**Questionnaire for Risk Assessment of the Presence of Residual Solvents in Raw Materials Used in the Manufacture of Medicines According to ICH Q3C**

|  |  |
| --- | --- |
| **Material Comercial Name** | Click here to enter text. |
| **Material Code (Used by Manufacturer)** | Click here to enter text. |
| **Manufacturer Name** | Click here to enter text. |
| **Production Site Address** | Click here to enter text. |

**This questionnaire must be answered by the qualified person of the manufacturers of raw materials and has the objective of verifying the accomplishment of current international directives to control the amount of residual solvents in raw materials used in the manufacture of medicines.**

**Any changes in the manufacturing process of the material described above that can CHANGE THE STATUS OF THIS DOCUMENT must be immediately informed to Farmanguinhos.**

**Please, answer the following questions according to the manufacturing process of the material identified above:**

|  |
| --- |
| **1 – During the manufacturing process of the material is it used or generated any organic volatile chemical?**[ ]  **YES**[ ]  **NO**If **YES**, complete the following sections.If **NO**, mark “Not applicable” in the following sections. |

**A - Class 1 Solvents**

|  |  |
| --- | --- |
| Were Class 1 Solvents used or generated in any step of the manufacturing process of the material? | [ ] **Not applicable**[ ] **YES**[ ] **NO** |
| If **YES**, fill out the table below:

|  |  |  |
| --- | --- | --- |
| Name of Class 1 Solvent | Maximum concentration (in ppm) | Is it in compliance with the current revision of ICH Q3C? |
| **YES** | **NO** |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |

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**B - Class 2 Solvents**

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| --- | --- |
| Were Class 2 Solvents used or generated in any step of the manufacturing process of the material? | [ ] **Not applicable**[ ] **YES**[ ] **NO** |
| If **YES**, fill out the table below:

|  |  |  |
| --- | --- | --- |
| Name of Class 2 Solvent | Maximum concentration (in ppm) | Is it in compliance with the current revision of ICH Q3C? |
| **YES** | **NO** |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |

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**C - Class 3 Solvents**

|  |  |
| --- | --- |
| Were Class 3 Solvents used or generated in any step of the manufacturing process of the material? | [ ] **Not applicable**[ ] **YES**[ ] **NO** |
| If **YES**, fill out the table below:

|  |  |  |
| --- | --- | --- |
| Name of Class 3 Solvent | Maximum concentration (in ppm) | Is it in compliance with the current revision of ICH Q3C? |
| **YES** | **NO** |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |
| **Click here to enter text.** | **Click here to enter text.** | [ ]  | [ ]  |

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**D – Analytical Methodology**

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| --- | --- |
| Is a validated ou verified compendial analytical methodology used for detection and quantification of Class 1, 2 and / or 3 Solvens? | [ ] **Not applicable**[ ] **YES**[ ] **NO** |

I confirm that the material is in compliance with the current revision of ICH Q3C and that the information above are true and can be verified.

**Issued by:**

|  |  |
| --- | --- |
| Name | **Click here to enter text.** |
| Job title | **Click here to enter text.** |
| Signature |  |
| Date |  |