EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation

eAF Version Number: 1.23.1.0

Revision 13

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Module 1.2: Administrative information
Application form

February 2018

This application form will be included in:

The Rules governing Medicinal Products in the European Union
The Notice to Applicants - Volume 2B - Common Technical Document - Module1 - Administrative information

To be noted:
As from 01/01/2016, mandatory use of electronic application forms for all procedures. This document is for information purposes only. Not to be used for submissions.

Revision 13
Update from February 2018.

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

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APPLICATION FORM

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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 CHLORHEXIDINE ALCOOLIQUE GILBERT HEALTHCARE 2%, solution pour application cutanée

Pharmaceutical form (s): Cutaneous solution

Strength:	Units
2	% (W/V)

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):
CHLORHEXIDINE DIGLUCONATE (20% SOLUTION)

*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)

Strength:	Units
70	% (V/V)

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):
ISOPROPYL ALCOHOL

*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	Laboratoires Gilbert
Address	928 Avenue du Général de Gaulle
City / Locality / Town / Village	Hérouville Saint-Clair
State	
County	
Postcode	14200
Country	France
Telephone	[redacted]
E-mail	[redacted]

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	[redacted]
First name*	[redacted]
Surname	[redacted]

Function
Responsible Pharmacist

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:
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Clear Address

Company name	Laboratoires Gilbert
Address	928 Avenue du Général de Gaulle
City / Locality / Town / Village	Hérouville Saint-Clair
State	
County	
Postcode	14200
Country	France
Telephone	[redacted]
E-mail	[redacted]

Date
2018-11-28

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)

◉ **1.1.4 A NATIONAL PROCEDURE**

Member State France

Application number (if available)

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**

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**

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:

CHLORHEXIDINE ALCOOLIQUE GILBERT HEALTHCARE 2%, solution pour application cutanée

(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)	+
CHLORHEXIDINE DIGLUCONATE (20% SOLUTION)	
Base/active moiety of the active substance(s) (if different from above)	—
ISOPROPYL ALCOHOL	
Base/active moiety of the active substance(s) (if different from above)	—

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 D08AC02

Group Chlorhexidine

☐ **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: Cutaneous solution + —

Strength:	Units
2	% (W/V)

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*)
CHLORHEXIDINE DIGLUCONATE (20% SOLUTION)
ISOPROPYL ALCOHOL

*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

Strength:	**Units**
70	% (V/V)

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*)
ISOPROPYL ALCOHOL

*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 Cutaneous 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 125 mL

2.2.3.1 Package size 250 mL

2.2.3.1 Package size 500 mL

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

Description
Bottle of polyethylene with a tamper-proof closure cap

For each container give:

Container Bottle

Material Polyethylene

Closure Cap

Administration Device n/a

2.2.3.2 Proposed shelf life 18 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)* 1 Months

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)* N/A

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
This medicinal product does not require any special storage conditions

2.2.3.6 Proposed storage conditions after first opening
This medicinal product does not require any special storage conditions

☒ **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

Does this application include one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC intended to administer a medicinal product?

☒ **No** ☐ **Yes**

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)***

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

European Union / Member State France

2.3.2 For products subject to medicinal prescription

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

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

☐ **Product on special prescription***

☐ **Product on restricted prescription***

(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)**

Member State France

2.3.4 Promotion for products not subject to medical prescription

☒ **Promotion to health care professionals only**

Member State France

☐ **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

Member State France

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	Laboratoires Gilbert
Address	928 Avenue du Général de Gaulle
City/Locality/Town/Village	Hérouville Saint-Clair
State	
County	
Postcode	14200
Country	France
Telephone	[redacted]
E-mail	[redacted]

☒ **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 France

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

Copy contact details from Declaration Section

Title	[redacted]
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:
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Clear Address

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Address	928 Avenue du Général de Gaulle
City / Locality / Town / Village	Hérouville Saint-Clair
State	
County	
Postcode	14200
Country	France
Telephone	[redacted]
E-mail	[redacted]

☐ **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

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

Title [redacted]

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 Laboratoires Gilbert

Address 928 Avenue du Général de Gaulle

City / Locality / Town / Village Hérouville Saint-Clair

State

County

Postcode 14200

Country France

24 H Telephone [redacted]

E-mail [redacted]

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

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

Pharmacovigilance system master file

Number [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 Laboratoires Gilbert

Address 928 Avenue du Général de Gaulle

City / Locality / Town / Village Hérouville Saint-Clair

State

County

Postcode 14200

Country France

☒ **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)

European Union / Member State where application is made France

Name of the contact person

Title [redacted]

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:
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County	
Postcode	14200
Country	France
Telephone	[redacted]
E-mail	[redacted]

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):

[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 [redacted]

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

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Address	928 Avenue du Général de Gaulle
City / Locality / Town / Village	Hérouville Saint-Clair
State	
County	
Postcode	14200
Country	France
24 H Telephone:	[redacted]
E-mail	[redacted]

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	
Address	
City / Locality / Town / Village	
State	
County	
Postcode	
Country	
Telephone	
E-mail	

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

☐ **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.)

