



Produktion
Synthese
Entwicklung

Certificate of Analysis

Amifampridin
3,4-Diaminopyridine

(GMP conform)

Product number 504.01

Batch 33-16-I-77P3018

Formula $C_5H_7N_3$

Molecular Mass 109.13

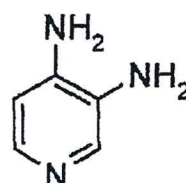
CAS-Nr. [54-96-6]

Type of manufacturing: Synthetic

Date of manufacturing: October 20th 2016

Expiry date: October 19th 2019

Storage conditions: protected from light



Test	Specification	Result
Appearance (Visual)	white to off-white crystalline powder	white crystalline powder
Appearance of solution (DAC 2013)	clear solution and colour intensity is less than reference B ₅	complies
Melting point (DAC 2013)	217 – 221 °C	219.5 °C
Identity by ¹ H NMR (in-house)	complies with suggested structure	complies
Purity by HPLC (DAC 2013)	impurity A ≤ 0.1% each further impurity ≤ 0.10% total impurities ≤ 0.5%	< 0.05% < 0.05% < 0.05%
Assay by Titration (DAC 2013)	99.0 - 101.0%	99.5%
Water content (KF) (DAC 2013)	≤ 1.0 %	0.03%
Residual solvents (ICH guidelines)	Methanol ≤ 3000 ppm	< 3000 ppm



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Test	Specification	Result
Sulphated Ash (DAC 2013)	< 0.1 %	< 0.05 %
Palladium (in-house)	< 10 ppm	< 0.01 ppm
Microbiological Test: (according to E.P. 2.6.12 and E.P. 2.6.13)		
TAMC CFU/g	< 10 ³	< 10
TYMC CFU/g	< 10 ²	< 10
E.Coli	absence	absent



Quality control

Luckenwalde, November 14th 2016

Page 2 of 2