EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation

eAF Version Number: 1.26.0.0

Revision 15

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Module 1.2: Administrative information
Application form

September 2021

[1] OJ L 299 of 27.10.2012, p. 1

TABLE OF CONTENTS

APPLICATION FORM

SUMMARY OF THE DOSSIER

APPLICATION FORM : ADMINISTRATIVE DATA

For all applications for a marketing authorisation of a medicinal product for human use submitted to (a) the European Medicines Agency under the centralised procedure or (b) a Member State (as well as Iceland, Liechtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure and for submissions to the European Medicines Agency under the centralised procedure use the electronic Application form available from http://esubmission.ema.europa.eu/eaf/index.html.

Usually a separate application form for each strength and pharmaceutical form is required.
For centralised procedures a combined application form should be used (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name Trientine Waymade 200 mg hard capsules

Pharmaceutical form (s): Capsule, hard

Strength:	Units
200	mg

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Full name of the active substance(s) (including salt or hydrate, if applicable):
TRIENTINE DIHYDROCHLORIDE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s)

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct,
please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Applicant	Waymade B.V
Address	Herikerbergweg 88
City / Locality / Town / Village	Amsterdam
State	
County	
Postcode	1101CM
Country	Netherlands
Telephone	[redacted]
E-mail	margi.shah@waymade.co.uk

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate and that such data are not subject to regulatory data exclusivity in the Union.

It is hereby confirmed that fees will be paid/have been paid according to the national/European Union rules**.

On behalf of the applicant

Copy contact details from previous section

Title	Ms.
First name*	Margi
Surname	Shah

Function
Head of Regulatory Affairs

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct,
please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Waymade Plc
Address	Sovereign House, Miles Gray Road
City / Locality / Town / Village	Basildon
State	
County	Essex
Postcode	SS14 3FR
Country	United Kingdom (Northern Ireland)
Telephone	[redacted]
E-mail	margi.shah@waymade.co.uk

Date
2022-05-25

Signatory

[redacted]

* ☐ ***Note: please attach letter of authorisation for communication/signing on behalf of the applicant in (Annex 5.4)***

** ☒ ***Note: if fees have been paid, attach proof of payment in (Annex 5.1) - see information on fee payments on EMA/CMDh website.***

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

◯ **1.1.1 A CENTRALISED PROCEDURE**

(according to Regulation (EC) No 726/2004)

◯ **1.1.2 A MUTUAL RECOGNITION PROCEDURE**

(according to Article 28(2) of Directive 2001/83/EC)

◉ **1.1.3 A DECENTRALISED PROCEDURE**

(according to Article 28(3) of Directives 2001/83/EC)

Reference Member State	Germany
Procedure number:	DE/H/6991/001/DC

Concerned Member State (specify)	Austria
Concerned Member State (specify)	Denmark
Concerned Member State (specify)	Greece
Concerned Member State (specify)	Spain
Concerned Member State (specify)	Finland
Concerned Member State (specify)	France
Concerned Member State (specify)	Italy
Concerned Member State (specify)	Netherlands
Concerned Member State (specify)	Norway
Concerned Member State (specify)	Portugal
Concerned Member State (specify)	Sweden
Proposed / Agreed common renewal date	As agreed after DCP in EOP

◯ **1.1.4 A NATIONAL PROCEDURE**

1.2 ORPHAN MEDICINAL PRODUCT DESIGNATION

1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

◯ **Yes** ◉ **No**

1.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY
Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?

◉ **Yes** ◯ **No**

Please specify the EU Orphan Designation Number:	EU/3/20/2321
Please specify the EU Orphan Designation Number:	EU/3/17/1898
Please specify the EU Orphan Designation Number:	EU/3/15/1573
Please specify the EU Orphan Designation Number:	EU/3/12/1089
Please specify the EU Orphan Designation Number:	EU/3/08/539

Has any of the designated orphan medicinal product(s) been granted a marketing authorisation in the EU?

◯ **Yes** ◉ **No**

1.3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION , WHERE APPLICABLE?

◯ **Yes** ***(complete sections below and also complete 1.4 + 1.6)*** ◉ **No** ***(complete section 1.4 + 1.6)***

1.4 APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC[2]

Note: Section to be completed for any application, including applications referred to in section 1.3
For further details, refer to Notice of Applicants, Volume 2A, Chapter 1
information on active substance status (new/known) should be provided in section 2.1.2

1.4.1 ◯ **Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*)**

1.4.2 ☒ **Article 10(1) generic application**

Note: . application for a generic medicinal product as defined in Article 10(2)(b) referring to a so-called reference medicinal product with a marketing authorisation granted in a Member State or in the Community.
. complete administrative and quality data, appropriate pre-clinical and clinical data when applicable.
. refer to Notice to Applicants, Volume 2A, Chapter 1.

