

# CERTIFICATE OF ANALYSIS

(Certificate No. KMD010007-01)

Release Date: 27/09/2024

Re-test Date: 26/09/2027

## Doxepin Related Compound B

### Identification

**Chemical Name :**

11-(3-(dimethylamino)propyl)-6,11-dihydrodibenzo[b,e]oxepin-11-ol

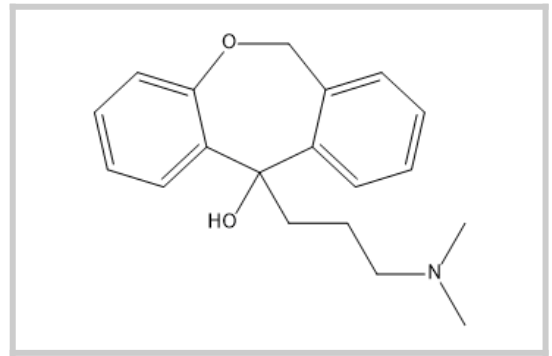
**Alt. Name** : Doxepin USP Related Compound B

**CAT No.** : KMD010007

**CAS No.** : 4504-88-5

**Molecular Formula** : C<sub>19</sub>H<sub>23</sub>NO<sub>2</sub>

**Molecular Weight** : 297.4



### Analytical Information

**Batch No.** : DOXE-EPB-019-127

**Solubility** : Methanol

**Description** : White Solid

**Mass** : Confirm

**HPLC Purity** : 98.58 %

**IR** : Confirm

**Weight Loss By TGA** : 0.64 %

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

**% Potency** : 97.95 %

**<sup>13</sup>C 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** =  $[100 - 0.64(\text{Weight Loss By TGA})] \times [98.58(\text{HPLC Purity})]/100 = 97.95 \%$

-Re-tested on 27.09.2024

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		28/09/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		28/09/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, <sup>13</sup>C NMR, IR and TGA