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| Prepared By: | Damini Gour |
| Approved By: |  |
| Date: | 02-06-2023 |
| Version: | 0.1 |
| Status: |  |

Dashbo

EMCURE PHARMACEUTICALS LIMITED

**Change Request DOCUMENT**

**(PIDF to Launch)**

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| **Change Request Description** | | | |
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| **Change No.:** 01 | | | |
| **Project Name:** PIDF to Launch | **Change Name:** Project tracking & Management | | **Date:** |
| **Change Requested –**  Need to add project tracking for In licensed projects in tracking mechanism.  Create repository for projects before identification stage –  Create a view using following filters-   1. Current filed products 2. Current products under development 3. Wish list –products geographies want. First search will happen within filed and under development products. 4. Vendor product list –for updating the product list received from vendors (new/existing)   For adding the data w.r.t. this filter, following input field should be there in the form –   1. Type (filed, u/development, wish list, vendor product list) – **Dropdown list.** 2. Geography – **Dropdown list.** 3. Country – **Dropdown list (Geography and country should be mapped.)** 4. Molecule name – **Textbox** 5. Strength – **Textbox** 6. In house/In licensed **- Radio button.** 7. Date of filing (actual filing date in case of filed, expected filing in case of u/development) – **Date picker** 8. Date of approval (in case of filed and approved) – **Date picker** 9. Name of vendor (for IL products) - **Textbox** 10. Vendor evaluation remark (green, yellow, red) – **Textbox with color coding.** 11. Reference drug product (if available) - **Textbox** 12. Remarks – **Textbox** | | | |
| **Comment:** | | **Signature:** | |

**Note - Attaching the wireframes for the same, for better understanding.**

1. **Wishlist Grid View Page -**

Note – This grid will be displayed according to the selection of above options.

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| **Type** | **Geography** | **Country** | **Molecule Name** | **Strength** | **Date of Filing** | **Date of Approval** | **Vendor Remark** |
| Type 1 | Latam | Chile | Daptomycin | 100mg | 18-03-2022 | 01-04-2022 | Remark 1 |
| Type 2 | Latam | Peru | Trientine | 50mg | 18-03-2022 | 01-04-2022 | Remark 2 |
| Type 3 | Latam | Chile | Treosulfan | 200mg | 18-03-2022 | 01-04-2022 | Remark 3 |
| Type 4 | Latam | Peru | Midodrine | 50mg | 18-03-2022 | 01-04-2022 | Remark 4 |
| Type 5 | Latam | Chile | Fingolmod | 50mg | 18-03-2022 | 01-04-2022 | Remark 5 |



**Add Wishlist**

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**Wishlist**

Search product

**Vendor Product List**

**Wishlist**

**Current filed products**

**Current products under development**

1. **Add Wishlist Form -**



**Add Wishlist**

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**Wishlist**

Search product

**Vendor Product List**

**Wishlist**

**Current filed products**

**Current products under development**

**Note- Geography and country should be mapped together.**

**Country:**

**Geography:**

**Type:**

**In house**

**In licensed**

**Strength:**

**Molecule name:**

**Date of Approval:**

**Date of Approval:**

**Date of Filing:**

**Vendor evaluation remark:**

**Reference drug product (if available):**

**Name of vendor:**

**Cancel**

**Save**

**Save as Draft**

**Remarks:**

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| **Change Request Description** | | | |
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| **Change No.:** 02 | | | |
| **Project Name:** PIDF to Launch | **Change Name:** RA | | **Date:** |
| **Change Requested –**  In PIDF tool -> PIDF Management -> PBF Management -> edit PIDF -> Add one more tab “RA” after “Clinical” tab  Attaching screen shot for better understanding.    In the RA tab below details should be added –   1. **Regulatory Details –**  * RA responsible person - **Dropdown** * Pivotal batch manufactured – **Date Picker** * Last data from R&D - **Date Picker** * BE final report - **Date Picker** * Therapeutic indications - **Textbox** * Dossier ready date - **Date Picker** * File quality - **Dropdown** * Date submitted - **Date Picker** | | | |
| **Comment:** | | **Signature:** | |