Reference medicinal product:

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.

■ **Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA:**

Product (invented) name Trientine dihydrochloride capsules 300 mg

Pharmaceutical form(s) Capsule, hard + —

Strength (s)	Units	Marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation
300	mg	Univar Solutions BV	PL 41626/0001	--	1985-08-08

Marketing authorisation granted by

☐ **Union**

☒ **Member State(EEA)** United Kingdom (Northern Ireland)

Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.

■ **Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:**

Member State(s) Austria

Member State(s) Germany

Member State(s) Denmark

Member State(s) Finland

Member State(s) France

Member State(s) Greece

Member State(s) Italy

Member State(s) Netherlands

Member State(s) Norway

Member State(s) Portugal

Member State(s) Spain

Member State(s) Sweden

Product (invented) name Cufence 200 mg hard capsules

Pharmaceutical form(s) Capsule, hard

Strength (s)	Units	Marketing authorisation holder (note 1)	Marketing authorisation number	Procedure number for MRP / DCP (if applicable)
200	mg	Univar Solutions BV	EU/1/19/1365/001	--

Marketing authorisation granted by

☒ **Union**

☐ **Member State(EEA)**

Note 1: Should be considered the "same" as the one identified above, as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licencees")

■ **Medicinal product which is or has been authorised in accordance with Union provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:**

Note: Should be in accordance with the notion of global marketing authorisation, if different from the medicinal product identified above..

Product (invented) name Cufence 200 mg hard capsule

Pharmaceutical form(s) Capsule, hard

Strength (s)	Units	Marketing authorisation holder (note 1)	Marketing authorisation number	Procedure number for MRP / DCP (if applicable)	Date of authorisation
200	mg	Univar Solutions BV	EU/1/19/1365/001	--	2019-07-25

Member State of source Germany

Bioavailabilty study(ies) reference number(s) / EudraCT numbers(s): 62420

Marketing authorisation granted by

☒ **Union**

☐ **Member State(EEA)**

Note: Section to be duplicated for each product used for the demonstration of bioequivalence.

1.4.3 ☐ **Article 10(3) hybrid application**

1.4.4 ◯ **Article 10(4) similar biological application**

1.4.5 ◯ **Article 10a well-established use application**

Note: For further details, refer to Notice to Applicants, Volume 2A, Chapter 1.
For extensions of bibliographical applications, cross references can only be made to pre-clinical and clinical data

1.4.6 ◯ **Article 10b fixed combination application**

Note: Complete administrative and complete quality, pre-clinical and clinical data on the combination only; for further details refer to Notice of Applicants, Volume 2A, Chapter 1.
For extensions of fixed combination applications, cross references can only be made to pre-clinical and clinical data

1.4.7 ◯ **Article 10c informed consent application**

Note: - Application for a medicinal product possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application
- Complete administrative data should be provided with consent to pharmaceutical, preclinical and clinical data
- The authorised product and the informed consent application can have the same or different MAH

1.4.8 ◯ **Article 16a Traditional use registration for herbal medicinal product**

Note: Complete application
Refer to Notice to Applicants, Volume 2A, Chapter 1

1.5 CONSIDERATION OF THIS APPLICATION REQUESTED UNDER THE FOLLOWING ARTICLE DIRECTIVE 2001/83/EC OR REGULATION (EC) NO 726/2004[3]

1.5.1 ◯ **Conditional Approval**

Note: centralised procedure only according to Article 14(7) of Regulation (EC) No 726/2004 and Commission Regulation (EC) No 507/2006

1.5.2 ◯ **Exceptional Circumstances**

Note: According to Article 22 of Directive 2001/83/EC and Article 14(8) of Regulation (EC) No 726/2004

1.5.3 ☐ **Accelerated Review**

Note: Centralised procedure only according to Article 14(9) of Regulation (EC) No 726/2004

1.5.4 ◯ **Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004**

(one year of market protection for a new indication)

1.5.5 ◯ **Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)**

1.5.6 ◯ **Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)**

1.6 REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')

☒ **Sections 1.6.1, 1.6.2 and 1.6.3 not applicable for well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products**

1.6.4 ☐ **ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:**

(Note: Also applies to Extension applications of PUMA)

1.6.5 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

◯ **Yes** ◯ **No** ◉ **Not Applicable**

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S) AND ATC CODE

2.1.1 Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway:

Trientine Waymade 200 mg hard capsules

(Value populated from the "Declaration" section.)

☒ **If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in (Annex 5.19)**

2.1.2 Active substance(s)

*Note: * active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field:*

Name should be based on the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name.*

(The value of the active substances field has been populated from "Declaration" section.)

Full name of the active substance(s) (including salt or hydrate, if applicable)	+
TRIENTINE DIHYDROCHLORIDE	
Base/active moiety of the active substance(s) (if different from above)	—
TRIENTINE	

Substance type : (e.g. chemical substance, recombinant biological Chemicals

For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC :

◯ **Claim for new active substance(s)**

Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)

☐ ***please provide evidence and justification to support the claim of new active substance status in annex 5.23***

◯ **Known active substance**

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code A16AX12

Group Other alimentary tract and metabolism, various alimentary tract and metabolism products

☐ **If no ATC code has been assigned, please indicate if an application for ATC code has been made**

2.2 STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)

(The values of the following fields have been populated from "Declaration" section.)

Pharmaceutical Form: Capsule, hard + —

Strength:	**Units**
200	mg

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

Active substance(s) (as used for expression of strength*)
TRIENTINE

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Add Active Substance(s) or Base / active moiety

2.2.2 Route(s) of administration (use current list of standard terms - European Pharmacopoeia)

Route of Administration	Oral use

2.2.3 Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

For each type of pack give:

2.2.3.1 Package size 1 bottle of 100 hard capsules

Note: For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed

Description
Trientine Waymade 200 mg hard capsules are packed in high density polyethylene (HDPE) bottles, containing silica gel strip, and closed with white polypropylene screw cap with induction heat seal liner.

For each container give:

Container	Bottle
Material	150cc white High Density Polyethylene round bottle closed with 38 mm white polypropylene screw cap with induction heat seal liner along with a 1 gm silica gel Strip.
Closure	Stopper
Administration Device	n/a

(Note: please also refer to section 2.2.4)

2.2.3.2 Proposed shelf life 30 Months

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

2.2.3.3 Proposed shelf life *(after first opening container)* 90 Days

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

2.2.3.4 Proposed shelf life *(after reconstitution or dilution)*

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

2.2.3.5 Proposed storage conditions
Store in a refrigerator (2°C – 8°C)

2.2.3.5 Proposed storage conditions
Do not freeze

2.2.3.5 Proposed storage conditions
Store in the original package

2.2.3.5 Proposed storage conditions
Keep the container tightly closed

2.2.3.5 Proposed storage conditions
in order to protect from moisture

2.2.3.6 Proposed storage conditions after first opening
n/a

2.2.3.7 Proposed storage conditions after reconstitution or dilution

☐ **Attach a list of Mock-ups or Samples / specimens sent with the application, as appropriate (see EMA / CMDh website) (Annex 5.17)**

2.2.4 Medical devices

Please tick the applicable statement(s) and duplicate section 2.2.4. as needed for each device component used with the medicinal product.

Does this application refer to one or more medical devices within the meaning of Article 2(1) of Regulation (EU) 2017/745 or one or more accessories to a medical device within the meaning of Article 2(2) of Regulation (EU) 2017/745 and meets any one of the following conditions:

a) medical device which incorporates, as an integral part, a medicinal product and the action of that medicinal product is principal and not ancillary to that of the device (Art 1(8), second subparagraph of Regulation (EU) 2017/745)

◯ **Yes** ◉ **No**

b) medical device intended to administer a medicinal product where they form a single integral product which is intended exclusively for use in the given combination and which is not reusable (Art 1(9) second subparagraph of Regulation (EU) 2017/745)

◯ **Yes** ◉ **No**

Note: in accordance with Annex I, Section 3.2, point 12 to Directive 2001/83/EC as amended by Article 117 of Regulation (EU) 2017/745, conformity of the device part with the general safety and performance requirements of Annex I to Regulation 2017/745 should be demonstrated by providing a manufacturer's EU declaration of conformity, a EU certificate issued by a Notified Body or a Notified Body opinion where applicable.

c) medical device incorporated as integral part of an ATMP (article 2 (d) of Regulation 1394/2007)

◯ **Yes** ◉ **No**

d) medical device is co-packaged with the medicinal product.
Note: the device must comply with Regulation (EU) 2017/745 including being CE-marked.

◯ **Yes** ◉ **No**

e) medical device which is supplied separately but referenced in the product information of the medicinal product
Note: the device must comply with Regulation (EU) 2017/745, including being CE-marked

◯ **Yes** ◉ **No**

2.2.5 Companion diagnostic

2.2.5.1

Is the medicinal product to be used with a companion diagnostic within the meaning of Article 2(7) of Regulation 2017/746?

