

- [54] **SUBSTITUTED
BIS-(4-AMINOPHENYL)-SULFONES**
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- [22] Filed: **Jun. 15, 1987**

Related U.S. Application Data

- [63] Continuation of Ser. No. 732,024, May 8, 1985, abandoned.

Foreign Application Priority Data

May 22, 1984 [DE] Fed. Rep. of Germany 3419009

- [51] Int. Cl.⁴ **C07C 103/22**
- [52] U.S. Cl. **514/155; 260/397.6**
- [58] Field of Search **260/397.6; 514/155**

References Cited**U.S. PATENT DOCUMENTS**

2,382,924	8/1945	Tschesche	260/397.6
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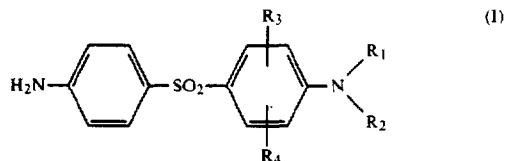
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- Stacey et al., J.O.C. 24, pp. 1892-1896, 1959.

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Mary-Ellen M. Timbers; Alan R. Stempel

[57] ABSTRACT

Disclosed are substituted bis(4-aminophenyl)-sulfones of general formula



wherein

R₁ is hydrogen, alkyl or cycloalkyl; group,
R₂ is hydrogen or C₁-C₃ alkyl,
R₃ is nitrile, C₁-C₃ alkylaminocarbonyl, di C₁-C₃ alkylaminocarbonyl, C₃-C₇ N-cycloalkyl-C₁-C₃ alkylaminocarbonyl C₁-C₃ alkylamino, C₁-C₃, di alkylaminocarbonyl alkoxy, alkylaminosulfonyl, di C₁-C₃ alkylaminono, diC₁-C₃ alkylaminosulfonyl, hydroxy C₁-C₃ alkyl, C₁-C₃ alkylcarbonyl, amino C₁-C₃ alkyl or C₁-C₃ alkoxy C₁-C₃ alkyl group
or, when R₁ and R₂ are each hydrogen, R₃ can be hydroxy, hydroxycarbonyl C₁-C₃ alkoxy or di C₁-C₃ aminocarbonylalkoxy;
or, when R₁ is C₁-C₃ alkyl or C₁-C₃ cycloalkyl and R₂ is hydrogen or C₁-C₃ alkyl, R₃ can also be halogen, trifluoromethyl, nitro, amino, aminosulfonyl, aminocarbonyl, C₁-C₃ alkyl, carboxy or C₁-C₃ alkoxy carbonyl; and
R₄ is hydrogen or, when R₁ and R₂ are each hydrogen and R₃ is halogen or hydroxy, R₄ can also be halogen, hydroxy or C₁-C₃ alkoxy; or a nontoxic, pharmaceutically acceptable salt thereof. Also disclosed are pharmaceutical compositions comprising such compounds alone and in combination with dihydrofolic acid-reductase inhibitors. The compounds and compositions are useful for their inhibiting effect on bacteria, mycobacteria and plasmodia.

11 Claims, No Drawings

**SUBSTITUTED
BIS-(4-AMINOPHENYL)-SULFONES**

This is a continuation of application Ser. No. 732,024, filed May 8, 1985 now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

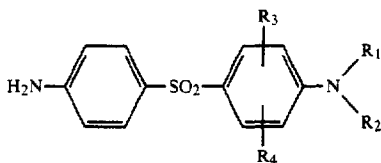
The present invention relates to the field of compounds useful for inhibiting bacteria, mycobacteria and plasmodia, particularly to sulfone compounds which are useful in this regard and in treating animals and humans suffering from infections of such organisms.

2. Brief Information Disclosure Statement

U.S. Pat. No. 2,385,899 describes the compound bis-(4-aminophenyl)-sulfone which has an inhibiting effect on the growth of bacteria, mycobacteria and plasmodia.

