|  |
| --- |
| **Form** |
| **Manufacturer information** |
| **Identification number:** | ZL000\_00\_037 |
| **Version:** | 1.5 |
| **Valid from:** | 11.09.2023 |

01.01.2099 / Name and dosage form

# Basic information

|  |  |
| --- | --- |
| **Name of medicinal product:** | Name and dosage form |
| **Authorisation no.:***If known* | …… |
| **Application ID:***If known* | …… |
| **Dosage strength(s):** | …… |
| **Dosage strength number(s):***(allocated with the authorisation; please specify only if the information below does not apply to all dosage strengths)* | …… |
| **Primary container(s):***(type and material)* | …… |
| **Date of last previously submitted *Manufacturer information* form\*:**  | …… |
| *\*Enter the date of the most recently submitted "Manufacturer information" form here, even if the application for which it was submitted is still under evaluation.* |

# General comments

* The purpose of this form is to provide comprehensive information about the manufacturer and test laboratory declared in the authorisation documents (CTD, NTA, VNEES).
* Fully completed and signed, it has to be submitted for new applications, changes in manufacturers and upon request by Swissmedic, e.g. within the context of market surveillance.
* If the information is not uniform for all dosage strengths, a separate form should be submitted for each uniform group of dosage strengths.
* If several manufacturers require a variation at the same time (exception: deletion of several manufacturers), a separate variation application has to be submitted for each manufacturer. In this case, combine all the variations in one form, Manufacturer information, and enclose it with each variation application.
* All manufacturers should always be listed, including those with no changes.
* Additional lines for entering manufacturer information can be inserted by copying and pasting.
* Subsections 2.1 and 3.1: If several sites or companies are involved in the manufacture of an active substance or a finished product (shared manufacturing), the form must indicate clearly which manufacturer performs which (individual) steps. This can generally be done by providing a brief description of the steps in question (choose the “Individual steps as per free text” option). If the manufacturing situation is complex, however, it may be most effective to submit flowcharts (choose the “Individual steps as per flowchart” option). Embed the flowcharts in section 5 of the form. The easiest way to do this is to use copies/snippets of the flowcharts in the CTD. If the flowcharts do not already include the names of the manufacturers, these should be added.
Please note: Sections 2 to 4 of the form must be completed even if flowcharts are being submitted.
* For transplant products / gene therapy and treatments with genetically modified organisms, the following should also be observed: The processing steps include, for example, cell extraction, cell expansion, cell differentiation, insertion of matrices, sublethal radiation, etc.

01.01.2099 / Name and dosage form

# Further information

|  |  |
| --- | --- |
| **Reason for submission:** |  |
| [ ]  New application (first authorisation) |  |
| [ ]  Submission at the request of Swissmedic | °°°°° *(details/reference)* |
| [ ]  Correction | °°°°° *(details/reference)* |
| [ ]  Changes concerning the manufacturer | Specific change(s):[ ]  2.1 Active substance manufacture (incl. micronisation,stabilisation, sterilisation, recrystallisation)[ ]  2.2 Quality control of active substance[ ]  3.1 Galenical production[ ]  3.2 Packaging/packer[ ]  3.3 Quality control[ ]  3.4 Batch release (all participants) |

|  |
| --- |
| **Additional information**[ ]  Co-marketing medicinal products involved (section 4)[ ]  Flowcharts available (section 5)[ ]  Additional information / Remarks / Other (section 6) |
| **All the entries made in this form are certified to be complete and accurate:***(company stamp of the applicant / authorisation holder)*……………… |
| *Authorised signatory* | *Other responsibilities (optional signature)* |
| Venue: ……Date: 01.01.2099Signature: …………………………….. | Venue: ……Date: ……Signature: …………………………….. |
| Last name: | …… | Last name: | …… |
| First name: | …… | First name: | …… |
| Position: | …… | Position: | …… |
| Telephone: | …… |  |
| E-mail: | …… |
|  |
| **The application must be sent to** | **For enquiries contact** |
| SwissmedicSwiss Agency for Therapeutic ProductsOperational Support ServicesHallerstrasse 73012 Bern | Telephone +41 58 462 02 11Fax +41 58 462 02 12E-mail Anfragen@swissmedic.ch |

