



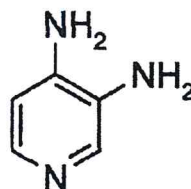
Produktion
Synthese
Entwicklung

Certificate of Analysis

Amifampridin
3,4-Diaminopyridine
(GMP conform)

Product number 504.01
Batch 33-16-I-52P2966
Formula $C_5H_7N_3$
Molecular Mass 109.13
CAS-Nr. [54-96-6]

Type of manufacturing: Synthetic
Date of manufacturing: July 29th 2016
Expiry date: July 28th 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	219.8 °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%	100.2%
Water content (KF) (DAC 2013)	≤ 1.0 %	0.04%
Residual solvents (ICH guidelines)	Methanol ≤ 3000 ppm	≤ 3000 ppm

Quality control
Luckenwalde, August 12th 2016

