

## **CERTIFICATE OF ANALYSIS**

## Product Is Cytotoxic And Handle With Care! Product Is For Research Only, Not For Human Use!

| DESCRIPTION:        | Doxoves <sup>®</sup> Liposomal Doxorubicin HCI |
|---------------------|--|
| CATALOGUE #:        | F30204B-D                                      |
| BATCH #:            | 06281201                                       |
| DATE OF PRODUCTION: | 07/02/2012                                     |
| LIPID COMPOSITION:  | HSPC/CHOL/mPEG2000-DSPE (56.3:38.4:5.3 mol%)   |
| ACTIVE:             | Doxorubicin HCL                                |

## ANALYTICAL DATA:

| Lipid concentration:           | $40.8 \pm 1.1 \text{ mM} (30.3 \pm 0.8 \text{ mg/mL}) (Stewart assay)$ |
|--------------------------------|--|
| Drug concentration:            | 4.01 ± 0.07 mg/mL (UV)   |
| Free Drug concentration:       | 0.03 mg/mL (filtration/UV)   |
| Drug encapsulation efficiency: | >99~% (calculated from free drug and total drug concentrations)        |
| Hydration solution (battery):  | 250 mM ammonium sulfate  |
| External buffer solution:      | 10 wt% sucrose, 10mM histidine pH 6.5                                  |
| Particle size (ZetaPALS):      | Mean diameter: 84.0 $\pm$ 0.4 nm; Half-width: 14.9 $\pm$ 1.1 nm        |
|                                | Polydispersity: $0.03 \pm 0.01$  |
| Zeta Potential (ZetaPALS):     | - 16.7 $\pm$ 1.0 mV (measured in 1mM NaCl)                             |
|                                |  |

- Form/Color: Translucent, red and free flow liposomal dispersion, no visible particles/aggregates with naked eye or under microscope
- Stability: Product is sterile filtered (0.2µm) and filled in autoclaved vials. Free from bacteria growth for 6 month for unopened vials stored at  $2 - 8 \, ^{\circ}\text{C}$ .

## STORAGE, HANDLING AND CLEANING:

- Store refrigerated (2-8 deg C). Avoid freezing. Warm to room temperature before use. Visually exam the • uniformity of the product. Mix before opening the vial.
- Method of cleaning: alcohol/bleach/detergent mixture. •

HSPC: fully hydrogenated phosphatidylcholine CHOL: cholesterol mPEG2000-DSPE: 1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-[methoxy(polyethylene glycol)-2000]

| FormuMax Scientific Inc.            | 4062 Fabian Way, Palo Alto, CA 94303 |
|-------------------------------------|--------------------------------------|
| E-mail: <u>service@FormuMax.com</u> | Tel: (650) 856-7948                  |
| Home page: <u>www.FormuMax.com</u>  | Fax: (408) 465-5338                  |