◯ **Yes** ◉ **No**

2.3 LEGAL STATUS

2.3.1 Proposed dispensing/classification

(Classification under Article 1(19) of Directive 2001/83/EC)

☒ **Subject to medical prescription** ***(Complete 2.3.2)***

Add Selected

European Union / Member State	Austria
European Union / Member State	Germany
European Union / Member State	Denmark
European Union / Member State	Finland
European Union / Member State	France
European Union / Member State	Greece
European Union / Member State	Italy
European Union / Member State	Netherlands
European Union / Member State	Norway
European Union / Member State	Portugal
European Union / Member State	Spain
European Union / Member State	Sweden

☐ **Not subject to medical prescription** ***(Complete 2.3.3 & 2.3.4)***

2.3.2 For products subject to medicinal prescription

☒ **Product on prescription which may be renewed (if applicable)**

Add Selected

Member State	Austria
Member State	Germany
Member State	Finland
Member State	France
Member State	Greece
Member State	Italy
Member State	Netherlands
Member State	Norway
Member State	Portugal
Member State	Spain

Member State Sweden

☐ **Product on prescription which may not be renewed (if applicable)**

☐ **Product on special prescription***

☒ **Product on restricted prescription***

Add Selected ?

Member State Denmark

(Not all the listed options are available in each Member State. Applicants are invited to indicate which categories they are requesting, however, the Member States reserve the right to apply only those categories provided for in their national legislation)
*Note: *For further information, please refer to Article 71 of Directive 2001/83/EC*

2.3.3 Supply for products not subject to medical prescription

☐ **Supply through pharmacies only**

☐ **Supply through non-pharmacy outlets and pharmacies (if applicable)**

2.3.4 Promotion for products not subject to medical prescription

☐ **Promotion to health care professionals only**

☐ **Promotion to general public and health care professionals**

2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State

◯ **Centralised procedure** ◉ **National procedure including mutual recognition/decentralised procedure**

Copy contact details from Declaration Section

Add Selected ?

Member State	Austria
Member State	Denmark
Member State	Greece
Member State	Spain
Member State	Finland
Member State	France
Member State	Italy
Member State	Netherlands
Member State	Norway
Member State	Portugal
Member State	Sweden
Member State	Germany

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Waymade B.V
Address	Herikerbergweg 88
City / Locality / Town / Village	Amsterdam
State	
County	
Postcode	1101CM
Country	Netherlands
Telephone	+44 (0) 1268 535200
E-mail	margi.shah@waymade.co.uk

☒ **Attach proof of establishment of the applicant / MAH in the EEA (Annex 5.3)**

Has SME status been assigned by the EMA?

◯ **Yes** ◉ **No**

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

◉ **Yes (for fees paid, attach proof of payment in) (Annex 5.1)**

◯ **No**

For Member State	Greece
For Member State	Spain
For Member State	France
For Member State	Italy
For Member State	Portugal

◯ **Yes (for fees paid, attach proof of payment in) (Annex 5.1)**

◉ **No**

Copy address from above address details

Add Selected

For Member State	Austria
For Member State	Germany
For Member State	Denmark

For Member State	Finland
For Member State	Netherlands
For Member State	Norway
For Member State	Sweden

Billing address (when relevant)

VAT number	GB 321 6958 95

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Waymade PLC
Address	Sovereign House Miles Gray Road
City / Locality / Town / Village	Basildon
State	
County	Essex
Postcode	SS14 3FR
Country	United Kingdom (Northern Ireland)
Telephone	+44 (0) 1268 535200
E-mail	accounts.payable@waymade.co.uk
Purchase order(PO) number	

2.4.2 Person/Company authorised for communication on behalf of the applicant during the procedure in the European Union/ each Member State

Add Selected

Member State(s)	Austria
Member State(s)	Denmark
Member State(s)	Greece
Member State(s)	Spain
Member State(s)	Finland
Member State(s)	France
Member State(s)	Italy
Member State(s)	Netherlands
Member State(s)	Norway
Member State(s)	Portugal
Member State(s)	Sweden

Member State(s)	Germany

The below applicant details relates to all member states selected, if the applicant details are different for each member states then please repeat section.

Copy contact details from Declaration Section

Title	Ms.
First name	Margi
Surname	Shah

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Waymade Plc
Address	Sovereign House, Miles Gray Road
City / Locality / Town / Village	Basildon
State	
County	Essex
Postcode	SS14 3FR
Country	United Kingdom (Northern Ireland)
Telephone	[redacted]
E-mail	margi.shah@waymade.co.uk

☒ **If different to 2.4.1 above, attach letter of authorisation** **(Annex 5.4)**

2.4.3 Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union/each Member State

Add Selected

Member State(s)

Copy contact details from Declaration Section

Title	
First name	
Surname	

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City / Locality / Town / Village

State

County

Postcode

Country

Telephone

E-mail

☐ **If different to 2.4.1 above, attach letter of authorisation** **(Annex 5.4)**

2.4.4 Summary of the applicant pharmacovigilance system

Qualified person in the EEA for Pharmacovigilance

Add Selected

Member State(s)	Austria
Member State(s)	Denmark
Member State(s)	Greece
Member State(s)	Spain
Member State(s)	Finland
Member State(s)	France
Member State(s)	Italy
Member State(s)	Netherlands
Member State(s)	Norway
Member State(s)	Portugal
Member State(s)	Sweden
Member State(s)	Germany

Title	Mr.
First name	[redacted]
Surname	[redacted]

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	ProPharma Group GmbH
Address	Siemensdamm 62
City / Locality / Town / Village	Berlin
State	
County	
Postcode	13627
Country	Germany
24 H Telephone	+44 (0) 1279 406759
E-mail	joreilly@diamondpharmaservices.com

☒ **The above-mentioned qualified person resides[6] and operates in the EEA**

☒ **The qualified person is registered with Eudravigilance**

Pharmacovigilance system master file

Number	MFL3985

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	ProPharma Group GmbH
Address	Siemensdamm 62
City / Locality / Town / Village	Berlin
State	
County	
Postcode	13627
Country	Germany

☒ **The Pharmacovigilance system master file location has been registered in Article 57 database**

Note: For Risk Management Plan, see module 1, 1.8.2

[6] For the purposes of this application form, a Qualified Person Responsible for Pharmacovigilance "resides" in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.

2.4.5 Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)

Add Selected

European Union / Member State where application is made	Austria
European Union / Member State where application is made	Denmark
European Union / Member State where application is made	Greece
European Union / Member State where application is made	Spain
European Union / Member State where application is made	Finland
European Union / Member State where application is made	France
European Union / Member State where application is made	Italy
European Union / Member State where application is made	Netherlands
European Union / Member State where application is made	Norway
European Union / Member State where application is made	Portugal
European Union / Member State where application is made	Sweden
European Union / Member State where application is made	Germany

Name of the contact person

Title	Ms.
First name	[redacted]
Surname	[redacted]

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Dimond PV Services Ltd
Address	Suite 2, Ground Floor Field House
City / Locality / Town / Village	Harlow
State	
County	Essex
Postcode	CM20 2FB
Country	United Kingdom (Northern Ireland)
Telephone	+44 (0) 203 911 9501
E-mail	catherine.kenny@diamondpharmaservices.com

2.5 MANUFACTURERS

Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

2.5.1 a Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):

Batch Importing and Release Site-1

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Drehm Pharma GmbH
Address	Hietzinger Hauptstraße 37/2,
City / Locality / Town / Village	Wien
State	
County	
Postcode	1130
Country	Austria
Telephone	+43187952450
Manufacturer Facility E-mail	management@drehm.at

Manufacturing Authorisation number 481712

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

☐ **Enter EudraGDMP document reference number**

If available

☒ **Attach latest GMP certificate (Annex 5.9)**

Or

☐ **Enter EudraGDMP document reference number**

Batch Importing and Release Site-2

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name [redacted]

Address [redacted]

City / Locality / Town / Village [redacted]

County [redacted]

Postcode [redacted]

Country [redacted]

OrgID [redacted]

LocID [redacted]

Telephone [redacted]

Manufacturer Facility E-mail [redacted]

Manufacturing Authorisation number [redacted]

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

☐ **Enter EudraGDMP document reference number**

If available

☐ **Attach latest GMP certificate (Annex 5.9)**

Or

☐ **Enter EudraGDMP document reference number**

2.5.1 b Official batch release for Blood products and Vaccines
Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)

Laboratory name

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City / Locality / Town / Village

State

County

Postcode

Country

Telephone

E-mail

2.5.1.1 Contact person in the EEA for product defects and recalls

Title	Mr.
First name	Lawrence
Surname	Brown

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Waymade PLC
Address	Sovereign House Miles Gray Road
City / Locality / Town / Village	Basildon
State	
County	Essex
Postcode	SS14 3FR
Country	United Kingdom (Northern Ireland)
24 H Telephone:	07813857111
E-mail	lawrence.brown@waymade.co.uk

2.5.1.2 Batch control Testing arrangements
Site(s) in the EEA or in countries where an MRA or other European Union arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	[redacted]
Address	[redacted]
City / Locality / Town / Village	[redacted]
Postcode	[redacted]
Country	[redacted]
OrgID	[redacted]
LocID	[redacted]
Telephone	[redacted]
E-mail	[redacted]

Brief description of control tests carried out by the laboratory(ies) concerned
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Chemical/Physical

☒ **Attach copy of manufacturing authorisation(s) or other proof of GMP compliance** **(Annex 5.6)**

Or

☐ **Enter EudraGDMP document reference number**

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	[redacted]
Address	[redacted]
City / Locality / Town / Village	[redacted]
Postcode	[redacted]
Country	[redacted]
OrgID	[redacted]
LocID	[redacted]
Telephone	[redacted]
E-mail	[redacted]

Brief description of control tests carried out by the laboratory(ies) concerned
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Microbiological - non-sterility

☒ **Attach copy of manufacturing authorisation(s) or other proof of GMP compliance** **(Annex 5.6)**

Or

☐ **Enter EudraGDMP document reference number**

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name [redacted]

Address [redacted]

City / Locality / Town / Village [redacted]

County [redacted]

Postcode [redacted]

Country [redacted]

OrgID [redacted]

LocID [redacted]

Telephone

E-mail [redacted]

Brief description of control tests carried out by the laboratory(ies) concerned
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - non-sterility

☒ **Attach copy of manufacturing authorisation(s) or other proof of GMP compliance** **(Annex 5.6)**

Or

☐ **Enter EudraGDMP document reference number**

2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture:
(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.)

