

Version 1.1 Revision Date: 03/21/2018

# Standard Doxosome<sup>TM</sup> Kit-Doxorubicin Liposomes (PEGylated)

#### **DESCRIPTION**

The kit is composed of one vial of PEGylated doxorubicin liposomes and one vial of PEGylated control liposomes. PEGylated doxorubicin liposome formulation is similar to commercial Doxil® in size, lipid composition and the amount of encapsulated drug. The formulation is for research purposes only and for injection to laboratory animals. Doxorubicin drug is already loaded into the liposomes using remote loading by ammonium sulfate gradient. The formulation is ready for injection. The control formulation of PEGylated doxorubicin is similar to PEGylated doxorubicin in size and lipid composition, but it does not contain doxorubicin drug. The formulation is made in ammonium sulfate gradient.



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### FORMULATION INFORMATION

## Standard Doxosome<sup>TM</sup> Kit-Doxorubicin Liposomes (PEGylated)

-Vial Kit for Doxosome™ (PEGylated)	Specification
Vial 1	Preformed liposomes composed of HSPC:Cholesterol:DSPE-PEG(2000) (57:38:5 molar ratio)
Vial 2	Preformed liposomes composed of HSPC:Cholesterol:DSPE-PEG(2000) (57:38:5 molar ratio)

Lipid Composition for Vial 1	Concentration (mg/ml)	Concentration (mM)	Molar Ratio Percentage
Hydrogenated Soy PC	9.58	12.22	57
Cholesterol	3.19	1.14	38
DSPE-PEG(2000)	3.19	8.26	5
Total	15.96 mg/ml	21.62 mM	100



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Buffers, Liposome Size and Encapsulated Drug Concentration for Vial 1	Specification
Inside Buffer	Ammonium Sulfate
Outside Buffer	Histidine/Sucrose Buffer
рН	6.5
Liposome Size	80-100 nm
Encapsulated Doxorubicin	2 mg/ml (3.45 mM)

Lipid Composition for Vial 2	Concentration (mg/ml)	Concentration (mM)	Molar Ratio Percentage
Hydrogenated Soy PC	9.58	12.22	57
Cholesterol	3.19	1.14	38
DSPE-PEG(2000)	3.19	8.26	5
Total	15.96 mg/ml	21.62 mM	100

Buffers and Liposome Size for Vial 2	Specification
Inside Buffer	Ammonium Sulfate
Outside Buffer	Histidine/Sucrose Buffer
рН	6.5
Liposome Size	80-100 nm



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#### **APPEARANCE**

Doxosome<sup>TM</sup> (vial 1) is a red, and Doxosome<sup>TM</sup> Control (vial 2) is a white translucent liquid both made of nano size unilamellar liposomes. Usually due to the small size of liposomes no settling will occur in the bottom of the vial. The liposomes are packaged in amber vials.

#### STORAGE AND SHELF LIFE

#### Storage

Doxosome<sup>TM</sup> products should always be stored at in the dark at 4 °C, except when brought to room temperature for brief periods prior to animal dosing. DO NOT FREEZE. If the suspension is frozen, the encapsulated drug can be released from the liposomes thus limiting its effectiveness. In addition, the size of the liposomes will also change upon freezing and thawing.

#### Shelf Life

Doxosome<sup>TM</sup> is made on daily basis. The batch that is shipped is manufactured on the same day. It is advised to use the products within 4 months of the manufacturing date.

#### REFERENCES AND BACKGROUND READING

- 1. Hermanson GT. Bioconjugate techniques. Academic press; 2013 Jul 25.
- 2. <u>Torchilin V, Weissig V, editors. Liposomes: a practical approach. Oxford University Press; 2003 Jun 5.</u>
- 3. <u>Grabarek Z, Gergely J. Zero-length crosslinking procedure with the use of active esters.</u> Analytical biochemistry. 1990 Feb 15;185(1):131-5.



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- 4. <u>Yan L, Crayton SH, Thawani JP, Amirshaghaghi A, Tsourkas A, Cheng Z. A pH-Responsive Drug-Delivery Platform Based on Glycol Chitosan–Coated Liposomes.</u> Small. 2015 Oct 1;11(37):4870-4.
- 5. <u>Silva-López EI, Edens LE, Barden AO, Keller DJ, Brozik JA. Conditions for liposome adsorption and bilayer formation on BSA passivated solid supports. Chemistry and physics of lipids. 2014 Oct 31;183:91-9.</u>
- 6. <u>Hazra M, Singh SK, and Ray S. Surface Modification of Liposomal Vaccines by Peptide</u> Conjugation. Journal of PharmaSciTech, 2011; 1(1): 41-47.