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| **PRODUCT DEVELOPMENT** | |
| Product: : BINIMETINIB | |
| **Market:** | **Strength:** |
| Source: MSNO | Reference: : In-house |
| **Shelf-life:** |  |

|  |  |  |
| --- | --- | --- |
| TEST | RESULT | SPECIFICATION |
| Total impurities | 0.14% | Not more than 1.0% |
| Assay by HPLC (On anhydrous and solvents free basis) | 99.27%w/w | Not less than 98.0% w/w and not more than 102.0% w/w |
|  |  |  |
| Acetic acid content by HPLC |  |  |
| Acetic acid | Not detected | Not more than 5000 ppm |
| Residual solvents by GC (Method-I) |  |  |
| Methanol | 15 ppm | Not more than 3000 ppm |
| Isopropyl alcohol | 15 ppm | Not more than 5000 ppm |
| Acetonitrile | 59 ppm | Not more than 410 ppm |
| Dichloromethane | 153 ppm | Not more than 600 ppm |
| Ethyl acetate | Not detected | Not more than 5000 ppm |
| Tetrahydrofuran | Not detected | Not more than 720 ppm IES |
| Toluene | 4 ppm | Not more than 890 ppm |
| Residual solvents by GC(Method-II) |  | ₾ 2.02.2 4 |
| N,N-Dimethyl formamide | Not detected | Not more than 880 ppm |
| Dimethyl sulphoxide | 30 ppm | Not more than 5000 ppm |

**Storage Conditions:**

Store the material in a tightly closed containers at 2º℃ to 8℃ temperature protected from light and moisture

**Packaging details:**

**Revision History**

Changes in the current version and high-level summary of changes of all listed previous versions are maintained below.

|  |  |  |
| --- | --- | --- |
| **Version**  **Effective Date** | **Reason for change** | **Summary of changes** |
|  |  |  |

**Author**

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**Document Type**

This document is designed to be used as a template.

(NOTE: Templates are designed to be amendable and forms are not, i.e. content of forms must not be changed when used, but populated with data/information only).

**GxP rating**

According to SOP-7039031, Document Management Processes for ESOPS D2, this document was assessed as low GxP impact.

Based on the rating, protection is applied as necessary. At minimum those rated as ‘high GxP impact’ need protection applied as per WP-7004901, Creating Protected Forms.

(NOTE: Templates are always considered low GxP impact and as they are designed to be amendable, no protection is applied).

**Revision History**

Changes in the current version and high-level summary of changes for all listed previous versions are maintained below.

| **Version**  **Effective Date** | **Reason for Change** | **Summary of Changes** |
| --- | --- | --- |
| 1.0 | New From created | Content Change(s):  Not Applicable |

**Documents replaced**

Not Applicable

This disclaimer is applicable for forms only and can be deleted when creating templates.

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