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# Active substance manufacture

## Active substance manufacture (incl. micronisation, stabilisation, sterilisation, (re)crystallisation)

|  |
| --- |
| *To read the quickinfos place the cursor over the relevant field.* |
| [General information](#_Active_substance_manufacture) | [Active substances with CEP](#_Active_substance_manufacture) | [Premixes for active substance/excipient](#_Active_substance_manufacture) |
| [Intermediate manufacturer](#_Active_substance_manufacture) | [Homeopathically manufactured active substances](#_Active_substance_manufacture) | [Atypical active substances](#_Active_substance_manufacture) |
| * An RP Declaration must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*. The Annex Number references the corresponding RP Declaration.
* For details regarding manufacturers of herbal active substances, see guidance document *Details required regarding manufacturers of herbal active substances*.
* PLEASE list test/release laboratories under section 2.2
 |

|  |
| --- |
| **Active substance**(designation according to DCI, INN or pharmacopoeia): …… |
| **Currently approved** | **Applied for** | **Submitted but not yet approved** | **Manufacturer***Full address of the manufacturing site (no correspondence addresses, distributors or suppliers),**If available: also give the D-U-N-S Number or IDMP* | **Manufacturing activities***Select as appropriate* | **Type of change***Select as appropriate* |
| [ ]  | [ ]  | [ ]  | …… | [ ]  own doc.[ ]  ASMF[ ]  CEPMaster number(YYYY-nnn):…… | Select an option.*Free text only if none of the options above applies*…… | Select an option.*Free text only if none of the options above applies*…… |
|  |  |  |
| Annex number: …… |

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## Quality control of the active substance

|  |
| --- |
| *To read the quickinfos place the cursor over the relevant field.* |
| [General information](#_Quality_control_of) | [QC active substance (drug substance)](#_Quality_control_of) | [QC of intermediates](#_Quality_control_of) |
| [QC by several laboratories](#_Quality_control_of) | [QC by only one laboratory](#_Quality_control_of) | [Complementary medicinal products](#_Quality_control_of) |
| No further documents required, see guidance document *GMP compliance by foreign manufacturers.* |

|  |
| --- |
| **Active substance**(designation according to DCI, INN or pharmacopoeia): …… |
| **Currently approved** | **Applied for** | **Submitted but not yet approved** | **Manufacturer***Full address of the manufacturing site (no correspondence addresses, distributors or suppliers),**If available: also give the D-U-N-S Number or IDMP* | **Test laboratory for***Select as appropriate* | **Type of change***Select as appropriate* |
|  | **Quality control involves the following tests** |  |  |
| [ ]  | [ ]  | [ ]  | …… | [ ]  All[ ]  Physical/chemical[ ]  Microbiol. excludingsterility test[ ]  Sterility test[ ]  Biological | Select an option.*Free text only if none of the options above applies*…… | Select an option.*Free text only if none of the options above applies*…… |
|  |  |  |

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# Manufacture of finished product

## Galenical production of ready-to-use medicinal product

|  |
| --- |
| *To read the quickinfos place the cursor over the relevant field.* |
| [General information](#_Galenical_production_of) | [Terminal sterilisation](#_Galenical_production_of) | [Packer](#_Galenical_production_of) |
| [Assign manufacturing steps](#_Galenical_production_of) | [Solvent / diluent](#_Galenical_production_of) |  |
| An RP Declaration must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*. The Annex Number references the corresponding RP Declaration. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Currently approved** | **Applied for** | **Submitted but not yet approved** | **Manufacturer***Full address of the manufacturing site (no correspondence addresses, distributors or suppliers),**If available: also give the D-U-N-S Number or IDMP* | **Manufacturing activities***Select as appropriate* | **Type of change***Select as appropriate* |
| [ ]  | [ ]  | [ ]  | …… | [ ]  Details of the manufacturer of a solvent/diluent | Select an option.*Free text only if none of the options above applies*…… | Select an option.*Free text only if none of the options above applies*…… |
|  |  |  |
| Annex number: …… |

