**		
	1.5.2	*Secondary packing*	

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

Quality control testing: no microbiological tests;
1.2.1.1 Capsules, hard shell: Hormones or substances with hormonal activity: corticosteroid hormones;
1.2.1.8 Other solid dosage forms: Powders and granules;

Agenzia Italiana del Farmaco

Rome, 01/17/2011

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

Dott. Renato Massimi
AIFA – Manufacturing Authorization Unit

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1349

VI
GMP