

CERTIFICATE OF ANALYSIS

(Certificate No. KMI004001-01)

Release Date: 13/03/2024

Re-test Date: 12/03/2027

Imatinib EP Impurity F

Identification

Chemical Name :
6-methyl-N1-(4-(pyridin-3-yl)pyrimidin-2-yl)benzene-1,3-diamine

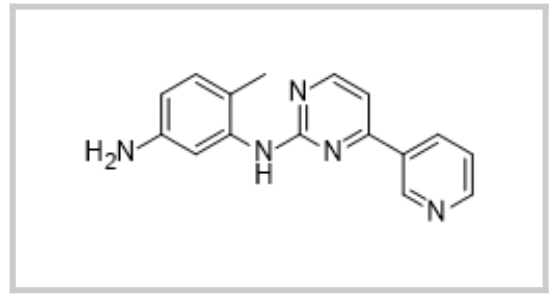
Alt. Name : Imatinib Diamine Impurity

CAT No. : KMI004001

CAS No. : 152460-10-1

Molecular Formula : C₁₆H₁₅N₅

Molecular Weight : 277.32



Analytical Information

Batch No. : IMA-EPF-073-123

Description : Yellow Solid

HPLC Purity : 99.44 %

Weight Loss By TGA : 0.20 %

% Potency : 99.24 %

Solubility : ACN

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be shipped at room temperature

% Potency = [100 - 0.20(Weight Loss By TGA)] x [99.44(HPLC Purity)]/100 = 99.24 %

Recommendation : Released

| | Department | Name | Signature | Date |
|-----------------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 22/11/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 22/11/2024 |

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA