

CERTIFICATE OF ANALYSIS

(Certificate No. KMC022012-01)

Release Date: 07/10/2024

Re-test Date: 06/10/2027

Carbidopa EP Impurity E

Identification

Chemical Name :

Methyl (2S)-3-(3,4-dihydroxyphenyl)-2-hydrazino-2-methylpropanoate (as per EP)

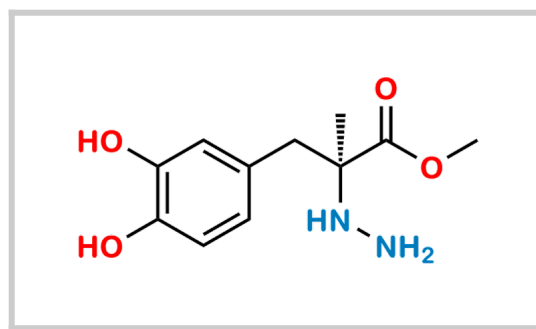
Alt. Name : (S)-Carbidopa Methyl Ester ;
Carbidopa Impurity 2

CAT No. : KMC022012

CAS No. : 52514-63-3

Molecular Formula : C₁₁H₁₆N₂O₄

Molecular Weight : 240.3



Analytical Information

Batch No. : C022012-073-403

Description : Yellow Solid

HPLC Purity : 93.99 %

Weight Loss By TGA : 0.73 %

% Potency : 93.3 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C 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 - 0.73(Weight Loss By TGA)] x [93.99(HPLC Purity)]/100 = 93.3 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		08/10/2024

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA