GMP Recombinant Human Interleukin-4

50µg : Quantity
rHuIL-4-50µg : Code
G017/LC1/030526/PV : Batch
09/2015 : Exp.Date
-20°C : Storage

CERTIFICATE OF ANALYSIS

Source	E.coli
Appearance	Colourless, clear liquid free of particles
Identity	1 band at 15kDa as measured by SDS-PAGE/Western Blot
Specific activity	12.4 x 10 exp6 units / mg compared to NIBSC standard (Bioassay)
Endotoxin content	< 0.1EU/µg (LAL)
Protein content	50±10 µg/vial (Lowry/µBCA)
Trehalose	6±0.5 mg/ml (HPLC)
Sterility	Absence of growth (FTM (30-35°C))
	Absence of growth (TSB (20-25°C))
Abnormal toxicity General Growth	No weight loss, no abnormal reaction in mice No weight loss, no abnormal reaction in guinea pigs
Physical state	Freeze-dried
Stability	12 months at -20°C to -80°C At least 3 months after reconstruction when stored at -20°C to -80°C
Reconstruction	Use 500µL water for injection
Packaging unit	50 µg protein (Lowry test)
Purity	>98% as determined by SDS-PAGE and HPLC

GMP certification: GENTAUR rh IL-4 is manufactured in full compliance with cGMP in facilities approved by the Belgian Ministry of Health for the production and storage of medicinal products. The manufacturing process does not involve the use of products of animal origin.

BSE/TSE Declaration : GENTAUR BVBA declares that this recombinant human IL-4 (04-GMPhuIL4) is manufactured under strict GMP controls and certifies that the entire product line is BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) free. GENTAUR BVBA manufactures this product in Belgium.

Use GENTAUR rh IL-4 is not an approved medicinal product and ONLY be injected as such to patients after the ethical commission approval of your university.

STABILITY TESTING NB: Time 0 = Final Container

After 7 days at 37°C

TEST	APPLICATION	SPECIFICATION	RESULT	CONCL,
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Activity	Bioassay	> 5 10^6 U/mg	10,9 10^6 U/mg	PASS
Abnormal toxicity / General safety	on mice	No weight loss, no abnormal Reaction	Absence of symptoms	PASS
Abnormal toxicity / General safety	on guinea-pigs	No weight loss, no abnormal Reaction	Absence of symptoms	PASS
Sterility test	FTM 30-35°C	Absence of growth	Absence of growth	PASS
Sterility test	TSB 20-25°C	Absence of growth	Absence of growth	PASS

After 3 months at -20°C

Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 16 kDa	PASS
Activity	Bioassay	> 5 10^6 U/mg	11,8 10^6 U/mg	PASS

After 6 months at -20°C

Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Activity	Bioassay	> 5 10^6 U/mg	12,7 10^6 U/mg	PASS

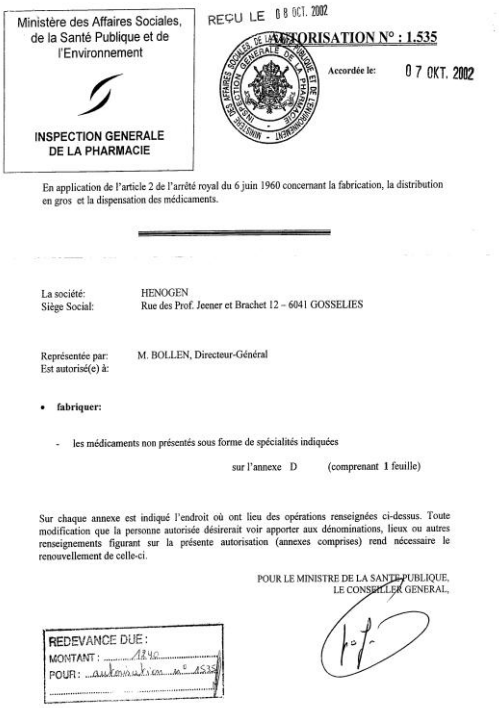
After 9 months at -20°C

Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS

Gentaur Molecular products
Avenue de l'Armée 68/B4
B1040 Brussel
Tel : +32 16 58 90 45
Fax : +32 16 50 90 45
www.gentaur.com

Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Activity	Bioassay	> 5 10^6 U/mg	12,0 10^6 U/mg	PASS
		After 12 months at -20°C		
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Activity	Bioassay	> 5 10^6 U/mg	13,8 10^6 U/mg	PASS
		After 18 months at -20°C		
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Activity	Bioassay	> 5 10^6 U/mg	13,2 10^6 U/mg	PASS
		After 24 months at -20°C		
Electrophoretical pattern	SDS-PAGE	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Identity	Western Blot	1 band between 12 and 16 kDa	1 band between 12 and 15 kDa	PASS
Abnormal toxicity / General safety	on mice	No weight loss, no abnormal Reaction	Absence	PASS
Abnormal toxicity / General safety	on guinea-pigs	No weight loss, no abnormal Reaction	Absence	PASS
Sterility test	FTM 30-35°C	Absence of growth	Absence of growth	PASS
Sterility test	TSB 20-25°C	Absence of growth	Absence of growth	PASS

GENTAUR rh IL-4 is manufactured in full compliance with cGMP in facilities approved by the Belgian Ministry of Health for the production and storage of medicinal products. GMP production at HENOGEN SA and GMP Lyophilisation at GSK Inc, Rixensart.



Ministère des Affaires Sociales, de la Santé Publique et de l'Environnement

INSPECTION GENERALE DE LA PHARMACIE

REÇU LE 08 OCT. 2002

AUTORISATION N° : 1.535

Accordée le: 07 OKT. 2002

En application de l'article 2 de l'arrêté royal du 6 juin 1960 concernant la fabrication, la distribution en gros et la dispensation des médicaments.

La société: HENOGEN
Siège Social: Rue des Prof. Jeener et Brachet 12 – 6041 GOSSELIES

Représentée par: M. BOLLEN, Directeur-Général
Est autorisé(e) à:

- **fabriquer:**

- les médicaments non présentés sous forme de spécialités indiquées

sur l'annexe D (comprenant 1 feuille)

Sur chaque annexe est indiqué l'endroit où ont lieu des opérations renseignées ci-dessus. Toute modification que la personne autorisée désirerait voir apporter aux dénominations, lieux ou autres renseignements figurant sur la présente autorisation (annexes comprises) rend nécessaire le renouvellement de celle-ci.

POUR LE MINISTRE DE LA SANTE PUBLIQUE,
LE CONSEILLER GENERAL,

REDEVANCE DUE:
MONTANT : 124,0
POUR : autorisation n° 1535

Use
GENTAUR rh IL-4 is not an approved medicinal product and cannot be injected as such to patients.
However this GMP IL-4 is used in clinical tests for DC Therapy today in Belgium, France, Denmark, USA and Japan.
CE CERTIFIED FOR EX VIVO CELL CULTURE AND DC THERAPY CLINICAL TESTS

Brussels, 04/02/2010 GNT#04GMPHUIL4-50UG