SUMMARY OF THE INVENTION

The present invention provides substituted bis-(4-aminophenyl)-sulfones of formula I



wherein

R₁ is hydrogen, C₁-C₇ alkyl or C₃-C₇ cycloalkyl;
 R₂ is hydrogen or C₁-C₃ alkyl;
 R₃ is nitrile, C₁-C₃ alkylaminocarbonyl, di C₁-C₃ alkylaminocarbonyl, C₃-C₇ N-cycloalkyl C₁-C₃ alkylaminocarbonyl, C₁-C₃ alkylamino, di C₁-C₃ alkylamino, di C₁-C₃ alkylaminocarbonyl, C₁-C₃ alkoxy, C₁-C₃ alkylaminosulfonyl, di C₁-C₃ alkylaminosulfonyl, hydroxy C₁-C₃ alkyl, C₁-C₃ alkylcarbonyl, amino C₁-C₃ alkyl or C₁-C₃ alkoxy C₁-C₃ alkyl or, when R₁ and R₂ are each hydrogen, R₃ can be hydroxy or hydroxycarbonyl C₁-C₃ alkoxy or, when R₁ is C₁-C₃ alkyl or C₃-C₇ cycloalkyl and R₂ is hydrogen or C₁-C₃ alkyl, R₃ can also be halogen, trifluoromethyl, nitro, amino, aminosulfonyl, aminocarbonyl, C₁-C₃ alkyl, carboxy or C₁-C₃ alkoxy carbonyl; and
 R₄ is hydrogen, or when R₁ and R₂ are each hydrogen and R₃ is halogen or hydroxy in the 2-position, R₄ can also be halogen, hydroxy or C₁-C₃ alkoxy, or a nontoxic, pharmaceutically acceptable salt thereof.
 One subgeneric aspect includes compounds of formula I wherein:
 R₁ is hydrogen, C₁-C₇ alkyl or a C₄-C₇ cycloalkyl;
 R₂ is hydrogen or methyl;
 R₃ is nitrile, methylaminocarbonyl, N-cyclohexylmethylaminocarbonyl, methylamino, dimethylamino, dimethylaminocarbonylmethoxy, hydroxymethyl, hydroxyethyl, methylcarbonyl, aminocarbonyl or methoxymethyl;
 or when, R₁ and R₂ are each hydrogen, R₃ can also be hydroxy or hydroxycarbonylmethoxy
 or, when R₁ is alkyl or cycloalkyl and R₂ is hydrogen or methyl, R₃ can also be chlorine, bromine, methyl, trifluoromethyl, nitro, amino or aminocarbonyl; and
 R₄ is hydrogen or, when R₁ and R₂ are each hydrogen and R₃ is hydroxy, chlorine or bromine in the 2-position, R₄ can also be chlorine, bromine, hydroxy or

methoxy, or a nontoxic, pharmaceutically acceptable salts thereof.

A further subgeneric aspect includes compounds of formula I wherein:

R₁ is hydrogen, C₁-C₃ alkyl or C₄-C₇ cycloalkyl;

R₂ is hydrogen or, when R₁ is methyl, R₂ can also be methyl;

R₃ is chlorine, bromine, methyl, trifluoromethyl, hydroxymethyl, hydroxyethyl, methylamino, dimethylamino, cyano or methylcarbonyl in the 2-position; and

R₄ is hydrogen; or a nontoxic, pharmaceutically acceptable addition salt thereof.

The present invention thus relates to the compounds of formula I above, the addition salts thereof, particularly the acid addition salts thereof with pharmaceutically acceptable inorganic or organic acids, pharmaceutical compositions containing these compounds including their addition salts, their preparation and the use thereof for inhibiting bacteria, mycobacteria and plasmodia and for treating animals and humans suffering from infections of such organisms.

This invention further relates to combinations of the substituted bis(4-aminophenyl)-sulfones of formula I including their nontoxic, pharmaceutically acceptable addition salts with a dihydrofolic acid-reductase inhibitor such as pyrimethamine, trimethoprim or trimethoprim derivatives.

**DETAILED DESCRIPTION OF THE
INVENTION**

Examples of groups R₁ to R₄ include the following.

R₁ can be hydrogen, methyl, ethyl, n-propyl, isopropyl, n-butyl, isobutyl, n-pentyl, isoamyl, n-hexyl, n-heptyl, cyclobutyl, cyclopentyl, cyclohexyl or cycloheptyl.

R₂ can be hydrogen, methyl, ethyl, n-propyl or isopropyl.