[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

[redacted]

[redacted]

[redacted]

☒ **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	+
CHLORHEXIDINE DIGLUCONATE (20% SOLUTION)	—

Copy contact details from Declaration Section

[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

[redacted]

☐ **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?

[redacted]

(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	+
CHLORHEXIDINE DIGLUCONATE (20% SOLUTION)	—

Copy contact details from Declaration Section

[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

[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_[redacted]

[redacted]

☐ **Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites**

[redacted]

[redacted]

(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).

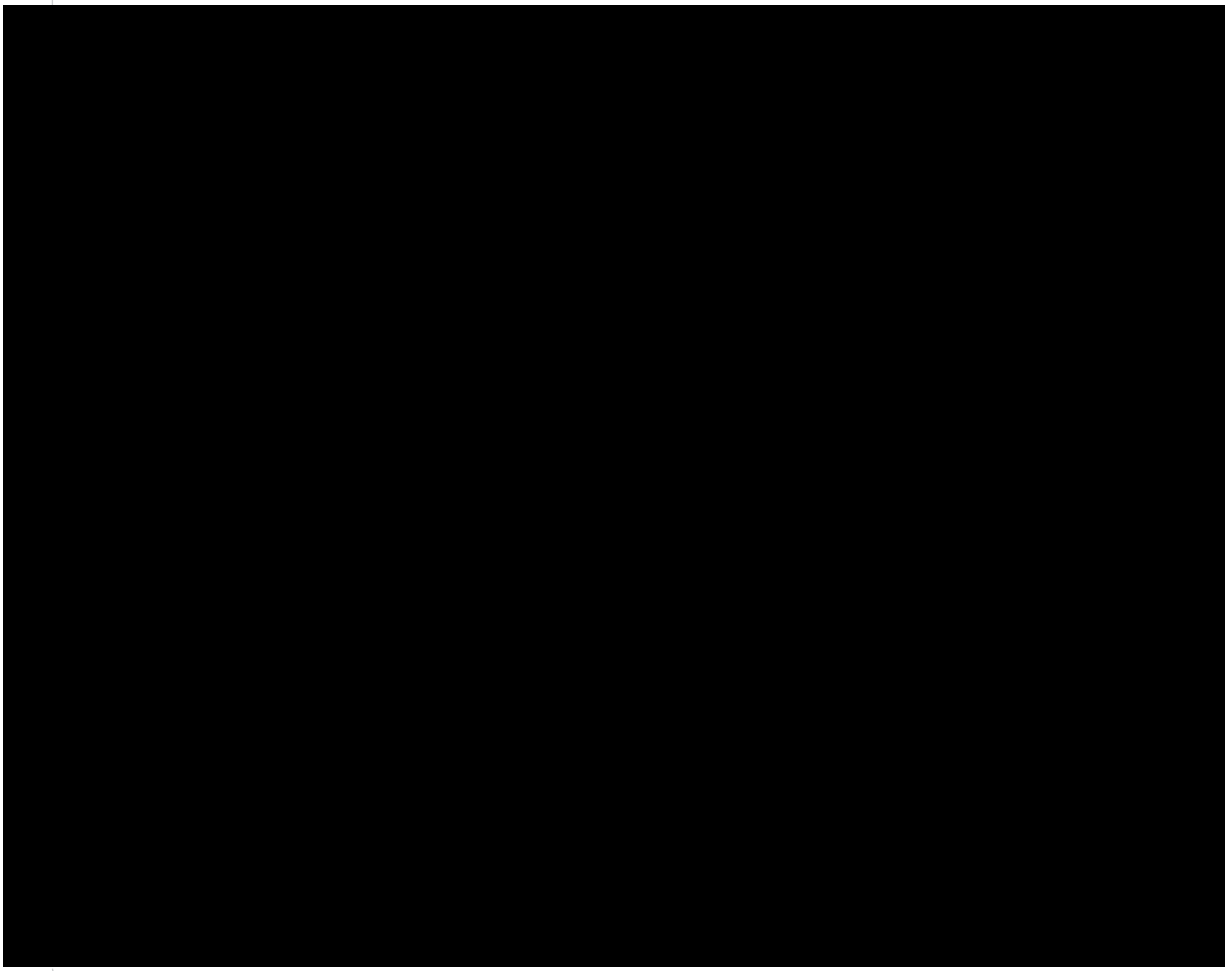
Active Substance	+
ISOPROPYL ALCOHOL	—

Copy contact details from Declaration Section

[redacted]

