

CERTIFICATE OF ANALYSIS

(Certificate No. KMP003002-01)

Release Date: 05/03/2024

Re-test Date: 04/03/2027

Pirfenidone EP Impurity A

Identification

Chemical Name :
5-methylpyridin-2-amine

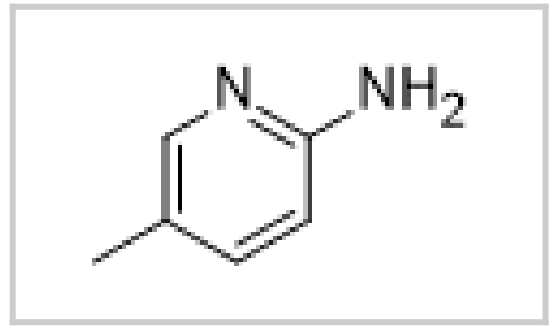
Alt. Name : Pirfenidone USP Related Compound A

CAT No. : KMP003002

CAS No. : 1603-41-4

Molecular Formula : C₆H₈N₂

Molecular Weight : 108.14



Analytical Information

Batch No. : PIR-IMP-A-073-102

Description : White Solid

HPLC Purity : 99.76 %

Weight Loss By TGA : 1.20 %

% Potency : 98.56 %

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 - 1.20(Weight Loss By TGA)] x [99.76(HPLC Purity)]/100 = 98.56 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		05/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		05/03/2024

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