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| 1. **GENERAL INFORMATION OF THE PRODUCT TO BE DEVELOPED** | |
| Product name: | {{ product\_information[“product\_name”] }} |
| Type of product (OTC, RX, nutraceutical, cosmetic, other?) | {{ product\_information[“product\_type”] }} |
| Brand name / Generic name | {{ product\_information[“generic\_name”] }} |
| API(s) | {% for api in product\_information[“APIs”] %}  {{api[“API\_name”]}}  {% endfor %} |
| Strength(s) | {{ product\_information[“product\_strength”] }} |
| Dosage form | {{ product\_information[“product\_dosage\_form”] }} |
| Route of administration | {{ product\_information[“route\_of\_administration”] }} |
| Dose(s) | {{ product\_information[“product\_dose”] }} |
| Physical characteristics (Color, size, shape, text printed, etc.) | {{ product\_information[“physical\_characteristics”] }} |
| Type of packaging material | {{ product\_information[“packaging\_type”] }} |
| Commercial presentations | {{ product\_information[“commercial\_presentations”] }} |
| Expiration time required | {{ product\_information[“required\_expiration\_time”] }} |
| **Observations:**  {{observations}} | |

{% for info in api\_literature\_data %}

|  |  |
| --- | --- |
| 1. **GENERAL INFORMATION OF THE ACTIVE PHARMACEUTICAL INGREDIENT (API) ({{ api }})** | |
| Common name: | {{ info[“api\_name”] }} |
| CAS number: | {{ info[“cas\_number”] }} |
| Description: | {{ info[“description”] }} |
| Solubility: | {{ info[“solubility”] }} |
| Melting point: | {{ info[“melting\_point”] }} |
| Polymorphs: | {{ info[“polymorphs”] }} |
| Stability (Solid state/solution, general information): | {{ info[“stability”] }} |
| Scheme of degradation route | {{ info[“scheme\_of\_degradation\_route”] }} |
| Stability indicators | {{ info[“stability\_indicators”] }} |
| Impurities (Synthetic origin, degradation products and/or metabolites) | {{ info[“impurities”]}} |
| Biopharmaceutical classification (Biopharmaceutical classification system) | {{ info[“biopharmaceutical\_classification”] }} |
| Toxicological classification (Contention level): |  |
| Other information: | **INN:** {{ info[“api\_name”] }}  **Chemical names:** {{ info[“chemical\_name”] }}  **Structure:**  **Molecular formula:** {{ info[“molecular\_formula”] }}  **Molecular mass:** {{ info[“molecular\_weight”] }}  **Type of substance:**  **Dissociation constant (pKa):** {{ info[“pka”] }}  **Partition coefficient:** {{ info[“log\_p”] }}  **Hygroscopicity:** {{ info[“hygroscopicity”] }}  **Chirality/Specific optical rotation:** {{ info[“chirality\_or\_specific\_optical\_rotation”] }}  **Degradation temperature:**{{info[“degradation\_temperature”]}}  {{info[“glass\_transition\_temperature”]}}  **Boiling point:** {{ info[“boiling\_point”] }} |

{% endfor %}

{% for info in rld\_research\_data %}

| 1. **INFORMATION OF THE REFERENCE LISTED DRUG (RLD)**   (The information of this section should be filled in for the RLD and those similar products that appear in the FDA Orange Book) | |
| --- | --- |
| Brand name/Generic name | {{ info[“brand\_name”] }} |
| Packaging\_imgs | |
| Manufacturer | {{ info[“manufacturer”] }} |
| API | {{ info[“API\_name\_with\_UNII”] }} |
| Excipients | {{ info[“inactive\_ingredients\_with\_UNII\_str”] }} |
| Strength(s) | {{ info[“strengths”] }} |
| Type of packaging material | {{ info[“type\_pckg\_material”] }} |
| How supplied | {{ info[“rld\_how\_supplied”] }} |
| Physical characteristics (Color, size, shape, text printed, etc.) | {{ info[“rld\_physical\_characteristics”] }} |
| Storage conditions | {{ info[“rld\_storage\_conditions”] }} |
| Special characteristics of API and excipients (crystalline form used for the RLD, particle size, etc.) | {{ info[“rld\_special\_characteristics”] }} |
| Manufacturing process information (Controls, recommended process conditions): | Data not available. |
| **Observations:** | |

{% endfor %}

{% for info in patent\_research\_data %}

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| 1. **REVISION OF PATENTS FOR {{ info[“api\_name”] }} (FORMULATION AND ROUTE SYNTHESIS ANALYSIS)** |
| **{{ info[“api\_name”] }}**  {{ info[“patent\_research\_report\_api”] }} |

{% endfor %}

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| 1. **REFERENCES** (Specify the references throughout the document with numbers between brackets i.e. [1]) |
|  |

| 1. **ANNEXES** | |
| --- | --- |
| **ANNEX** | **DESCRIPTION** |
|  |  |

| 1. **RELATED DOCUMENTS** | |
| --- | --- |
| **CODE** | **DESCRIPTION** |
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| 1. **AUTHORIZATIONS** |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **PERFORMED BY:** | | | **REVIEWED BY:** | | | **APPROVED BY:** | |
| Name: |  |  | Name: |  |  | Name: |  |
| Job title: |  |  | Job title: |  |  | Job title: |  |
| Area: |  |  | Area: |  |  | Area: |  |
| Signature: |  |  | Signature: |  |  | Signature: |  |
| Date: |  |  | Date: |  |  | Date: |  |