TECHNICAL PROBLEM

[0011]

The present invention has been made in view of these problems, and an object of the present invention is to provide a liposome-containing liquid reagent for measuring blood coagulation ability with a small difference in production lots.

SOLUTION TO PROBLEM

[0012]

The present inventor conducted intensive studies in view of the object to find a surprising result that, contrary to conventional expectations, the coefficient of variation between lots changed significantly depending on the particle size of liposomes. Based on this finding, the present invention has succeeded in producing a liposome-containing liquid reagent for measuring blood coagulation ability with a small difference in production lots by controlling the cumulative integrated value of liposomes with particle sizes of 351 nm to the maximum particle size to 0% or more and less than 35% relative to the cumulative integrated value of total liposomes.

[0012a]

In one aspect, the present disclosure refers to a liposome-containing liquid reagent for measuring blood coagulation ability, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes. In another aspect, the present disclosure refers to a process of manufacturing a liposome-containing liquid reagent for measuring blood coagulation ability, said process comprising: step A: the step of mixing phospholipids; step B: the step of forming liposomes by dispersing the mixed phospholipids in an aqueous solution; and step C: the step of preparing uniform liposomes from the liposomes using a liposome particle size adjusting means, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes. In yet another aspect, the present disclosure refers to a method for reducing a difference in production lots of a liposome-containing liquid reagent for measuring blood coagulation ability, said method comprising step A: the step of mixing phospholipids; step B: the step of forming liposomes by dispersing the mixed phospholipids in an aqueous solution; and step C: the step of preparing uniform liposomes from the liposomes using a liposome particle size adjusting means, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes.

[0013]

The present invention relates to:

[1] a liposome-containing liquid reagent for measuring blood coagulation ability, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes,

[2] the reagent of [1], wherein the reagent is an activated partial thromboplastin time measuring reagent, a prothrombin time measuring reagent, a complex factor measuring reagent, a specific factor activity measuring reagent, or a blood coagulation factor inhibitor measuring reagent,

[3] a process of manufacturing a liposome-containing liquid reagent for measuring blood

CLAIMS

1. A liposome-containing liquid reagent for measuring blood coagulation ability, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes.

2. The reagent according to claim 1, wherein the reagent is an activated partial thromboplastin time measuring reagent, a prothrombin time measuring reagent, a complex factor measuring reagent, a specific factor activity measuring reagent, or a blood coagulation factor inhibitor measuring reagent.

3. A process of manufacturing a liposome-containing liquid reagent for measuring blood coagulation ability, said process comprising:

step A: the step of mixing phospholipids;

step B: the step of forming liposomes by dispersing the mixed phospholipids in an aqueous solution; and

step C: the step of preparing uniform liposomes from the liposomes using a liposome particle size adjusting means, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes.

4. A method for reducing a difference in production lots of a liposome-containing liquid reagent for measuring blood coagulation ability, said method comprising

step A: the step of mixing phospholipids;

step B: the step of forming liposomes by dispersing the mixed phospholipids in an aqueous solution; and

step C: the step of preparing uniform liposomes from the liposomes using a liposome particle size adjusting means, wherein a cumulative integrated value of liposomes with particle sizes of 351 nm to a maximum particle size is 0% or more and less than 35% relative to a cumulative integrated value of total liposomes.