

EO-002

## RAPID SHELF LIFE DETERMINATION OF PALM OIL-BASE INTRAVENOUS NANO EMULSION

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### ABSTRACT

Intravenous lipid emulsions are designed, formulated, and prepared to be kinetically stable and remain suspended as submicron oil droplets in aqueous medium for long period of time. The determination of long term stability of parenteral products (2 years shelf life) is a difficult and high cost step in the development of new formulations. We have determined rapidly the shelf life of stable formulations 24 hours after production of 10% and 20% palm oil-based intravenous nanoemulsion with accelerated centrifugal force testing. The measurement shelf life using LUMIfuge® a recently introduced analytical centrifuge which measures near-infrared (NIR) transmission profiles continuously during centrifugation for measuring the sedimentation velocity in the centrifugal fields. The aim of this study was to predict stability of this emulsion for 2 years period. We set up the shelf life stability for 19.2 hours under accelerated centrifugal force 3025 rpm at 15 °C and 25 °C. For emulsions with 10 % oil the resulted integral transmission (IT) below 30 % light transmission were  $\pm 18429.85$  second ( $5.11 \pm 0.0543$  hours) and, this value equal with prediction of shelf life about 6 months and 4 months at 15 °C and 25 °C respectively. For nanoemulsion with 20 % oil the integral transmission under 30 % were  $\pm 49921.14$  second ( $13.86 \pm 0.0106$  hours) and  $\pm 31604.33$  second ( $8.87 \pm 0.00109$  hours) or prediction shelf life equal for 18 months and 12 months if stored at 15° C and 25 °C respectively. This value was equal with shelf life of Lipofundin® from the market when measurement was carried out at the same time. We concluded that the formulation of intravenous palm oil-based lipid emulsion can be stored at 15 °C during 18 months without any degradation physically.

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