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## Packaging of the ready-to-use medicinal product

|  |
| --- |
| *To read the quickinfos place the cursor over the relevant field.* |
| [General information](#_Packaging_of_the) | [Primary packer of sterile products](#_Packaging_of_the) | [Several companies concerned](#_Packaging_of_the) |
| [Packaging by one company only](#_Packaging_of_the) | [Solvent/diluent 1](file://adb.intra.admin.ch/SMC%24/ORG/INFR/OSS/INTERN/Vorgabenmanagement/00_VMS/12_Projekt_Neues-Layout-externe-VD/ZL/2023-06-27-Liste-SiteCollection-ZL-FO-extern-Status-Freigegeben/ZL000_00_037e_FO_Manufacturer_information_HMV4.docx#SD1) | [Solvent/diluent 2](#_Packaging_of_the) |
| The documents must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers.* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Currently approved** | **Applied for** | **Submitted but not yet approved** | **Manufacturer***Full address of the manufacturing site (no correspondence addresses, distributors or suppliers),**If available: also give the D-U-N-S Number or IDMP* | **Manufacturing activities***Select as appropriate* | **Type of change***Select as appropriate* |
| [ ]  | [ ]  | [ ]  | …… | [ ]  Details of the manufacturer of a solvent/diluent | Select an option.*Free text only if none of the options above applies*…… | Select an option.*Free text only if none of the options above applies*…… |
|  |  |  |

01.01.2099 / Name and dosage form

## Quality control of the ready-to-use medicinal product

|  |
| --- |
| *To read the quickinfos place the cursor over the relevant field.* |
| [General information](#_Quality_control_of_1) | [Laboratories/companies to list](#_Quality_control_of_1) [1](file://adb.intra.admin.ch/SMC%24/ORG/INFR/OSS/INTERN/Vorgabenmanagement/00_VMS/12_Projekt_Neues-Layout-externe-VD/ZL/2023-06-27-Liste-SiteCollection-ZL-FO-extern-Status-Freigegeben/ZL000_00_037e_FO_Manufacturer_information_HMV4.docx#Kap33Abs2)[Laboratories/companies to list](#_Quality_control_of_1) [2](file://adb.intra.admin.ch/SMC%24/ORG/INFR/OSS/INTERN/Vorgabenmanagement/00_VMS/12_Projekt_Neues-Layout-externe-VD/ZL/2023-06-27-Liste-SiteCollection-ZL-FO-extern-Status-Freigegeben/ZL000_00_037e_FO_Manufacturer_information_HMV4.docx#Kap33Abs2) | [Solvent/diluent](#_Quality_control_of_1) | [QC by several companies](#_Quality_control_of_1) |
| The documents must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Currently approved** | **Applied for** | **Submitted but not yet approved** | **Manufacturer***Full address of the manufacturing site (no correspondence addresses, distributors or suppliers),**If available: also give the D-U-N-S Number or IDMP* | **Test laboratory for***Select as appropriate* | **Type of change***Select as appropriate* |
|  | **Quality control involves the following tests** |  |  |
| [ ]  | [ ]  | [ ]  | …… | [ ]  All[ ]  Physical/chemical[ ]  Microbiol. excludingsterility test[ ]  Sterility test[ ]  Biological | Select an option.*Free text only if none of the options above applies*…… | Select an option.*Free text only if none of the options above applies*…… |
|  |  |  |
|  | [ ]  Details of the manufacturer of a solvent/diluent |

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## Batch release of the ready-to-use medicinal product (technical release)

(To read the quickinfos place the cursor over the relevant field)

|  |  |  |  |
| --- | --- | --- | --- |
| [General information](#_Batch_release_of) | [Release of a batch](#_Batch_release_of) | [Laboratories/companies to list](#_Batch_release_of) | [Solvent/diluent](#_Batch_release_of) |
| The documents must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Currently approved** | **Applied for** | **Submitted but not yet approved** | **Manufacturer***Full address of the manufacturing site (no correspondence addresses, distributors or suppliers),**If available: also give the D-U-N-S Number or IDMP* | **Release stage***e.g. batch release for contract manufacturer**(Free text)* | **Type of change***Select as appropriate* |
| [ ]  | [ ]  | [ ]  | …… | [ ]  Details of the manufacturer of a solvent/diluent | …… | Select an option.*Free text only if none of the options above applies*…… |
|  |  |  |

01.01.2099 / Name and dosage form

# List of all affected co-marketing medicinal products

You also hereby confirm that you have informed the authorisation holders of the co-marketing medicinal products concerned.

|  |
| --- |
| **Co-marketing medicinal products:**…… |

01.01.2099 / Name and dosage form

# Flowcharts

If flowcharts are used to depict complex manufacturing situations, please insert these in the relevant subsection and refer to the instructions in “General comments” on page 1 of this form.

