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| **Form** |
| **Substances of animal and human origin** |
| **Identification number:** | ZL000\_00\_031 |
| **Version:** | 1.2 |
| **Valid from:** | 11.07.2023 |

# Form A: TSE substancesi of animal origin

# Basic information

|  |  |
| --- | --- |
| Name of medicinal product: | …… |
| Authorisation no.:*If known* | …… |
| Application ID:*If known* | …… |
| Date: | …… |

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| *For homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication in the notification procedure:* |
| Name of Master Dossier: | …… |
| Master Dossier no.: | …… |

# Further information

|  |  |  |  |
| --- | --- | --- | --- |
| Name of substance | …… | …… | …… |
| Name and address of manufacturerii | …… | …… | …… |
| Species and tissue from which substance is a derivative | …… | …… | …… |
| Country/ies of origin of the source animals used in the manufacture of the substance | …… | …… | …… |
| Is the substance exempt from mandatory declaration according to the TSE instructions?If not, its origin (species and organ/tissue) must be declared in the composition section of the medicinal product texts | [ ]  yes[ ]  no: …… | [ ]  yes[ ]  no: …… | [ ]  yes[ ]  no: …… |
| Do you have a TSE Certificate of Suitability issued by the EDQMiii? If yes, please state CEP number and date and attach a copy of the CEP | [ ]  no[ ]  yes: | [ ]  no[ ]  yes: | [ ]  no[ ]  yes: |
| Use of substance | As active substance | …… | …… | …… |
| As excipient | …… | …… | …… |
| As reagent/culture medium component used in routine manufacture | …… | …… | …… |
| As reagent/culture medium component used in the production of master/working cell banks | …… | …… | …… |
| As starting material used in the manufacture of active substances | …… | …… | …… |
| As starting material used in the manufacture of excipients | …… | …… | …… |
| Other, give details | …… | …… | …… |

i Substances obtained from animals susceptible to TSE (excluding experimentally induced TSE) and substances within the scope of Chapter 5.2.8. of the European Pharmacopoeia.

ii Use a separate column for each manufacturer.

iii A TSE Certificate of Suitability may be obtained from the European Directorate for the Quality of Medicines based on the general text of the European Pharmacopoeia, Chapter 5.2.8., "Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products".

Please check appropriate box(es):

[ ]  Form B (Other substances of animal origin) is not applicable.

[ ]  Form C (Albumin and other substances of human origin) is not applicable.

# Form B: Other substances of animal origin

# Basic information

|  |  |
| --- | --- |
| Name of medicinal product: | …… |
| Authorisation no.:*If known* | …… |
| Application ID:*If known* | …… |
| Date: | …… |

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| *For homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication in the notification procedure:* |
| Name of Master Dossier: | …… |
| Master Dossier no.: | …… |

# Further information

|  |  |  |  |
| --- | --- | --- | --- |
| Name of substance | …… | …… | …… |
| Species and tissue from which substance is a derivative | …… | …… | …… |
| Country/ies of origin of the source animals used in the manufacture of the substance | …… | …… | …… |
| Use of substance | As active substance | …… | …… | …… |
| As excipient | …… | …… | …… |
| As reagent/culture medium component used in routine manufacture | …… | …… | …… |
| As reagent/culture medium component used in the production of master/working cell banks | …… | …… | …… |
| As starting material used in the manufacture of active substances | …… | …… | …… |
| As starting material used in the manufacture of excipients | …… | …… | …… |
| Other, give details | …… | …… | …… |

Please check appropriate box(es):

[ ]  Form A (TSE substances of animal origin) is not applicable.

[ ]  Form C (Albumin and other substances of human origin) is not applicable.

# Form C: Albumin and other substances of human origin

# Basic information

|  |  |
| --- | --- |
| Name of medicinal product: | …… |
| Authorisation no.:*If known* | …… |
| Application ID:*If known* | …… |
| Date: | …… |

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| *For homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication in the notification procedure:* |
| Name of Master Dossier: | …… |
| Master Dossier no.: | …… |

# Further information

|  |  |  |  |
| --- | --- | --- | --- |
| Name of substance | …… | …… | …… |
| Tissue from which substance is a derivative | …… | …… | …… |
| Country of origin of substance | …… | …… | …… |
| Use of substance | As active substance | …… | …… | …… |
| As excipient | …… | …… | …… |
| As reagent/culture medium component used in routine manufacture | …… | …… | …… |
| As reagent/culture medium component used in the production of master/working cell banks | …… | …… | …… |
| As starting material used in the manufacture of active substances | …… | …… | …… |
| As starting material used in the manufacture of excipients | …… | …… | …… |
| Other, give details | …… | …… | …… |
| Is the substance used authorised as a medicinal product (authorisation number/country)? | [ ]  yes: ……[ ]  no | [ ]  yes: ……[ ]  no | [ ]  yes: ……[ ]  no |

Please check appropriate box(es):

[ ]  Form A (TSE substances of animal origin) is not applicable.

[ ]  Form B (Other substances of animal origin) is not applicable.

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.2 | New layout, no content adjustments to the previous version. | dei |
| 1.1 | Formal adjustments to the header and footerNo content adjustments to the previous version. | dei |
| 1.0 | Implementation of TPO4 | dts / lac |