

Certificate of Analysis

Product Name : Mecloxadmine Dihydrogen Citrate
Product Number : ARK2061-25KG
Batch Number : 0000311011
Source Batch : 0000276712
Formula Weight : 509.97 g/mol
Retest Date : 06 Dec 2028
Date Of Release : 12 Feb 2024
Date of Manufacture : 06 Dec 2023

Test	Specification	Result
DESCRIPTION	A white crystalline odourless powder	A white crystalline odourless powder
IDENTIFICATION - IR	Conforms to reference spectrum	Conforms to reference spectrum
IDENTIFICATION - TLC	The Rf value should be about 80	Conforms
PURITY - LIMPIDITY	A 5% solution in Methanol is clear and colourless.	Conforms
PURITY - PH	4.0 - 4.8	4.5
LOSS ON DRYING	≤ 1.0 %	0.0 %
SULPHATED ASH	≤ 0.1 %	0.0 %
ASSAY	98.0 - 102.0 %	99.9 %
RESIDUAL SOLVENT ANALYSIS Methyl Ethyl Ketone	≤ 1000 ppm	102 ppm
RESIDUAL SOLVENT ANALYSIS Toluene	≤ 890 ppm	4 ppm
RELATED SUBSTANCE (HPLC) Chlorophenylphenylethanol Crude (CPPE)	≤ 0.15 %	< 0.05 %
RELATED SUBSTANCE (HPLC) 4-Chlorbenzophenone	≤ 0.15 %	0.00 %
RELATED SUBSTANCE (HPLC) Largest Single unknown Impurity	≤ 0.10 %	0.00 %
RELATED SUBSTANCE (HPLC) Total Impurities	≤ 2.0 %	0.0 %
MICROBIAL PURITY Total Yeast and Mould Count	≤ 100 CFU/g	< 10 CFU/g

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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Batch 0000311011

MICROBIAL PURITY

≤ 1000 CFU/g

< 10 CFU/g

"Total Aerobic Microbial Count



Jamal Touitou
QC Manager

IE

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