

Certificate of Analysis

Product Name : Doxylamine Succinate EP, USP
Product Number : ARK2009-25KG
Batch Number : 0000414250
 Source Batch : 0000377265
 CAS Number : 562-10-7
 MDL Number : MFCD00056168
 Molecular Formula : $C_{17}H_{22}N_2O \cdot C_4H_6O_4$
 Formula Weight : 388.46 g/mol
 Expiry Date : 06 Nov 2028
 Date Of Release : 15 Jan 2025
 Date of Manufacture : 06 Nov 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 %
SUCCINIC ACID M.POINT (USP)	184 - 188 °C	185 °C
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
LOSS ON DRYING (USP)	≤ 0.5 %	0.0 %
SOLUBILITY (USP)	Very soluble in water and alcohol. Freely soluble in chloroform. Very slightly soluble in Ether	Conforms
ROI (USP)/SULP ASH (PhEur)	≤ 0.1 %	0.0 %
TAPPED DENSITY (USP)	0.65 - 0.82 g/mL	0.75 g/mL
PARTICLE SIZE 500µm	≤ 20 %	6 %
PARTICLE SIZE 63µm	≤ 40 %	30 %
RESIDUAL SOLVENTS Isopropanol	≤ 2000 ppm	536 ppm
RESIDUAL SOLVENTS Methanol	≤ 2000 ppm	< 300 ppm
RESIDUAL SOLVENTS	≤ 2000 ppm	0 ppm

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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Xylene		
HPLC ASSAY (USP)	98.0 - 102.0 %	99.8 %
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)	≤ 0.3 %	0.1 %
Carbinoxamine Rel Compound C (Perrigo)		
ORGANIC IMPURITIES (USP)	≤ 0.10 %	< 0.05 %
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		
FOREIGN MATTER	No significant matter	No significant matter
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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