## Flowchart(s) drug substance

……

## Flowchart(s) QC drug substance

……

## Flowchart(s) drug product

……

## Flowchart(s) packaging/packer

……

## Flowchart(s) QC drug product

……

## Flowchart(s) batch release

……

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# Additional information / Remarks / Other

Further details on section ……

# Annex – Explanations concerning the form

## General note

From page 1, the new Manufacturer information form contains a page identifier at the top left, below the header. This is composed of two bookmarks ([Name and dosage form] from page 1 and the compulsory [date] from page 2, e.g. [Headache tablets 200mg / 12.08.2016]. Under no circumstances may this page identifier be edited or deleted.

Bookmarks are an option of MS Word 2010/2013 and are shown in square brackets. In order to view them, select the **File** tab, then **Options** and the **Advanced** section. Then enable the **Show bookmarks** option under **Show document content**.

Double-click between the square brackets to open the **Options for text form fields** window. You can now edit the **Default text** field. Click OK to close the window again.

The page identifier can be updated as follows: Select all of the text on the form by pressing CTRL A, then press F9. The selection can be cancelled again by positioning the cursor anywhere in the document.

| Page/Section/Paragraph | Explanation(s) |
| --- | --- |
| 01/Below the header/01.01.2099 / Name and dosage form | Page identifier composed of the two bookmarks ([Name and dosage form] from page 1 and the compulsory [date] from page 2.N.B.: Under no circumstances may this page identifier be edited or deleted. |
| 01//Name and dosage form of the medicinal product | This is a bookmark, see above. |
| 01//Dosage strength(s) | The entries on the form apply to:* 1 DS or
* 1 DS group or
* 1 medicinal product
 |
| 01//Gen. comments, bullets 1 and 2 | The purpose of this form is to provide comprehensive information about the manufacturer and test laboratory declared in the authorisation documents (CTD, NTA, VNEES).Fully completed and signed, it has to be submitted for new applications, changes in manufacturers and upon request by Swissmedic, e.g. within the context of market surveillance. |
| 01//Gen. comments, bullet 3 | If the information is not uniform for all dosage strengths, a separate form should be submitted for each uniform group of dosage strengths. |
| 01//Gen. comments, bullet 4 | Basically, changes relating to just one manufacturer are allowed for each application.Exception: Deletion of more than one manufacturer. |
| 01//Gen. comments, bullet 4 | If several manufacturers require a variation at the same time (see above for exception), a separate variation application must be submitted for each manufacturer. In this case all variations can be combined in one Manufacturer information form and enclosed with each variation application. |
| 01//Gen. comments, bullet 5 | All manufacturers should always be listed, including those with no changes. |
| 01//Gen. comments, bullet 6 | Additional lines for entering manufacturer information can be inserted by copying and pasting.[[1]](#footnote-1) |
| 01//Gen. comments, bullet 7 | Subsections 2.1 and 3.1: If several sites or companies are involved in the manufacture of an active substance or a finished product (shared manufacturing), the form must indicate clearly which manufacturer performs which (individual) steps. This can generally be done by providing a brief description of the steps in question (choose the “Individual steps as per free text” option). If the manufacturing situation is complex, however, it may be most effective to submit flowcharts (choose the “Individual steps as per flowchart” option). Embed the flowcharts in section 5 of the form. The easiest way to do this is to use copies/snippets of the flowcharts in the CTD. If the flowcharts do not already include the names of the manufacturers, these should be added.Please note: Sections 2 to 4 of the form must be completed even if flowcharts are being submitted. |
| 02/1./Reason for submission, correction | If, for a pending application, a corrected version of the previous version of the form must be submitted within a few days, please check this item and briefly justify the correction (Details/reference) |
| 02/1./Reason for submission | Section 2 was renamed to 2.1 for AS manufacture |
| 02/1./Reason for submission | New section 2.2 for QC AS, which was previously lacking |
| 02/1./Additional information | This information provides a better description of the submitted data |
