MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_NW_03_MIA_2022_0008/24.05.05.01-Lindopharm
2. Name of authorisation holder	Lindopharm GmbH
3. Address(es) of manufacturing site(s)	Lindopharm GmbH Neustraße 82 40721 Hilden
4. Legally registered address of authorisation holder	Neustraße 82 40721 Hilden
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (AMG, German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Ute Neuberger
8. Signature	On behalf
9. Date	11/03/2022
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories) Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
Lindopharm GmbH, Neustraße 82, 40721 Hilden

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.13 Tablets
	1.2.1.17 Other non-sterile medicinal product Powder Granulates
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.13 Tablets
	1.5.1.17 Other non-sterile medicinal products Powder Granulates
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.2.1.13: Manufacturing tablets includes tablets, that contain substances with hormonal activity. Lindopharm Gmbh has an external warehouse at Hofstr. 64, 40723 Hilden, Germany.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
	2.2.3 Biological products
	2.2.3.6 Human or animal extracted products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

2.2 + 2.3 refers exclusively to the active substance Glucosamine sulphate-sodium chloride.
The import licence is valid until March 6th, 2023.

Corporate Address:
Andhra Medi Pharma India PvT Ltd.
D.No-40-25-35/1 Opposite Kesava Towers,
Asramam Street, Patamatalanka,
Vijayawada-520010, Andhrapradesh, India

Manufacturing Site:
Andhra Medi Pharma India PvT Ltd.
Sy.No-263, veeravalli Village,
Bapulapadu Mandal, Krishna District,
Andhrapradesh-521110, India

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
Lindopharm GmbH, Neustraße 82, 40721 Hilden

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.1 Capsules, hard shell
	1.2.1.8 Other solid dosage forms Special requirements 7. Others Powder Granules
	1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.1 Capsules, hard shell
	1.5.1.8 Other solid dosage forms Special requirements 7. Others Powder Granules
	1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

1.2.1.13:
Manufacturing tablets includes tablets, that contain substances with hormonal activity.

Annex 4

Address(es) of Contract Laboratories	IMQ Institut für mikrobiologische Qualitätssicherung Benninghofer Weg 2 40822 Mettmann Testing of microbiological quality of non-sterile products Techpharm GmbH Draisstr. 14 76646 Bruchsal - thin layer chromatography (Ph.Eur. 2.2.27) - osmolality (Ph.Eur. 2.2.35) Henkel KGaA Henkelstr. 67 40191 Düsseldorf - thin layer chromatography (Ph.Eur. 2.2.27)

Annex 8

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).

Glucosaminsulfat-Natriumchlorid
Firmensitz:
Andhra Medi Pharma India PvT Ltd.
D.No-40-25-35/1 Opposite Kesava Towers,
Asramam Street, Patamatalanka,
Vijayawada-520010, Andhrapradesh, India

Hersteller:
Andhra Medi Pharma India PvT Ltd.
Sy.No-263, veeravalli Village,
Bapulapadu Mandal, Krishna District,
Andhrapradesh-521110, India