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| **Change Request Description** | | | |
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| **Change No.:** 02 | | | |
| **Project Name:** PIDF to Launch | **Change Name:** RA | | **Date:** |
| **…. Continued –**  **2. Other Details –**   * Filling strategy and countries - **Textbox** * Countries - **Textbox** * Earliest submission – D excel – **Date Picker** * Earliest launch – D excel – **Date Picker** * Alternate salts – **Textbox** * Recommended Ref product - **Textbox** * Non-standard product – **Radio Button** * Full application opportunity - **Radio Button** * Sites and labs – **Textbox**  1. **Only applicable for EU –**  * Day 0 - **Date Picker** * Day 70 - **Date Picker** * Day 105 - **Date Picker** * Day 106 - **Date Picker** * Day 120 - **Date Picker** * Day 150 - **Date Picker** * Day 180 - **Date Picker** * Day 210 - **Date Picker** * End of Proc - **Date Picker** * Comments -**Textbox** | | | |
| **Comment:** | | **Signature:** | |

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| **Change Request Description** | | |
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| **Change No.:** 03 | | |
| **Project Name:** PIDF to Launch | **Change Name:** Outsourced /In-licensing products | **Date:** |
| 1. We will have to reverse the change done for deletion of dropdown – Inhouse MFG or Outsourced, and have the same in the PIDF form 2. Upon selection of Inhouse Mfg, the flow for PIDF will follow as it is currently present (As-Is) 3. Upon selection of Outsourced Mfg, the flow for PIDF be modified as follows:  * Commercials – As-Is * Development – Now this section will not be sent to R&D and will be submitted by the Business development team only. We will have to provide 2 tabs – Commercials and Development Costs. In development cost, the costs and timelines will have to be input by Business development as follows: * The below activities need to be in a dynamic template that can be edited as per BU’s requirement. They may not have knowledge of all the fields and they need to be non-mandatory. Further fields can be added if needed.  |  |  |  | | --- | --- | --- | | **Development** | Cost | Tentative Timeline | | Purchase API |  |  | | Select API suppliers |  |  | | Formulation Finalised |  |  | | Manufacture Pivotal batches |  |  | | Test and Place on Stability |  |  | | Carry out Biostudy |  |  | | 3 month stability Report |  |  | | 6 month stability Report |  |  | | Give last data to RA |  |  | | Regulatory |  |  | | Dossier Ready Date |  |  | | Submission Dues and timelines |  |  | | DCP Procedure |  |  | | Pharmacovigilance requirements |  |  | | **Pre Launch Preparation per country** |  |  | | **Launch Activities per country** |  |  | | | |

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| **Change Request Description** | | | |
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| **Change No.:** 04 | | | |
| **Project Name:** PIDF to Launch | **Change Name:** Miscellaneous | | **Date:** |
| **User Interface Revamp –**  Remove Accordions as much as possible, as users have complained of infinite scroll and getting lost in application, i.e. PBF  Create tab based UI as much as possible to avoid scrolling  Save as raft functionality wherever applicable, for multiple sections in forms that would need time to complete. | | | |
| **Comment:** | | **Signature:** | |

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| **Change Request Description** | | | |
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| **Change No.:** 05 | | | |
| **Project Name:** PIDF to Launch | **Change Name:** Miscellaneous | | **Date:** |
| **Change request from bug list –**   1. Commercial Module -> Year detail should be pack size specific, where user will define pack size and add year details for every pack size. 2. Add IMS Value and IMS Volume for last three years in PIDF form. 3. Add Plant type dropdown in plant support cost according to that plant utilization rate will be displayed (create master of plant utilization rate put plant utilization master from saurabh). 4. In API form, Add Pop up, in that add text as API Source below that Add 2 radio buttons as –   a) Interested &  b) Not interested  after click on radio button, if interested then assign PIDF to group leader.   1. Business Unit -> We need another checkbox Domestic which will be used for decide medical form | | | |
| **Comment:** | | **Signature:** | |