| 02/1./Completeness and accuracy | The signing individual confirms that all entries in this form reflect the current situation.In the event of any discrepancies, Swissmedic will issue a complaint and request a statement. Depending on the contents of this statement, administrative proceedings may be initiated by MS. |
| 02/1./Completeness and accuracy (date in the “Obligatory” column) | This is a bookmark, see top of previous page. |
| 02/1./For enquiries | The stated phone number is for the Swissmedic switchboard (Reception) |
| 03/2.1/General informationQUICKINFO[[2]](#footnote-2) | For each active substance manufacturer, state whether separate documentation for the active substance, an Active Substance Master File (ASMF) or a Certificate of suitability (CEP) has been submitted. |
| 03/2.1/Active substances with CEPQUICKINFO | Enter the master no. here, e.g. 2013-015. |
| 03/2.1/Premixes for active substance/excipientQUICKINFO | Premixes for active substances/excipients are accepted only if these serve to ensure stability or safety.If a premix for AS/Ex is needed, the manufacturer that carries out the step in question should be stated. The step should be specified. |
| 03/2.1/Intermediate manufacturerQUICKINFO | The situation should in principle be documented in accordance with the entries in the CTD. List the relevant manufacturing steps in section 5 as a flowchart. |
| 03/2.1/Homeopathically manufactured active substances QUICKINFO | All manufacturers of mother tinctures, first triturations, intermediate and final potencies have to be specified. |
| 03/2.1/Documents to be submitted | An RP Declaration must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*.The Annex Number references the corresponding RP Declaration.[[3]](#footnote-3) |
| 03/2.1/Atypical active substances | For pharma-atypical active substances (e.g. paraffin, camphor, iodine, urea, etc.) please use the free text field for manufacturing activities.GMP compliance must be documented in Part D of the RP Declaration. |
| 03/2.1/Details regarding manufacturers of herbal active substances | The guidance document provides details of the information required.Test laboratories for active substances should be listed under section 2.2 |
| 03/2.1/ Manufacturer - Address | The address should be entered here.D-U-N-S Number or IDMP:If known, these identification numbers should be stated. |
| 03/2.1/ Manufacturer - Status (checkbox) | The corresponding checkbox should be checked depending on the status.For manufacturers that are “Proposed but not yet approved”, the date of the cover letter (for the corresponding application) should also be stated. |
| 03/2.1/Manufacturer - Documentation type (checkbox) | Documentation of the active substance:**One** box must be checked for own doc, ASMF or CEP.A CEP number RX-CEP 2000-001-rev YY consists of a fixed part, a master number (year of application + chronological number) and a variable part (to indicate "renewal" and "revision" of a certificate).Swissmedic only needs the master no. to identify the active substance, i.e. information on "renewal" or "revision" is not required. |
| 03/2.1/Manufacturer - Manufacturing activities | The appropriate manufacturing activity should be selected from the dropdown menu. Please avoid free text:Active substance manufacture – all steps[[4]](#footnote-4)Active substance manufacture – final step, incl. release[[5]](#footnote-5)Active substance manufacture – individual steps as per flowchartActive substance manufacture – individual steps as per free textMicronisation of active substanceSterilisation of active substance(Re)crystallisationPremix for active substance/excipientMaster cell bankWorking cell bankMother tinctureFirst triturationIntermediate potency/potenciesFinal potency |
| 03/2.1/Manufacturer - Type of change | The appropriate type of variation should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Manufacturer up to date/unchangedAddress change, same locationName change, same locationManufacturer deletedNew/additional manufacturerChangeover in active substance documentation |
| 04/2.2./General informationQUICKINFO | Quality control is a constituent part of manufacture and is also subject to GMP provisions. |
| 04/2.2/QC active substance (drug substance)QUICKINFO | All laboratories/companies (including third-party laboratories!) that carry out quality controls on drug substances should be listed per the entries in the CTD. |
| 04/2.2/QC IntermediatesQUICKINFO | Laboratories declared in the CTD as testing intermediates should also be listed. However, IPC labs should NOT.QC of the drug product: see section 3.3 |
| 04/2.2/QC by several laboratoriesQUICKINFO | The individual quality controls should be unequivocally assigned to the relevant test laboratory (manufacturer). If necessary, the sequences should be documented in section 5 Flowcharts. |