R₃ can be cyano, methylaminocarbonyl, ethylaminocarbonyl, isopropylaminocarbonyl, dimethylaminocarbonyl, diethylaminocarbonyl, di-n-propylaminocarbonyl, N-methylethylaminocarbonyl, N-methyl-cyclopentylaminocarbonyl, N-methyl-cyclohexylaminocarbonyl, N-methyl-cycloheptylaminocarbonyl, N-ethyl-cyclohexylaminocarbonyl, methylamino, ethylamino, n-propylamino, isopropylamino, dimethylamino, diethylamino, diisopropylamino, N-methyl-ethylamino, N-ethyl-n-propylamino, dimethylaminocarbonylmethoxy, diethylaminocarbonylmethoxy, 2-dimethylaminocarbonylethoxy, 2-diethylaminocarbonylethoxy, methylaminosulfonyl, ethylaminosulfonyl, isopropylaminosulfonyl, dimethylaminosulfonyl, diethylaminosulfonyl, hydroxymethyl, 1-hydroxyethyl, 2-hydroxyethyl, 1-hydroxypropyl, 3-hydroxypropyl, methylcarbonyl, ethylcarbonyl, n-propylcarbonyl, aminomethyl, 2-aminoethyl, 3-aminopropyl, methoxymethyl, 2-methoxyethyl, ethoxymethyl, 2-ethoxyethyl, n-propoxymethyl, 2-n-propoxyethyl, hydroxy, hydroxycarbonylmethoxy, 2-hydroxycarbonylethoxy, 3-hydroxycarbonylpropoxy, 2-dimethylaminoethoxy, 2-diethylaminoethoxy, trifluoromethyl, nitro, amino, aminosulfonyl, aminocarbonyl, methyl, ethyl, n-propyl, isopropyl, carboxy, methoxycarbonyl, ethoxycarbonyl, n-propoxycarbonyl, isopropoxycarbonyl, fluorine, chlorine, bromine or iodine.

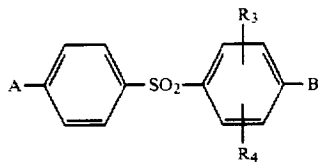
R₄ can be hydrogen, fluorine, chlorine, bromine, iodine, hydroxy, methoxy, ethoxy or n-propoxy.

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According to the invention the compounds of formula I can be obtained by the following processes.

Method A

In one method, compounds of formula I are made by reduction of a compound of formula II



wherein R_3 and R_4 are as previously defined, one of A and B is nitro and the other is

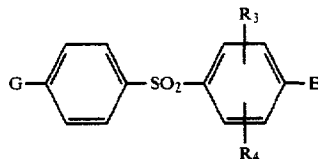


wherein R_1 and R_2 are as previously defined, or is also nitro.

The reduction is conveniently carried out in a solvent or mixture of solvents such as water, methanol, ethanol, glacial acetic acid, ethyl acetate, dimethylformamide, water/ethanol or water/tetrahydrofuran in the presence of a reduction agent, e.g. with hydrogen in the presence of a hydrogenation catalyst such as Raney nickel, platinum or palladium/charcoal, with metals such as iron, tin or zinc in the presence of an acid such as hydrochloric or acetic acid, with salts such as iron(II)sulphate, tin(II)chloride/hydrochloric acid or sodium dithionite in the presence of a base such as sodium hydroxide solution or pyridine or with hydrazine in the presence of Raney nickel, at temperatures of 0° to 50° C., preferably at ambient temperature.

Method B

In another method, one or two protecting groups are cleaved from a compound of formula III



wherein R_3 and R_4 are as previously defined, E is amino, C_1 - C_7 alkylamino or C_3 - C_7 cycloalkylamino protected by a protecting group, or is



wherein

R_1 and R_2 are as previously defined; and G is an amino group optionally protected by a protecting group. At least one of E and G must be one of the above-mentioned groups protected by a protecting group.

Suitable protecting groups are the protecting groups conventionally used for amino groups, e.g. hydrolytically removable protecting groups such as acetyl, pro-

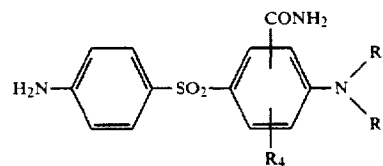
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nyonyl; benzoyl, p-toluenesulfonyl, methanesulfonyl or ethoxycarbonyl, or hydrogenolytically removable groups such as benzyl.

