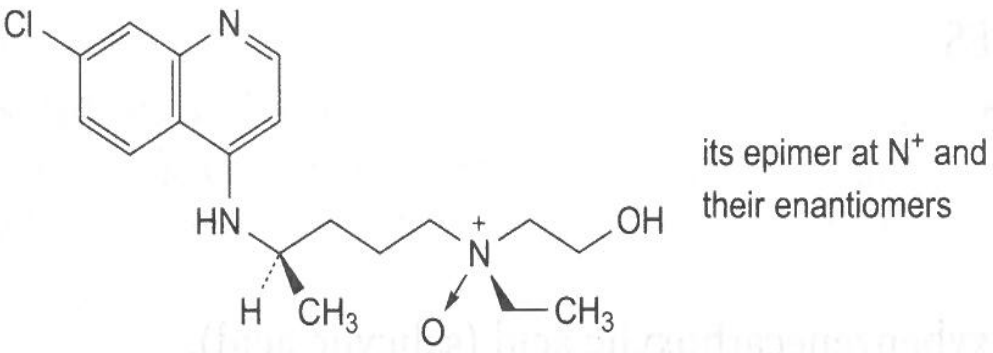
2.1.P.5.5 Characterisation of Impurities

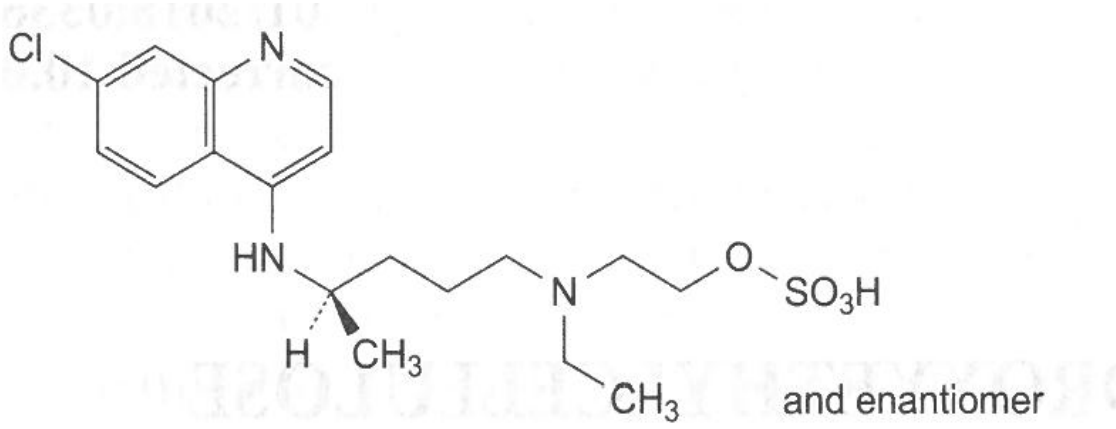
1 Potential organic impurities of hydroxychloroquine sulphate listed in the European Pharmacopoeial monograph are as follows:

Name: *impurity A*



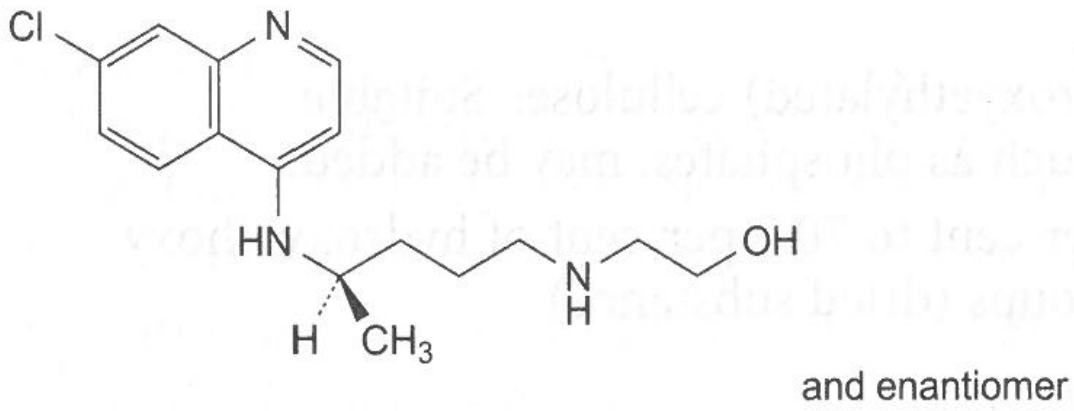
Synonym/chemical name: *mixture of diastereoisomers of 4-[(7-chloroquinolin-4-yl)amino]-N-(hydroxyethyl)penta-1-amine-N-oxide*