| 04/2.2/QC by only one laboratoryQUICKINFO | If the manufacturer carries out all quality controls, enter “All”. |
| 04/2.2/Homeopathic and anthroposophic medicinal productsQUICKINFO | All test laboratories from the testing of the starting materials onward should be listed. |
| 04/2.2/Documents to be submitted | No further documents required, see guidance document *GMP compliance by foreign manufacturers* |
| 04/2.2/Manufacturer - Address | The address should be entered here.D-U-N-S Number or IDMP:If known, these identification numbers should be stated. |
| 04/2.2/Manufacturer - Status (checkbox) | The corresponding checkbox should be checked depending on the status.For manufacturers that are “Proposed but not yet approved”, the date of the cover letter (for the corresponding application) should also be stated. |
| 04/2.2/Manufacturer - Quality control involves the following tests | **One** box per manufacturer must be checked:AllPhysical/chemical (tests)Microbiol. (tests) excluding sterility testSterility testBiological (tests)The term "All" means all tests performed according to specifications for the active substance or finished product.The four points listed are a selection of the most commonly used tests.The free text field is available for entering other tests. |
| 04/2.2/Manufacturer – Test laboratory for | The appropriate value should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Drug substanceIntermediate drug substance |
| 04/2.2/Manufacturer - Type of change | The appropriate type of variation should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Manufacturer up to date/unchangedAddress change, same locationName change, same locationManufacturer deletedNew/additional manufacturer |
| 05/3.1./General informationQUICKINFO | Processing steps to be entered here include, for example, granulation, tabletting, coating (film-coating), lyophilisation, filling of capsules, terminal sterilisation and the primary packaging of sterile preparations. |
| 05/3.1/Terminal sterilisationQUICKINFO | Sites that carry out terminal sterilisation should be entered separately if sterilisation involves irradiation, gassing or similar techniques. |
| 05/3.1/PackerQUICKINFO | The packer should be stated under 3.2 (exception: companies that carry out the primary packaging of sterile preparations should be entered here). |
| 05/3.1/Assign manufacturing stepsQUICKINFO | The individual manufacturing steps should be unequivocally assigned to the relevant manufacturer. If necessary, the steps should be documented in section 5 in a flowchart. |
| 05/3.1/Solvent/diluentQUICKINFO | If the finished product includes a solvent/diluent, its packer should also be stated and a cross entered in the Solvent/diluent checkbox in the following table. |
| 05/3.1/Documents to be submitted | An RP Declaration must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*.The Annex Number references the corresponding RP Declaration. |
| 05/3.1/Manufacturer - Address | The address should be entered here.D-U-N-S Number or IDMP:If known, these identification numbers should be stated. |
| 05/3.1/ Manufacturer - Status (checkbox) | The corresponding checkbox should be checked depending on the status.For manufacturers that are “Proposed but not yet approved”, the date of the cover letter (for the corresponding application) should also be stated. |
| 05/3.1/Manufacturer - Solvent / diluent (checkbox) | Packer of a solvent/diluent:**One** box should be checked if applicable.If the primary and secondary packers of the solvent/diluent are identical, please state this **only** under section 1.1. |
| 05/3.1/Manufacturer - Manufacturing activities | The appropriate value should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Galenical production - all stepsGalenical production - individual steps as per flowchartGalenical production - individual steps as per free textPrimary packing of sterile preparationsSterilisation |
| 05/3.1/Manufacturer - Type of change | The appropriate type of variation should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Manufacturer up to date/unchangedAddress change, same locationName change, same locationManufacturer deletedNew/additional manufacturer |
| 06/3.2./General informationQUICKINFO | Packing includes primary and secondary packing, labelling (sterile preparations: see entries under 3.1) |
| 06/3.2/Primary packer of sterile productsQUICKINFO | Primary packers of sterile products should be listed under 3.1 |
| 06/3.2/Several companies concernedQUICKINFO | The individual manufacturing steps (manufacturing activities) should be unequivocally assigned to the relevant manufacturer. If necessary, the steps should be documented in section 5 in a flowchart. |
| 06/3.2/Packaging by one company onlyQUICKINFO | If the manufacturer carries out all packing steps, enter “All steps”. |
