Federaal agentschap voor geneesmiddelen en gezondheidsproducten
Galileelaan 5/03
1210 BRUSSEL
www.fagg.be

VAN ROOIJEN PHARMA NV: VERGUNNING GMDP n° 1572 H

Bij toepassing van de artikels 12bis en 12ter van de wet van 25 maart 1964 op de geneesmiddelen voor menselijk gebruik :

de firma : **Van Rooijen Pharma NV**

ondernemingsnummer	0478.869.796
maatschappelijke zetel	Schietstandlaan 2300 Turnhout
administratieve zetel	Schietstandlaan 2300 Turnhout

met als plaats van verrichtingen :

- Industriedijk 15, 2300 Turnhout

wordt vergunning verleend om:

- de activiteiten uit te voeren aangegeven op de vergunning voor fabricage/invoer (MIA) (2 pagina's) en de distributieactiviteiten van de betreffende geneesmiddelen.
- de activiteiten uit te voeren aangegeven op de vergunning voor distributie (WDA) (2 pagina's)

Hugues Malonne
Administrateur-generaal
Afgevaardigde van de Minister van Volksgezondheid

In opdracht Ethel Mertens
Directeur-generaal
DG Inspectie

Ethel Mertens (Signature)
Digitally signed by Ethel Mertens (Signature)
Date: 2024.05.06 15:53:17 +02'00'

Elke wijziging van de gegevens, die op dit document zijn vermeld (met inbegrip van de vergunning voor fabricage/invoer (MIA) en distributie (WDA)), maakt deze vergunning ongeldig. Bij dergelijke wijzigingen moet de vergunning noodzakelijk worden vernieuwd. De authenticiteit van het document kan worden bevestigd door het Federaal agentschap voor geneesmiddelen en gezondheidsproducten (FAGG) door contact op te nemen met de mailbox «eudragmdp@fagg-afmps.be ». De authenticiteit van de MIA of de WDA kan worden geverifieerd door het raadplegen van de EudraGMDP databank (http://eudragmdp.eudra.org/). Alleen de eerste pagina is ondertekend. De handtekening op de eerste pagina geldt ook voor de MIA en/of de WDA die bij de eerste pagina zijn gevoegd.

Federal Agency for Medicines and Health Products (FAMHP)
Avenue Galilée - Galileelaan 5/03
1210 BRUSSELS (BELGIUM)
www.fagg.be – www.afmps.be - www.famhp.be

Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	1572 H
2. Name of authorisation holder	Van Rooijen Pharma NV
3. Address(es) of manufacturing site(s)	Van Rooijen Pharma NV (ORG-100020371 / LOC-100052564), Industriedijk 15, Turnhout, 2300, Belgium
4. Legally registered address of authorisation holder	Schietstandlaan 2, Turnhout, 2300, Belgium
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Mr. Xavier De Cuyper
8. Signature	
9. Date	2021-02-18
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: 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)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3] *The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Van Rooijen Pharma NV, Industriedijk 15, Turnhout, 2300, Belgium

Additional Details:

Human Medicinal Products

Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Any restrictions or clarifying remarks related to the scope of these Importation operations (for Public users)

2.3. Other importation activities: Hall 2

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Federal Agency For Medicines And Health Products

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number	:	1572 H
2. Name of Authorisation Holder	:	Van Rooijen Pharma (ORG-100020371 / LOC-100029125)
3. Legally registered address of Authorisation Holder	:	Schietstandlaan 2, Turnhout, 2300
4. Address(es) of Site(s)	:	Industriedijk 15, Turnhout, 2300, Belgium
5. Scope of authorisation (complete for each site under 4)	:	ANNEX 1
6. Legal basis of authorisation	:	Art. 77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	:	Ethel Mertens, +32 2 528 4000
8. Signature	:	
9. Date	:	2024-03-19
10. Annexes attached	:	Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 (Optional) Additional provisions based on national requirements

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Van Rooijen Pharma
(ORG-100020371 / LOC-100052564)
, Industriedijk 15, Turnhout, 2300, Belgium

Human medicinal products

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)
1.3 without a Marketing Authorisation in the EEA and intended for exportation

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

Any restrictions or clarifying remarks (for all users): 1.3. Warehouse under the authority of the customs.
2.2. Hall 2 & Hall 3 (with cross-dock zone)
1.3. Opslagplaats onder de bevoegdheid van de douanes.
2.2. Hal 2 & Hal 3 (met cross-dock zone)

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004
**Without prejudice to further authorisations as may be required according to national legislation