Finished product manufacturing site (manufacturing and primary packaging of the Trientine 200mg hard capsules is performed in Block B only)

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name [redacted]

Address [redacted]

[redacted]

City / Locality / Town / Village [redacted]

State [redacted]

County

Postcode [redacted]

Country [redacted]

Telephone [redacted]

E-mail [redacted]

Brief description of functions performed:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Processing of non-sterile medicinal product

Primary packaging

Secondary packaging

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - non-sterility

Storage and/or distribution

◯ **Site(s) is in the EEA:** ◉ **Site(s) is outside the EEA:**

if available,

D-U-N-S number[7]

☒ **Attach document equivalent of manufacturing authorisation in accordance with Article 8.3(k) of Directive 2001/83/EC (Annex 5.6)**

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of the agreement?

◉ **Yes** ◯ **No**

Please

☒ **Attach latest GMP certificate or other proof of GMP compliance (Annex 5.9)**

Or

Enter EudraGDMP document reference number:

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

◉ **Yes** ◯ **No**

☒ **If yes please provide summary information in (Annex 5.9) (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)**

[7] *The Data Universal Numbering System (D-U-N-S) is a system developed by Dun & Bradstreet (D&B) which assigns a unique digit numeric identifier to a single business entity. It is used in this case to facilitate the identification of manufacturing sites outside of EEA*

Secondary packaging site

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: *http://spor.ema.europa.eu/omswi/#/*

Clear Address

Company name	[redacted]
Address	[redacted]
	[redacted]
City / Locality / Town / Village	[redacted]
State	
County	[redacted]
Postcode	[redacted]
Country	[redacted]
Telephone	[redacted]
E-mail	[redacted]

Brief description of functions performed:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Secondary packaging

◉ **Site(s) is in the EEA:** ◯ **Site(s) is outside the EEA:**

Manufacturing authorisation number [redacted]

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

Enter EudraGDMP document reference number

Name of qualified person

(if not mentioned in manufacturing authorisation)

Secondary packaging site

Do you have a separate admin and manufacturer address? ◯ Yes ◉ No

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name [redacted]

Address [redacted]

City / Locality / Town / Village [redacted]

State

County [redacted]

Postcode [redacted]

Country [redacted]

Telephone [redacted]

E-mail [redacted]

Brief description of functions performed:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Secondary packaging

◉ **Site(s) is in the EEA:** ◯ **Site(s) is outside the EEA:**

Manufacturing authorisation number [redacted]

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

Enter EudraGDMP document reference number

Name of qualified person

(if not mentioned in manufacturing authorisation)

☒ **Attach flow chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 5.8)**

2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture

Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant.
For each site provide the relevant information.

(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

Active Substance	+
TRIENTINE DIHYDROCHLORIDE	—

Copy contact details from Declaration Section

Manufacturing of active substance

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name [redacted]

Address [redacted]

City / Locality / Town / Village [redacted]

State [redacted]

County

Postcode [redacted]

Country [redacted]

Telephone [redacted]

E-mail [redacted]

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

- Manufacturer of active substance by chemical synthesis
- Primary Packaging of active substance
- Quality Control Testing - Chemical/Physical
- Secondary Packaging of active substance
- Storage and/or distribution of active substance
- Quality Control Testing - Microbiological - non-sterility

☒ **Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)**

☒ **For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the principles and guidelines on good manufacturing practice for starting materials (Annex 5.22)**

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?

◯ **Yes** ◉ **No**

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

◉ **Yes** ◯ **No**

☒ **If yes, please provide summary information in(Annex 5.9) (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)**

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s)?

◯ **Yes** ◉ **No**

Is a Active Substance Master File to be used for the active substance(s)?