| 06/3.2/Solvent/diluent 1QUICKINFO | If the finished product includes a solvent/diluent, its secondary packer should also be stated and a cross entered in the Solvent/diluent checkbox in the following table. |
| 06/3.2/Solvent/diluent 2QUICKINFO | If the primary and secondary packers of the solvent/diluent are identical, please state this only under section 3.1. |
| 06/3.2/Documents to be submitted | The documents must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign*. |
| 06/3.2/Manufacturer - Address | The address should be entered here.D-U-N-S Number or IDMP:If known, these identification numbers should be stated. |
| 06/3.2/Manufacturer - Status (checkbox) | The corresponding checkbox should be checked depending on the status.For manufacturers that are “Proposed but not yet approved”, the date of the cover letter (for the corresponding application) should also be stated. |
| 06/3.2/Manufacturer - Solvent / diluent (checkbox) | Packer of a solvent/diluent:**One** box should be checked if applicable.If the primary and secondary packers of the solvent/diluent are identical, please state this **only** under section 3.1. |
| 06/3.2/Manufacturer - Manufacturing activities | The appropriate value should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Primary packingSecondary packingAll steps |
| 06/3.2/Manufacturer - Type of change | The appropriate type of variation should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Manufacturer up to date/unchangedAddress change, same locationName change, same locationManufacturer deletedNew/additional manufacturer |
| 07/3.3/GMP provisionsQUICKINFO | Quality control is a constituent part of manufacture and is also subject to GMP provisions. |
| 07/3.3/Laboratories/companies to listQUICKINFO | All laboratories/companies (including third-party laboratories!) that carry out quality controls of the finished product (drug product) should be listed in accordance with the entries in the CTD. Laboratories declared in the CTD as testing intermediates should also be listed. However, IPC labs should NOT.QC of the drug substance, see section 2.2 |
| 07/3.3/Solvent/diluentQUICKINFO | If the finished product includes a solvent/diluent, the corresponding test laboratory/laboratories should be stated and a cross entered in the Solvent/diluent checkbox in the following table. |
| 07/3.3/Assign testsQUICKINFO | The individual quality controls should be unequivocally assigned to the relevant test laboratory (manufacturer). If the manufacturer carries out all quality controls, enter “All tests”. If necessary, the sequences should be documented in section 5 in a flowchart. |
| 07/3.3/Documents to be submitted | The documents must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*. |
| 07/3.3/Manufacturer - Address | The address should be entered here.D-U-N-S Number or IDMP:If known, these identification numbers should be stated. |
| 07/3.3/Manufacturer - Status (checkbox) | The corresponding checkbox should be checked depending on the status.For manufacturers that are “Proposed but not yet approved”, the date of the cover letter (for the corresponding application) should also be stated. |
| 07/3.3/Manufacturer - Quality control involves the following tests | **One** box per manufacturer must be checked:AllPhysical/chemical (tests)Microbiol. (tests) excluding sterility testSterility testBiological (tests)The term "All" means all tests performed according to specifications for the active substance or finished product.The four points listed are a selection of the most commonly used tests.The free text field is available for entering other tests. |
| 07/3.3/Manufacturer - Solvent / diluent (checkbox) | Packer of a solvent/diluent:**One** box should be checked if applicable.If the primary and secondary packers of the solvent/diluent are identical, please state this **only** under section 1.1. |
| 07/3.3/Manufacturer – Test laboratory for | The appropriate value should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Drug productIntermediate drug product |
| 07/3.3/Manufacturer - Type of change | The appropriate type of variation should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Manufacturer up to date/unchangedAddress change, same locationName change, same locationManufacturer deletedNew/additional manufacturer |
| 08/3.4/Batch certificateQUICKINFO | This confirms that a batch of ready-to-use medicinal product conforms to the authorisation and was manufactured in compliance with GMP. |
| 08/3.4/Release of a batchQUICKINFO | The decision on whether to release a batch for the Swiss market is based on the batch certificate (market release is the task of the authorisation holder, see page 1 of this form) |