Any protecting group used is preferably split off by hydrolysis, e.g. with an acid such as hydrochloric, sulphuric or phosphoric acid or with a base such as sodium hydroxide or potassium hydroxide in a suitable solvent or a mixture of solvents such as water, water/methanol, ethanol, water/ethanol, water/isopropanol or water/dioxan at temperatures of -10° to 120° C., preferably ambient temperature to the boiling temperature of the reaction mixture, or by hydrogenolysis, e.g. with hydrogen in the presence of a hydrogenation catalyst such as palladium/charcoal in a suitable solvent such as methanol, ethanol, glacial acetic acid, ethyl acetate, dioxan or dimethylformamide at temperatures of 0° to 50° C., preferably at ambient temperature.

Method C

Compounds of formula I wherein R_3 is cyano are prepared by dehydration of a compound of formula IV

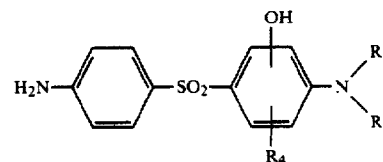


wherein R_1 , R_2 and R_4 are as previously defined.

The dehydration is conveniently carried out with a dehydrating agent such as phosphorus pentoxide, concentrated sulphuric acid, p-toluenesulphonic acid, thionylchloride, phosphorus oxychloride, sulfurylchloride, phosphoric acid or dicyclohexylcarbodiimide, optionally in a solvent such as methylene chloride, pyridine or chlorobenzene or in an excess of the dehydrating agent used such as thionyl chloride, phosphorus oxychloride, sulfurylchloride, or phosphoric acid at temperatures of 0° to 100°, preferably 20° to 80° C. However, the reaction can also be carried out without a solvent.

Method D

Compounds of formula I wherein R_3 is hydroxycarbonylalkoxy or dialkylaminocarbonylalkoxy can be prepared by alkylation of a compound of formula V



wherein R_1 , R_2 and R_4 are as previously defined with a compound of formula VI



wherein

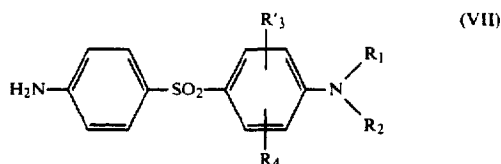
Alk is a C_1 - C_3 alkylene;
 R_5 is hydroxy, C_1 - C_3 alkoxy or di C_1 - C_3 alkylamino; and
 X is a nucleophilically exchangeable group such as chlorine or bromine, optionally with subsequent hydrolysis.

The reaction is preferably carried out in a solvent such as diethylether, tetrahydrofuran, dioxan, methanol, ethanol, pyridine or dimethylformamide, optionally with a base such as sodium hydride, potassium hydride, potassium carbonate or potassium tert.butoxide at temperatures of 0° to 75° C. preferably at ambient temperature.

The optional subsequent hydrolysis is preferably carried out either with an acid such as hydrochloric, sulphuric, phosphoric or trichloroacetic acid or with a base such as sodium hydroxide or potassium hydroxide in a suitable solvent such as water, water/methanol, ethanol, water/ethanol, water/isopropanol or water/dioxan at temperatures of -10° C. to 120° C., e.g. ambient temperature to the boiling temperature of the reaction mixture.

Method E

Compounds of formula I wherein R₃ is aminocarbonyl, alkylamino-carbonyl, dialkylaminocarbonyl or dialkylaminocarbonylalkoxy can be prepared by reaction of a compound of formula VII.



wherein

R₁, R₂ and R₄ are as hereinbefore defined; and R₃' is hydroxycarbonyl, hydroxycarbonyl-alkoxy or a reactive derivative thereof, with an amine of formula VIII



wherein

R₆ is hydrogen atom or C₁-C₃ alkyl; and R₇ is hydrogen or C₁-C₃ alkyl, or reactive derivatives thereof.

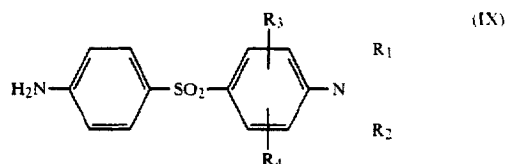
The reaction is conveniently carried out in a solvent such as methylene chloride, chloroform, carbon tetrachloride, ether, tetrahydrofuran, dioxan, benzene, toluene, acetonitrile or dimethylformamide, optionally in the presence of an acid-activating agent or a dehydrating agent, e.g. in the presence of ethylchloroformate, thionylchloride, phosphorus trichloride, phosphorus pentoxide, N,N'-dicyclohexylcarbodiimide, N,N'-dicyclohexylcarbodiimide/N-hydroxy succinimide, N,N'-carbonyldiimidazole or N,N'-thionyl diimidazole or triphenylphosphine/carbon tetrachloride, or an agent which activates the amino group, e.g. phosphorus trichloride, and optionally in the presence of an inorganic base such as sodium carbonate or a tertiary organic base such as triethylamine or pyridine, which can simultaneously serve as solvent, at temperatures of -25° C. to 250° C., preferably -10° C. to the boiling temperature of the solvent used. The reaction can also be carried out without a solvent and furthermore any water formed during the reaction can be removed by azeotropic distillation, e.g. by heating with toluene using a water separa-