◯ **Yes** ◉ **No**

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

◯ **Yes** ◉ **No**

2.5.4 Contract companies used for all clinical trial(s) (including bioavailability and bioequivalence trials) included in the application or used for the validation of blood product manufacturing processes.
For each contract company, state where analytical tests are performed and where clinical data are collected and give:

Title of study	An open label, balanced, randomized, two-treatment, two-period, two-sequence, single-dose, crossover oral bioequivalence study of Trientine Dihydrochloride Capsules 300 mg of Waymade Plc, UK comparing with that of Cufence 200 mg hard capsules (equivalent to 300 mg of Trientine hydrochloride) of Univar BV Schouwburgplein 30-34, 3012 CL Rotterdam, The Netherlands in healthy, adult, human subjects under fasting conditions.
Protocol code	P-62420
EudraCT number	P-62420

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	QPS Bioserve India Pvt Limited
Address	Plot No 47, IDA Balanagar,
City / Locality / Town / Village	Hyderabad
State	Telangana
County	India

Postcode	500037
Country	India
Telephone	[redacted]
E-mail	[redacted]

Duty performed according to contract

Bioequivalence study, Clinical Facility, Clinical Laboratory, Bioanalytical, Pharmacokinetic & Statistical Analysis and Reporting Facility

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

Dosage form unit to which quantity the composition refers (e.g. 1 capsule)

Pharmaceutical Form Capsule, hard	200	mg

(The values of the pharmaceutical form, strength and active substances fields have been populated from "Declaration" section.)

Strength	Units
200	mg

List the active substance(s) separately from the excipient(s)

Clone

Each capsule contain

Name of active substance	Quantity / Unit			Reference / Monograph Standard
TRIENTINE DIHYDROCHLORIDE	equal to	300	**mg**	
		For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002		USP
For salts and hydrates only, corresponding to (indicate base/active moiety)				
TRIENTINE	equivalent to	200	mg	USP
		For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002		

Clone

Clone

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
STEARIC ACID TYPE 50	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone

+ — Clone

Composition of capsule shell (Cap)

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
TITANIUM DIOXIDE	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone
GELATIN	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone
WATER PH. EUR.	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone

+ — Clone

Composition of capsule shell (Body)

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
TITANIUM DIOXIDE	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone
GELATIN	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone
WATER PH. EUR.	equal to [redacted] mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur	— Clone

+ — Clone

qualitative and quantitative composition of Black Ink

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
SHELLAC	range From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
DEHYDRATED ALCOHOL	range From [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone
ISOPROPYL ALCOHOL	range From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone
BUTYL ALCOHOL	range From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone
PROPYLENE GLYCOL	range From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone

STRONG AMMONIA SOLUTION	range	From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone
IRON OXIDE BLACK (E172)	range	From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	E172	— Clone
POTASSIUM HYDROXIDE	range	From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone
PURIFIED WATER PH. EUR	range	From: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* To: [redacted] % *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph. Eur.	— Clone

*Note: * active substance should be indicated first as full substance. If the substance is included in the product as a salt or hydrate, this corresponding base/active moiety should be indicated in the additional field.*

*Name should be based on the following order of priority: INN**, Ph.Eur., National Pharmacopoeia, common name, scientific name*

Details of any overages should not be included in the formulation columns but stated below:

Active Substance	Overage	+

Excipient	Overage	+

2.6.2 List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?

☐ **NONE**

or specify below:

Name GELATIN

Function* ☐ **AS** ☒ **EX** ☐ **R**

☒ **Animal Origin susceptible to TSE****

☐ **Other Animal Origin**

☐ **Human Origin**

☒ **Certificate of suitability for TSE**

TSE number	R1-CEP 2000-344-Rev 03
TSE number	R1-CEP 2001-211-Rev 01
TSE number	R1-CEP 2000-050-Rev 02
TSE number	R1-CEP 2003-172-Rev 02
TSE number	R1-CEP 2001-424-Rev 03
TSE number	R1-CEP 2000-027-Rev 02
TSE number	R1-CEP 2000-029-Rev 05
TSE number	R1-CEP 2010-043-Rev 00
TSE number	R1-CEP 2001-332-Rev 02
TSE number	R1-CEP 2002-115-Rev 02
TSE number	R1-CEP 2002-110-Rev 00
TSE number	R1-CEP 2000-045-Rev 04
TSE number	R1-CEP 2006-086-Rev 00
TSE number	R1-CEP 2008-048-Rev 00

* *AS=active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/ culture medium (incl. those used in the preparation of master and working cell banks)*

** *as defined in section 2 (scope) of the CHMP Note for Guidance*

☒ **If a Ph. Eur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the Council of Europe attach it in (Annex 5.12)**

2.6.3 Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

◯ **Yes** ◉ **No**

2.6.4 Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

◯ **Yes** ◉ **No**

3. SCIENTIFIC ADVICE

3.1 Was there formal scientific advice(s) given by EMA for this medicinal product?

◯ **Yes** ◉ **No**

Was there scientific advice(s) given by Member State(s) for this medicinal product?

◉ **Yes** ◯ **No**

Member State	240000000000|United Kingdom (Northern Ireland)
Date	2019-11-29
Reference(s) of the scientific advice(s)	2191/Trientine dihydrochloride

Member State	240000000000|United Kingdom (Northern Ireland)
Date	2020-05-19
Reference(s) of the scientific advice(s)	2295/Trientine dihydrochloride (follow-up meeting to SAM 2191)

☒ **Attach copy of scientific advice(s)** **(Annex 5.14)**

4. OTHER MARKETING AUTHORISATION APPLICATIONS

4.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)-(l) OF DIRECTIVE 2001/83/EC

4.1.1 Is there another Member State(s) where an application for the same* product is pending**?

◯ **Yes** ◉ **No** ◯ **Not Applicable**

If yes, section 4.2 must be completed

4.1.2 Is there another Member state(s) where an authorisation is granted for the same* product?

◯ **Yes** ◉ **No**

4.1.3 Is there another Member State(s) where an authorisation was refused/suspended/revoked by competent authorities for the same* product?

◯ **Yes** ◉ **No**

If yes, section 4.2 must be completed

*Note: * "same product" means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees".*
*** This is covering applications submitted at an earlier time or in parallel to this application if not already listed under 1.1.2 or 1.1.3*

4.2 MARKETING AUTHORISATION APPLICATIONS FOR THE SAME PRODUCT IN THE EEA (SAME QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM FROM APPLICANTS BELONGING TO THE SAME MOTHER COMPANY OR GROUP OF COMPANIES OR WHICH ARE "LICENSEES").

Note: refer to Commission Communications 98/C229/03

☐ **Authorised**

☐ **Submitted (which are not considered as a multiple/duplicate application - see Section 4.3)**

☐ **Refused**

☐ **Withdrawn (by applicant before authorisation)**

☐ **Withdrawn (by applicant after authorisation)**

☐ **Suspended/revoked (by competent authority)**

4.3 FOR MULTIPLE / DUPLICATE APPLICATIONS OF THE SAME MEDICINAL PRODUCT

Multiple/duplicate applications (submitted simultaneously or subsequently to the original product) for:

Name of other product

Date of application (s)
Applicant

Procedure number for MRP/DCP (if applicable)

☐ **Attach copy of letter from Commission services, for centralised procedures only** **(Annex 5.16)**

4.4 MARKETING AUTHORISATION APPLICATIONS FOR THE SAME PRODUCT OUTSIDE THE EEA (I.E. FROM APPLICANTS BELONGING TO THE SAME MOTHER COMPANY OR GROUP OF COMPANIES OR WHICH ARE "LICENSEES". SAME QUALITATIVE AND QUANTITATIVE COMPOSITION IN THE ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM).

☐ **Authorised**

☐ **Pending**

☐ **Refused**

☐ **Withdrawn (by applicant before authorisation)**

☐ **Withdrawn (by applicant after authorisation)**

☐ **Suspended / revoked (by competent authority)**

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

☒ **5.1** **Proof of payment**

☐ **5.2** **Informed consent letter of marketing authorisation holder of authorised medicinal product.**

☒ **5.3** **Proof of establishment of the applicant in the EEA.**

☒ **5.4** **Letter of authorisation for communication on behalf of the applicant/MAH.**

☐ **5.5** (empty)

☒ **5.6** **Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply); any proof of authorisation in accordance with Article 8.3(k) of Directive 2001/83/EC.**

☐ **5.7** **Copy of the "Qualification of SME Status".**

☒ **5.8** **Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.**

☒ **5.9** **GMP certificate(s) or other proof of GMP complaince; Where applicable a summary of other GMP inspections performed.**

☐ **5.10** **Letter(s) of access to Active Substance Master File(s) or copy of Ph.Eur. Certificate(s) of suitability.**

☐ **5.11** **Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.**

☒ **5.12** **Ph. Eur. Certificate(s) of suitability for TSE.**

☐ **5.13** **Written consent(s) of the competent authorities regarding GMO release in the environment.**

☒ **5.14** **Scientific Advice given by CHMP and/or by member state(s).**

☐ **5.15** **Copy of Marketing Authorisation(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorisation number, the date of authorisation and the page which has been signed by the authorising competent authority will suffice).**

☐ **5.16** **Letter by Commission services regarding multiple applications.**

☐ **5.17** **List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites).**

☐ **5.18** **Copy of the Orphan Designation Decision.**

☒ **5.19** **List of proposed (invented) names and marketing authorisation holders in the concerned member states.**

☐ **5.20** **Copy of EMA certificate for a Vaccine Antigen Master File(VAMF).**

☐ **5.21** **Copy of EMA certificate for a Plasma Master File (PMF).**

☒ **5.22** **For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holders (i.e located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the principles and guidelines of good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.**

☐ **5.23** **Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 8(3) of Directive 2001/83/EC.**

Note: To include attachments with this form, do not use the paper clip function. Attachments and annexes should be included in the same (eCTD) folder as the application form. For more detailed guidance see the eAF user guidance.