| 08/3.4/Laboratories/companies concernedQUICKINFO | All laboratories/companies involved in batch release should be listed. If necessary, the sequences should be documented in section 5 in a flowchart. |
| 08/3.4/Solvent/diluentQUICKINFO | If the finished product includes a solvent/diluent, the laboratories/companies involved in the batch release should also be stated and a cross entered in the Solvent/diluent checkbox in the following table. |
| 08/3.4/Documents to be submitted | The documents must be submitted for each proposed foreign manufacturer in accordance with the guidance document *GMP compliance by foreign manufacturers*. |
| 08/3.4/Manufacturer - Address | The address should be entered here.D-U-N-S Number or IDMP:If known, these identification numbers should be stated. |
| 08/3.4/Manufacturer - Status (checkbox) | The corresponding checkbox should be checked depending on the status.For manufacturers that are “Proposed but not yet approved”, the date of the cover letter (for the corresponding application) should also be stated. |
| 08/3.4/Manufacturer - Solvent / diluent (checkbox) | Packer of a solvent/diluent:**One** box should be checked if applicable.If the finished product includes a solvent/diluent, the laboratories/companies involved in the batch release should be stated and a cross entered in the Solvent/diluent checkbox in the following table. |
| 08/3.4/Manufacturer - Release stage | e.g. batch release for contract manufacturer:Please enter the corresponding free text here.The RP of the authorisation holder is always responsible for the market release in Switzerland. |
| 08/3.4/Manufacturer - Type of change | The appropriate type of variation should be selected from the dropdown menu. Free text may be entered only if none of the options applies.Manufacturer up to date/unchangedAddress change, same locationName change, same locationManufacturer deletedNew/additional manufacturer |
| 09/4./List of co-marketing medicinal products | With this list the company confirms that the authorisation holders concerned have also been informed by it |
| 10/5./Flowcharts | If flowcharts are used to depict complex manufacturing situations, please insert these in the relevant subsection and refer to the instructions in “General comments” on page 1 of this form. |
| 10/5.1/Flowchart(s) drug substance | Contains the flowcharts for the manufacture of the drug substance with its intermediates, if these are produced by different manufacturers |
| 10/5.2/Flowchart(s) QC drug substance | Contains the flowcharts for the QC of the drug substance with its intermediates, if these controls are carried out by different manufacturers |
| 10/5.4/Flowchart(s) packaging/packer | Contains the flowcharts for the manufacture of the drug product with the relevant packing steps if these are carried out by different manufacturers |
| 10/5.5/Flowchart(s) QC drug product/ | Contains the flowcharts for the QC of the drug product with the relevant testing and release steps if these are carried out by different manufacturers |
| 10/5.6/Flowchart(s) batch release | Contains the flowcharts for the batch release of the drug product with the relevant certificates if these are issued by different manufacturers |
| 11/6./Additional information / Remarks / Other | Entries relating to individual sections (please reference) and which have “no room” in the corresponding section can be entered here |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.5 | Correction formatting, Removal HMV4 from text | dei |
| 1.4 | New layout, no content adjustments to the previous version. | dei |
| 1.3 | Formal adjustments to the header and footerNo content adjustments to the previous version. | dei |
| 1.2 | Autor im System mit Autor in der Änderungshistorie synchronisiert. Freigabe durch Person im VM Team, da Dokument nicht in der VMS Suche angezeigt wird.Keine inhaltlichen Änderungen | tsj |
| 1.0 | Implementation of HMV4 | dts |

1. Select the corresponding row (N.B.: As a result of the nesting this usually consists of 3 sub-rows) from bottom right to top left, right-click “Copy”, place the cursor under the selected row then click under Start-Insert-Keep original table formatting (U).

CTRL-V does NOT work. [↑](#footnote-ref-1)
2. To read the quickinfos place the cursor over the relevant field. [↑](#footnote-ref-2)
3. IMPORTANT: Not all manufacturing activities require an RP Declaration, see information sheet and footnotes 4 and 5 [↑](#footnote-ref-3)
4. The manufacturing activity “Active substance manufacture – all steps” always requires an RP Declaration [↑](#footnote-ref-4)
5. The manufacturing activity “Active substance manufacture – last step incl. release” always requires an RP Declaration [↑](#footnote-ref-5)