

# CERTIFICATE OF ANALYSIS

(Certificate No. KMC015005-01)

Release Date: 09/05/2024

Re-test Date: 08/05/2027

## Clomipramine EP Impurity B

### Identification

**Chemical Name :**

3-(10,11-dihydro-5H-dibenzo[b,f]azepin-5-yl)-N,N-dimethylpropan-1-amine hydrochloride

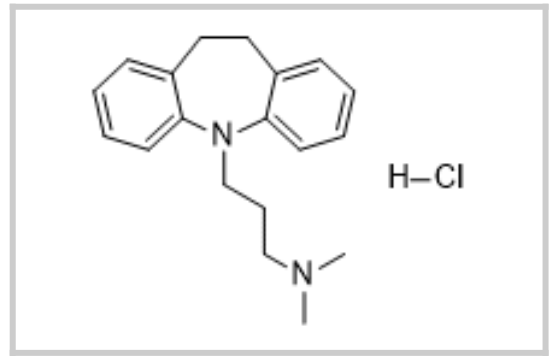
**Alt. Name** : Imipramine Hydrochloride (USP)

**CAT No.** : KMC015005

**CAS No.** : 113-52-0

**Molecular Formula** : C<sub>19</sub>H<sub>24</sub>N<sub>2</sub> : HCl

**Molecular Weight** : 280.41 : 36.5



### Analytical Information

**Batch No.** : CLO-EPB-073-201

**Solubility** : Water

**Description** : Off White Solid

**Mass** : Confirm

**HPLC Purity** : 99.98 %

**IR** : Confirm

**Weight Loss By TGA** : 0.55 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 99.43 %

### 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 - 0.55(Weight Loss By TGA)] x [99.98(HPLC Purity)]/100 = 99.43 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		10/05/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		10/05/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA