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Ph. Eur. Reference Standard - LEAFLET

AMIKACIN SULFATE CRS batch 3

Intended use

This leaflet supplements the currently valid European Pharmacopoeia monograph(s) and/or general chapter(s) describing the suitable use of this Reference Standard.

Further information about the Reference Standards is available in the on-line catalogue currently at <http://crs.edqm.eu> (such as, batch validity statement and material safety data sheet).

Instruction

Amikacin sulfate CRS batch 3 is suitable only for identification as prescribed in the monograph 01/2010:1290. For the assay and the related substances test amikacin CRS must be used instead as follows:

“Reference solution (a). Dissolve 7.5 mg of amikacin CRS in water R and dilute to 100.0 ml with the same solvent, then prepare as prescribed for test solution (a).

Reference solution (b). Dissolve 37.4 mg of amikacin CRS in water R and dilute to 50.0 ml with the same solvent, then prepare as prescribed for test solution (a).

Calculate the percentage content of amikacin sulfate $C_{22}H_{47}N_5O_{21}S_2$ from the declared content of $C_{22}H_{43}N_5O_{13}$ in amikacin CRS taking into account a conversion factor of $(782/585.6) = 1.335$ for the respective molecular weights.”

