

# Certificate of Analysis

**Product Name :** Doxylamine Succinate  
**Product Number :** ARK2009-10KG  
**Batch Number :** 0000324155  
**Source Batch :** 0000295384  
**CAS Number :** 562-10-7  
**Molecular Formula :** C<sub>17</sub>H<sub>22</sub>N<sub>2</sub>O · C<sub>4</sub>H<sub>6</sub>O<sub>4</sub>  
**Formula Weight :** 388.46 g/mol  
**Expiry Date :** 17 Jan 2028  
**Date Of Release :** 22 Mar 2024  
**Date of Manufacture :** 17 Jan 2024

Test	Specification	Result
DESCRIPTION (USP)	White or creamy white powder having a characteristic odour	White powder having a characteristic odour
ID – UV (USP)	≤ 3.0 %	1.9 %
HPLC RETENTION TIME (USP)	The retention time of doxylamine succinate in the sample solution corresponds to the retention time of doxylamine succinate in the standard solution	Conforms
SUCCINIC ACID M.POINT (USP)	184 - 188 °C	185 °C
SOLUBILITY (USP)	Very soluble in water and alcohol. Freely soluble in chloroform. Very slightly soluble in Ether	Conforms
LOSS ON DRYING (USP)	≤ 0.5 %	0.0 %
ROI (USP)/SULP ASH (PhEur)	≤ 0.1 %	0.0 %
HPLC ASSAY (USP)	98.0 - 102.0 %	99.6 %
Dried basis		
ORGANIC IMPURITIES (USP)	≤ 0.10 %	0.00 %
Doxylamine pyridinyl N-oxide		
ORGANIC IMPURITIES (USP)	≤ 0.10 %	0.00 %
Doxylamine Dioxide		
ORGANIC IMPURITIES (USP)	≤ 0.15 %	< 0.05 %
Doxylamine pyridine-4-yl isomer		
ORGANIC IMPURITIES (USP)	≤ 0.5 %	0.1 %
Carbinoxamine Rel Compound C		
ORGANIC IMPURITIES (USP)	≤ 0.10 %	< 0.05 %

Sigma-Aldrich warrants, that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current Specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchase must determine the suitability of the product for its particular use. See reverse side of website or packing slip for additional terms and conditions of sale

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**Product** ARK2009-10KG  
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Doxylamine ethylamine N-oxide		
ORGANIC IMPURITIES (USP)	≤ 0.15 %	0.00 %
Doxylamine alcohol		
ORGANIC IMPURITIES (USP)	≤ 0.15 %	0.00 %
2-Benzoylpyridine		
ORGANIC IMPURITIES (USP)	≤ 0.10 %	< 0.05 %
Any Unspecified Impurity		
ORGANIC IMPURITIES (USP)	≤ 1.0 %	0.1 %
Total Impurities		
TAPPED DENSITY (USP)	0.65 - 0.82 g/mL	0.74 g/mL
RESIDUAL SOLVENTS	≤ 2000 ppm	813 ppm
Isopropanol		
RESIDUAL SOLVENTS	≤ 2000 ppm	< 300 ppm
Methanol		
RESIDUAL SOLVENTS	≤ 2000 ppm	0 ppm
Xylene		
ELEMENTAL IMPURITIES	-----	-----
No elemental impurities exceeded the control threshold of the option 1 limit as stated in ICH Q3D		



Jamal Touitou  
QC Manager

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