(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

[redacted]



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:

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 Cutaneous solution

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

Strength	Units
2	% (W/V)

Strength	Units
70	% (V/V)

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

Clone

Name of active substance	Quantity / Unit			Reference / Monograph Standard
CHLORHEXIDINE DIGLUCONATE (20% SOLUTION) For salts and hydrates only, corresponding to (indicate base/active moiety)	approximately equal to	2	**% (V/W)** *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	European Pharmacopoeia

Clone

Name of active substance	Quantity / Unit			Reference / Monograph Standard	+
ISOPROPYL ALCOHOL For salts and hydrates only, corresponding to (indicate base/active moiety)	approximately equal to	70	**% (V/V)** *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002* *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	European Pharmacopoeia	— Clone

+ — Clone

Name of Excipient	Quantity / Unit			Reference / Monograph Standard	+
CITRIC ACID	approximately equal to	[redacted]	*For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	European Pharmacopoeia	— Clone
PURIFIED WATER Q.S	quantity sufficient	[redacted]	*For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	European Pharmacopoeia	— Clone

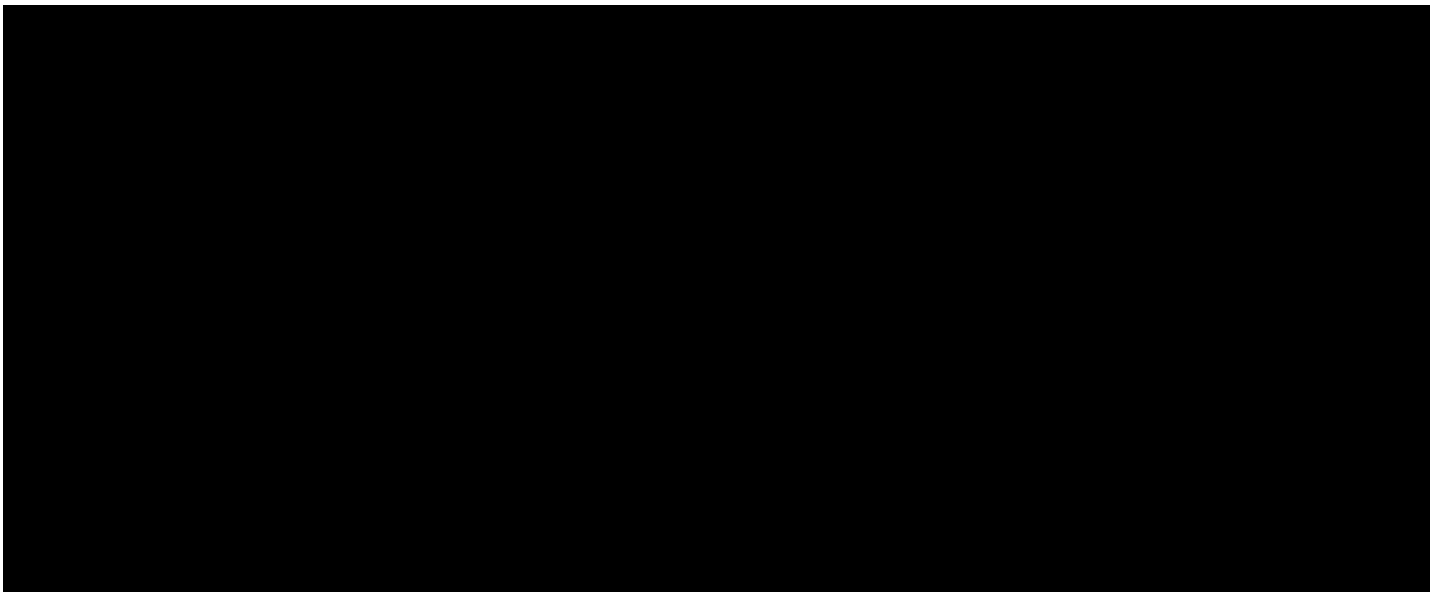
*Note: * active substance should be indicated first as full substance. If the substance is included in the product as a salt or hydrate, this corresponding base/active moiety should be indicated in the additional field.*

*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	+



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**

☐ **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.