Name: *impurity B*



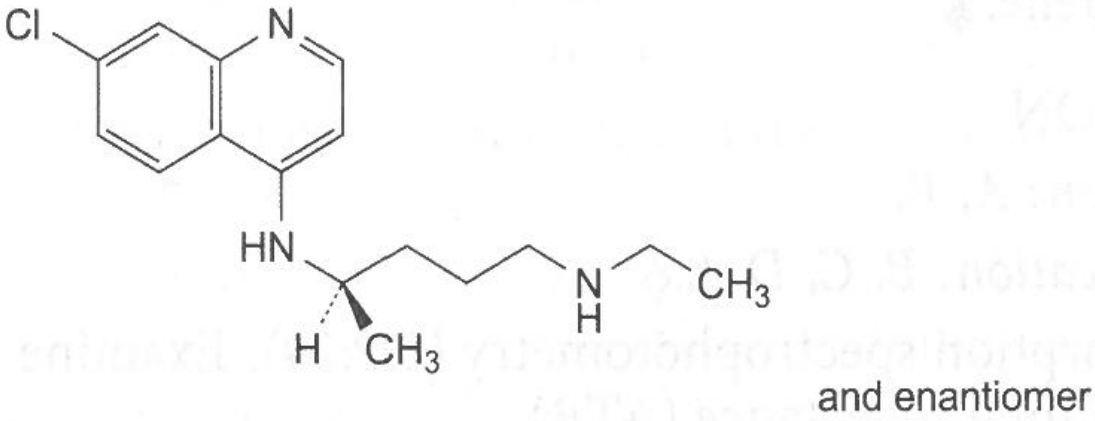
Synonym/chemical name: *2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethyl hydrogen sulphate*

Name: *impurity C*



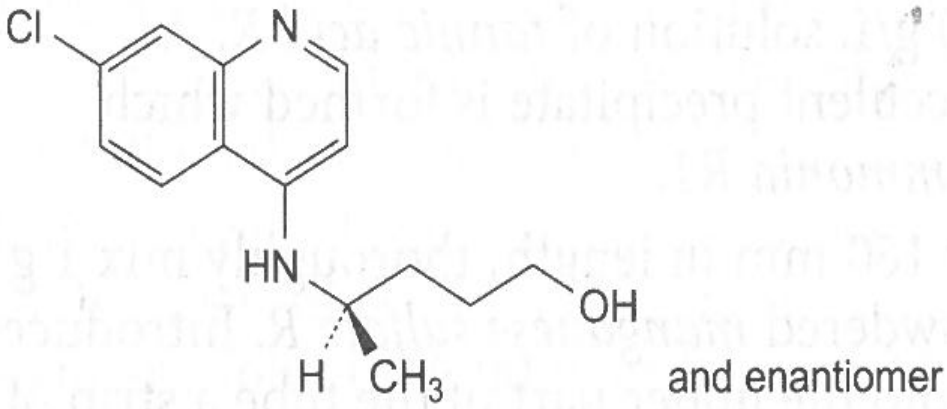
Synonym/chemical name: *2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethan-1-ol*

Name: *impurity D*



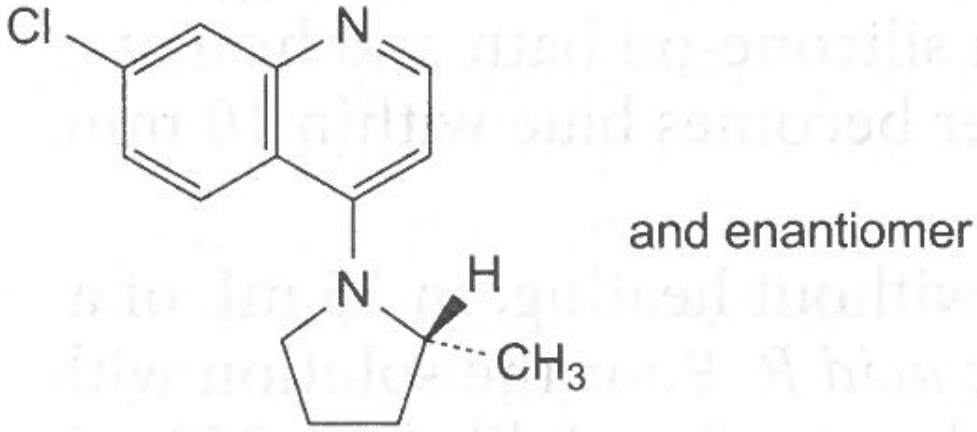
Synonym/chemical name: *(4RS)-N^4-(7-chloroquinolin-4-yl)-N^1-ethylpentane-1,4-diamine*

Name: *impurity E*



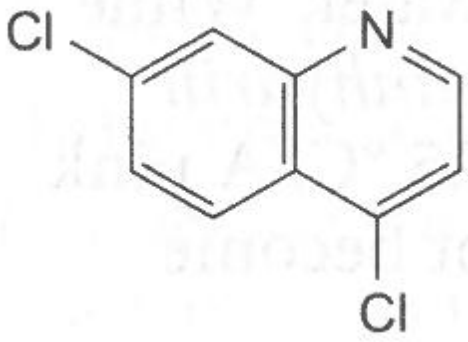
Synonym name: *(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentane-1-ol*

Name: *impurity F*



Synonym name: *7-chloro-4-[(RS)-2-methylpyrrolidi-1-yl]quinoline*

Name: *impurity G*



Synonym name: *4,7-dichloroquinoline*

Residual solvents

No residual solvents used during manufacturing. The potential residual solvents analysed and controlled during API testing.

Inorganic impurities

Inorganic impurities are analysed and controlled during the testing of the API and the excipients.

Genotoxic impurities

No information available about the potential genotoxic impurities.