

CERTIFICATE OF ANALYSIS

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

DESCRIPTION:	Doxoves [®] 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 ± 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