

Technical Information

Version 1.1 Revision Date: 03/21/2018

DoxosomeTM-Doxorubicin Liposomes (PEGylated)

DESCRIPTION

This formulation of doxorubicin liposomes is PEGylated, and it is similar to commercial Doxil® in size, lipid composition and the amount of the encapsulated drug. The formulation is for research purposes only and for the 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.

FORMULATION INFORMATION

| Lipid Composition | 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 | Specification |
|--|--------------------------|
| Inside Buffer | Ammonium Sulfate |
| Outside Buffer | Histidine/Sucrose Buffer |
| pH | 6.5 |
| Liposome Size | 80-100 nm |
| Encapsulated Doxorubicin | 2 mg/ml (3.45 mM) |

APPEARANCE

Doxosome[™]-Doxorubicin liposome is a red translucent liquid 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 an amber vial.

STORAGE AND SHELF LIFE

Storage

Doxosome[™] 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.



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Shelf Life

DoxosomeTM 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</u> <u>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.
- 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> <u>Small. 2015 Oct 1;11(37):4870-4.</u>
- 5. <u>Silva-López EI, Edens LE, Barden AO, Keller DJ, Brozik JA. Conditions for liposome</u> <u>adsorption and bilayer formation on BSA passivated solid supports. Chemistry and</u> <u>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> <u>Conjugation. Journal of PharmaSciTech, 2011; 1(1): 41-47</u>.