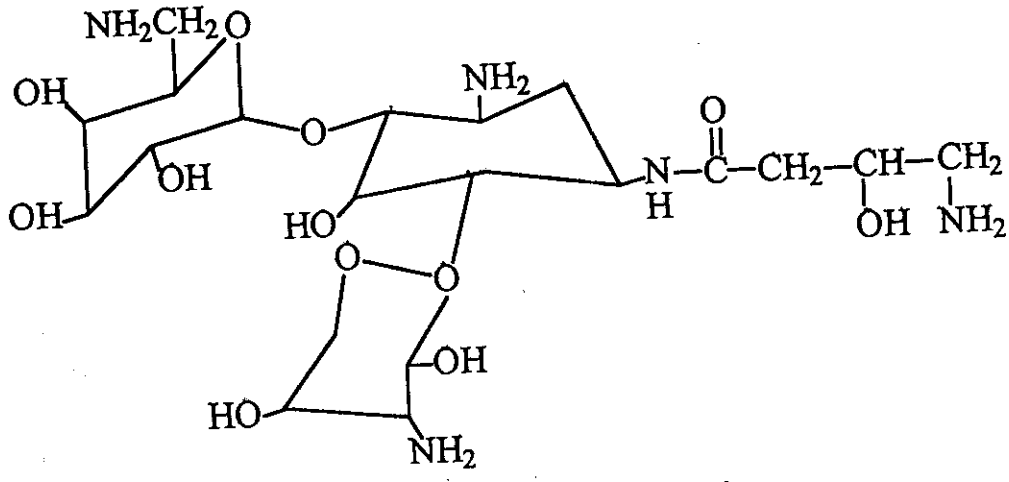
INTRODUCTION

1.1. Literature survey for determination of Amikacin

Amikacin is a white, crystalline powder. Amikacin is a semisynthetic aminoglycoside produced by the strategic chemical alteration of kanamycin A.



Amikacin

Quantitative determination of amikacin sulphate injection by charge-transfer spectrophotometric method was investigated [1]. Amikacin sulphate was determined in aqueous injection solution by charge-transfer spectrophotometry at 250 nm after complexation with tetrachlorobenzoquinone in a buffer solution of pH 3.0. The calibration graph was rectilinear from 4.0 to 16.0 μg mL^{-1} of amikacin sulphate and the average recovery was 99.9%. The method was simple, fast and accurate.

Spectroflourimetric method for amikacin determination was studied by Meng et al [2]. Aqueous sample solution was heated with the derivatization reagent (acetic acid / H_3PO_4 / H_3BO_4 / NaOH buffer of pH 2.6 containing acetylacetone and 30% formalin) at 100 °C for 10 min.

After cooling, the fluorescence intensity of the mixture was measured at 475 nm "excitation at 415 nm". The calibration graph was linear for ≤ 10 μg mL^{-1} of amikacin and the detection limit was 0.2 μg mL^{-1}. The average recovery was 101 % and the intra- and inter-batch relative standard deviation (RSD) were 3.52 and 2.94 %, respectively.

Spectrofluorimetric method for the determination of amikacin was investigated by Mai [3]. Amikacin solution containing 10 μg mL^{-1}, (0.5 mL) was mixed with 0.5 mL of borate buffer solution of pH 8.5 and 0.2 mL of fluorescanine solution was added. The mixture was diluted to 3.0 mL with distilled water. The fluorescance was measured at 483 nm after 3.0 min "excitation at 392 nm". Mean recovery was 100.3 % and the coefficient of variation was 1.0 % (n = 15).

Catalytic precolumn derivatization of amikacin was studied by Lung et al [4]. Sample of amikacin (125 μL) was heated at 75 °C for 75 min with 1.6 mL pyridine, 500 μL of 0.9% (W/V) 4-dimethylaminopyridine and 500 μL of 0.5% (W/V) 2,4,6-trinitrobenzene sulphonic acid. After cooling to room temperature, 500 μL of 20% tetrahydrofuran was added. A 20 μL portion of the reaction mixture was analysed by HPLC on a zorbax SB-C8 column (15 cm x 4.6 mm i.d.) with 0.02 M monobasic potassium phosphate, acetonitrile, methanol (45: 41: 14) adjusted to pH 7.7 with 50% NaOH as mobile phase (2 mL/ min) and detecting at 350 nm. The derivatization procedure was insensitive to the origin of the pyridine used and the sample solution was stable for more than four days. The method was linear and the average recovery was 99.1% with a relative standard deviation (RSD) of 1.1 %.

Determination of amikacin in parenteral dosage forms by high-performance thin-layer chromatography (HPTLC) was investigated by Argekar et al [5]. Amikacin sulphate solution equivalent to 1.0 mg mL^{-1} amikacin was applied to Al-backed silica gel $60F_{254}$ HPTLC plates as 8 mm bonds and developed to 7.0 cm with methanol 1/25 % NH_3 / $CHCl_3$ (5:5:1). After drying the spots, they were derivatized with 0.5 % ninhydrin in n-butanol for one second. Scanning at 498 nm performed quantitation, and the calibration graph (based on peak area) was from 500-3000 μg mL^{-1} of amikacin. Detection and quantitation limits were 0.2 and 0.8 μg, respectively. The RSD (n = 5) of three commercial products were 1.49, 1.22 and 1.37%. The method was applied to parenteral dosage forms; common excipients did not interfere. The method should be useful for routine quality control analysis.

Analysis of amikacin by liquid chromatography with pulsed electrochemical detection was investigated [6]. Samples were dissolved in water containing 500 μg mL^{-1} and 20 μL portion were infected into the column (25 cm x 2.6 mm i.d.) of PLRP-S (5 μm, 1000 Å pore sige) at 40 °C. The mobile phase was a two step gradient of Na_2SO_4 in 1 x 10^{-2} M phosphate buffer of pH 3.0, containing 0.18% sodium octanesulphonate. The elute was mixed post-column with 0.5 M-NaOH (0.3 mL / min) and the amikacin was determined at a pulsed electrochemical detector at 35 °C, with a gold working electrode. Ag / AgCl reference electrode and a stainless steel auxiliary electrode, with pulses from 0.0-0.75 and 0.75-0.15 V at given intervals was used. Calibration graphs for amikacin were linear for 20-120 % of the sample concentration. The RSD of the main peak in one sample was 1.6 % (n = 6). Up to ten components were separated in 1.0 hrs including two isomers of the antibiotic.