tor or by adding a drying agent such as magnesium sulphate or molecular sieve.

In this reaction it can also be advantageous to prepare an activated derivative of a compound of formula VII or VIII in the reaction mixture initially and then react this derivative with a compound of formula VIII or VII.

Method F

Compounds of formula I wherein R₃ is hydroxymethyl, aminomethyl or 1-hydroxyalkyl can be prepared by reduction of a compound of formula IX



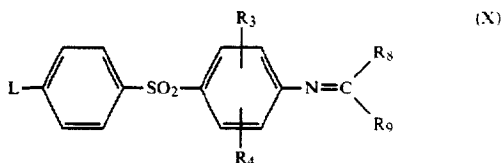
wherein

R₁ and R₂ and R₄ are as previously defined; and R₃' is hydroxycarbonyl, alkoxy carbonyl, aminocarbonyl or C₂-C₄ alkyl carbonyl.

The reaction is preferably carried out with a metal hydride such as sodium borohydride, lithium aluminium hydride or diborane in a solvent such as water, methanol, water/methanol, diethyl ether, tetrahydrofuran or dioxan at temperatures of 0° to 80° C., preferably ambient temperature to 70° C.

Method G

Compounds of formula I wherein R₁ is alkyl or cycloalkyl and R₂ is hydrogen can be prepared by reduction of a compound of formula X



wherein

R₃ and R₄ are as previously defined;

L is amino or nitro; and

R₈ and R₉ together with the carbon atom between them are a C₁-C₇ alkylidene or a C₃-C₇ cycloalkylidene.

The reduction is preferably carried out in a suitable solvent such as methanol, ethanol, methanol/water, ethyl acetate, tetrahydrofuran or dioxan with nascent or catalytically activated hydrogen or with a hydride such as diborane, sodium borohydride or lithium aluminium hydride at temperatures of 0° to 50° C., preferably at ambient temperature.

If L is nitro, the reduction is particularly advantageously carried out in a solvent such as methanol or ethyl acetate with hydrogen in the presence of a hydrogenation catalyst such as platinum or palladium/charcoal and under a hydrogen pressure of 0 to 5 bar or with a complex metal hydride such as lithium aluminium hydride or diborane at temperatures of 0° to 50° C., preferably at ambient temperature.

If L in a compound of formula X is amino, the reduction is carried out particularly advantageously in a solvent such as methanol, methanol/water, tetrahydrofuran or dioxan with a complex metal hydride such as sodium borohydride or lithium aluminium hydride at

temperatures of 0° to 50° C., preferably at ambient temperature.

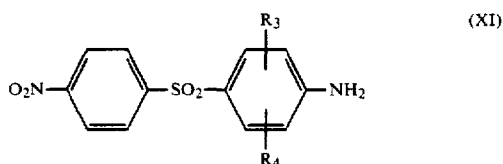
If a compound of formula I is obtained wherein R₃ is alkoxy-carbonyl or alkoxy-carbonylalkoxy, it can be converted by hydrolysis into a corresponding compound of formula I wherein R₃ is hydroxycarbonyl or hydroxycarbonylalkoxy. If a compound of formula I is obtained wherein R₃ and/or R₄ is chlorine or bromine, it can be converted by hydrolysis or alcoholysis into a corresponding compound of formula I wherein R₃ is hydroxy or alkoxy in the 2 position and R₄ is chlorine or bromine.

This hydrolysis is conveniently carried out either with an acid such as hydrochloric or sulphuric acid or with a base such as sodium hydroxide or potassium hydroxide in a suitable solvent such as water, water/methanol, ethanol, water/ethanol, water/isopropanol or water/dioxan at temperatures of -10° C. to 120° C., e.g. at temperatures of ambient temperature to the boiling temperature of the reaction mixture.

