3.2.P.1 Description and composition of the drug product

A brief description of the dosage composition of the drug, composition of the drug and the type of container and closure used for dosage form should be provided.

1. Description of the dosage form
2. Composition i.e. List of all components (active ingredients and excipients) of the dosage form and the their amount per unit including overages. The function of the components, and a reference to their quality standards.
3. Description of accompanying reconstitution diluent(s)
4. Type of container and closure used for the dosage form and accompanying reconstitution diluent

The finished product is presented as a <manufactured item colour> <manufactured dose form>. In case of a the manufacturered dose form equals the administrable dose form, apply the following: (PhPID: <PhPID>).

In case of a tablets and capsules, apply the following.

The <manufactured dose form> can be recognised by the following characteristics:

Size: <manufactured item size>

Imprint: <manufactured item imprint>

Colour: <manufactured item colour>

Shape: <manufactured item shape>

In case of reconstitution, apply the following.

The finished product needs to be reconstituted to a <Administrable dose form> prior to use.

In case the reconstitution diluent is co packed, apply the following.

The reconstitution diluent is presented as a <manufactured item colour> <manufactured dose form>.

In case of a solid/semi-solid manufactured dose form, apply the following.

Table 1 Composition of the solid/semi-solid finished product In case of a the manufacturered dose form equals the administrable dose form, apply the following: (PhPID: <PhPID>).

|  |  |  |  |
| --- | --- | --- | --- |
| Ingredient | Amount/Unit (incl. overages | Ingredient Role | Method |
| <Substance> | <Substance strength range (presentation)> | <Ingredient Role> | <Pharmacopoial | In house> |
| <Substance> | <Substance strength range (presentation)> | <Ingredient Role> | <Pharmacopoial | In house> |
| <Substance> | <Substance strength range (presentation)> | <Ingredient Role> | <Pharmacopoial | In house> |
| <Substance> | <Substance strength range (presentation)> | <Ingredient Role> | <Pharmacopoial | In house> |
| <Substance> | <Substance strength range (presentation)> | <Ingredient Role> | <Pharmacopoial | In house> |

In case of a liquid manufactured dose form, apply the following.

Table 2 Composition of the liquid finished product In case of a the manufacturered dose form equals the administrable dose form, apply the following: (PhPID: <PhPID>).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Amount/Unit (incl. overages | Ingredient Role | Method | SSID |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> | |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> | |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> | |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> | |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> | |

In case of a reconstituted administrable dose form, apply the following.

Table 3 Composition of the reconstituted product (PhPID: <PhPID>).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Amount/Unit (incl. overages | Ingredient Role | Method | SSID |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> |
| <Substance> | <Substance strength range (concentration)> | <Ingredient Role> | <Pharmacopoial | In house> | <SSID> |

The container concerns a < Package description> (PCID: <PCID>).

Table 4 Packaging

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Kind of pack | Package item (Container) Type | Package item (Container) Quantity | Package item (Container) material | PCID |
| Immediate pack | <Package item (Container) Type> | <Package item (Container) quantity> | <Package item (Container) material> | <PCID> |
| Intermediate pack | <Package item (Container) Type> | <Package item (Container) quantity> | <Package item (Container) material> | <PCID> |
| Intermediate pack | <Package item (Container) Type> | <Package item (Container) quantity> | <Package item (Container) material> | <PCID> |
| Intermediate pack | <Package item (Container) Type> | <Package item (Container) quantity> | <Package item (Container) material> | <PCID> |
| Outer pack | <Package item (Container) Type> | <Package item (Container) quantity> | <Package item (Container) material> | <PCID> |

Remove rows for the kind of packs if not applicable. If there is only one pack (e.g. bottle), it is considered the immediate pack.