

MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_HE_01_MIA_2013_0007/II23.2Ro-18I 02 (1)-M 145
2. Name of authorisation holder	Pharmaserv GmbH & Co. KG
3. Address(es) of manufacturing site(s)	Pharmaserv GmbH & Co. KG Emil-von-Behring-Str. 76 35041 Marburg
4. Legally registered address of authorisation holder	Emil-von-Behring-Str. 76 35041 Marburg
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Susanne Roth
8. Signature	On behalf
9. Date	04/05/2013
10. Annexes attached	Annex 1 Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Pharmaserv GmbH & Co. KG, Emil-von-Behring-Str. 76, 35041 Marburg

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 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 or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.5	Packaging only
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	<i>1.5.2 Secondary packing</i>
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Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).

Karma-HMG 75 I.U.

(Menotropin injection (HMG) for injection based on B.P. -British Pharmacopoeia- Human Menopausal Gonatropin)