The alcoholysis is conveniently carried out in a corresponding alcohol as the solvent such as methanol, ethanol or propanol, optionally in a pressure vessel, preferably with a base such as sodium hydroxide or potassium hydroxide at temperatures of 20° C. to 200° C., preferably 50° to 180° C.

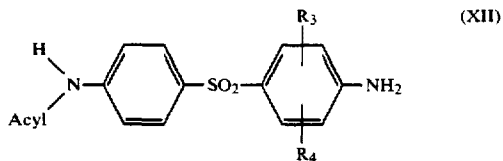
The compounds of general formulae II to X used as starting materials are known from the literature or can be obtained by methods known from the literature.

Thus, for example, a compound of formula II or III can be obtained by reacting an alkali metal salt of a corresponding acylaminophenyl-sulfinic acid with a corresponding p-halonitrobenzene. A compound of formula XI



optionally obtained after splitting off an acyl protecting group, wherein R₃ and R₄ are as previously defined, can subsequently be converted by reductive amination into a compound of formula II or after tosylation, subsequent alkylation and reduction of the nitro group and optionally subsequent acylation into a compound of formula III.

Moreover, a compound of formula XII

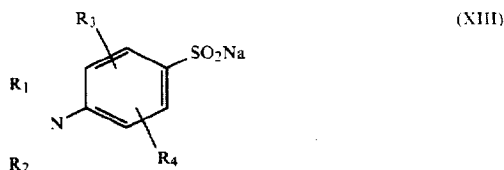


prepared by methods known from the literature, wherein R₃ and R₄ are as previously defined and Acyl is an organic acyl group, can be converted by reductive amination or by reduction of a Schiff's base obtained after reaction with a corresponding carbonyl compound into a compound of formula III wherein D is an aminoacyl group and E is



wherein, R₁ and R₂ are as previously defined.

Moreover a compound of formula XIII



wherein R₁ to R₄ are as previously defined and Na is a sodium ion, can be reacted with a 4-halonitrobenzene to form a corresponding diphenylsulfone of formula III.

A cycloalkylamino compound of formula II, however, is preferably obtained by reductive amination of a corresponding amino compound with a cycloalkanone in the presence of sodium cyanoborohydride or by reduction of the corresponding Schiff's base with a complex metal hydride.

A compound of formula X used as starting material is obtained by reacting a corresponding compound of formula XI with a corresponding carbonyl derivative, optionally in the presence of titanium(IV) chloride and optional subsequent reduction of the nitro group, for example with catalytically activated hydrogen.

As already mentioned hereinbefore, the new compounds of formula I including their nontoxic, pharmaceutically acceptable addition salts having an inhibiting effect on the growth of bacteria and parasites such as plasmodia and mycobacteria which is believed to be due to their inhibiting effect on 7,8-dihydropteroic acid-synthetase.

For example, the following compounds

A = 4-Ethylamino-4'-amino-2-chloro-diphenylsulfone,

B = 4'-Amino-2-chloro-4-isopropylamino-diphenylsulfone,

C = 4-Ethylamino-4'-amino-2-methyl-diphenylsulfone,

D = 4-Ethylamino-4'-amino-2-trifluoromethyl-diphenylsulfone,

E = 4,4'-Diamino-2-hydroxymethyl-diphenylsulfone,

F = 4,4'-Diamino-2-(1-hydroxyethyl)-diphenylsulfone,

G = 4,4'-Diamino-2-(N,N-dimethylamino)-diphenylsulfone,

H = 4,4'-Diamino-2-(N-methylamino)-diphenylsulfone,

I = 4,4'-Diamino-2-cyano-diphenylsulfone,

K = 4,4'-Diamino-2-methylcarbonyl-diphenylsulfone,

L = 4'-Amino-2-methyl-4-methylamino-diphenylsulfone and

M = 4'-Amino-2-methyl-4-propylamino-diphenylsulfone were tested for their biological activity in cell-free enzyme extract of *Plasmodium berghei* as follows.

1. Preparation of the enzyme extract

Plasmodia are isolated from mouse blood infected with *Plasmodium berghei* in accordance with the following reference (Heidrich, H.-G. et al., Z. Parasitenkd. 59: 151 (1979)). The plasmodia were opened by ultrasound. Proteins with 7,8-hydropteroic acid synthetase activity are concentrated by gel filtration.

2. Biological test system

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