



SAARLAND

Ministerium für Soziales, Gesundheit, Frauen und Familie

MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_SL_01_MIA_2021_0027/5006-101#002
2. Name of authorisation holder	Pharmycron Service GmbH
3. Address(es) of manufacturing site(s)	Pharmycron Service GmbH Am Schindwasen 16 66386 St. Ingbert
4. Legally registered address of authorisation holder	Am Schindwasen 16 66386 St. Ingbert
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Claudia Neumann
8. Signature	On behalf
9. Date	12/07/2021
10. Annexes attached	Annex 1 Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation

granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Pharmycron Service GmbH, Am Schindwasen 16, 66386 St. Ingbert

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS**1.4 Other products or manufacturing activity***1.4.1 Manufacture of:*

1.4.1.3 Other

Micronization and packaging of active ingredients,
except: β -lactam antibiotics, cephalosporins, CRM substances, BtM
includes:Tobramycin (USP) exclusively for export to Switzerland
and the following hormones:

Hydrocortisone acetate

Medroxyprogesterone

Prednisolone

Levothyroxine

Levothyroxine sodium

Liothyronine sodium

Liothyronine hydrochloride

1.4.2 Sterilisation of active substances/excipients/finished product

1.4.2.5 Gamma irradiation

1.6 Quality control testing*1.6.1 Microbiological: sterility**1.6.2 Microbiological: non-sterility**1.6.3 Chemical/Physical***Any restrictions or clarifying remarks related to the scope of these Manufacturing operations**

Pharmycron manufacturing activities:

Building A, Am Schindwasen 16, 66386 St. Ingbert

Pharmycron storage rooms:

Building A and B, Am Schindwasen 16 and 20, 66386 St. Ingbert

Zu 1.4.2.5: only release

Zu 1.6: only ID-check and Determination of the particle size of the micronized active substances with
the exception of tabramycin (USP, full analysis)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.2 Microbiological: non-sterility</i>
	<i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i>
	2.2.1.2 Terminally sterilised

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

Tobramycin (USP) exclusively for the Export into Switzerland