

NOFABLE ESO-9920

(Ultra-Purified Polysorbate 80)

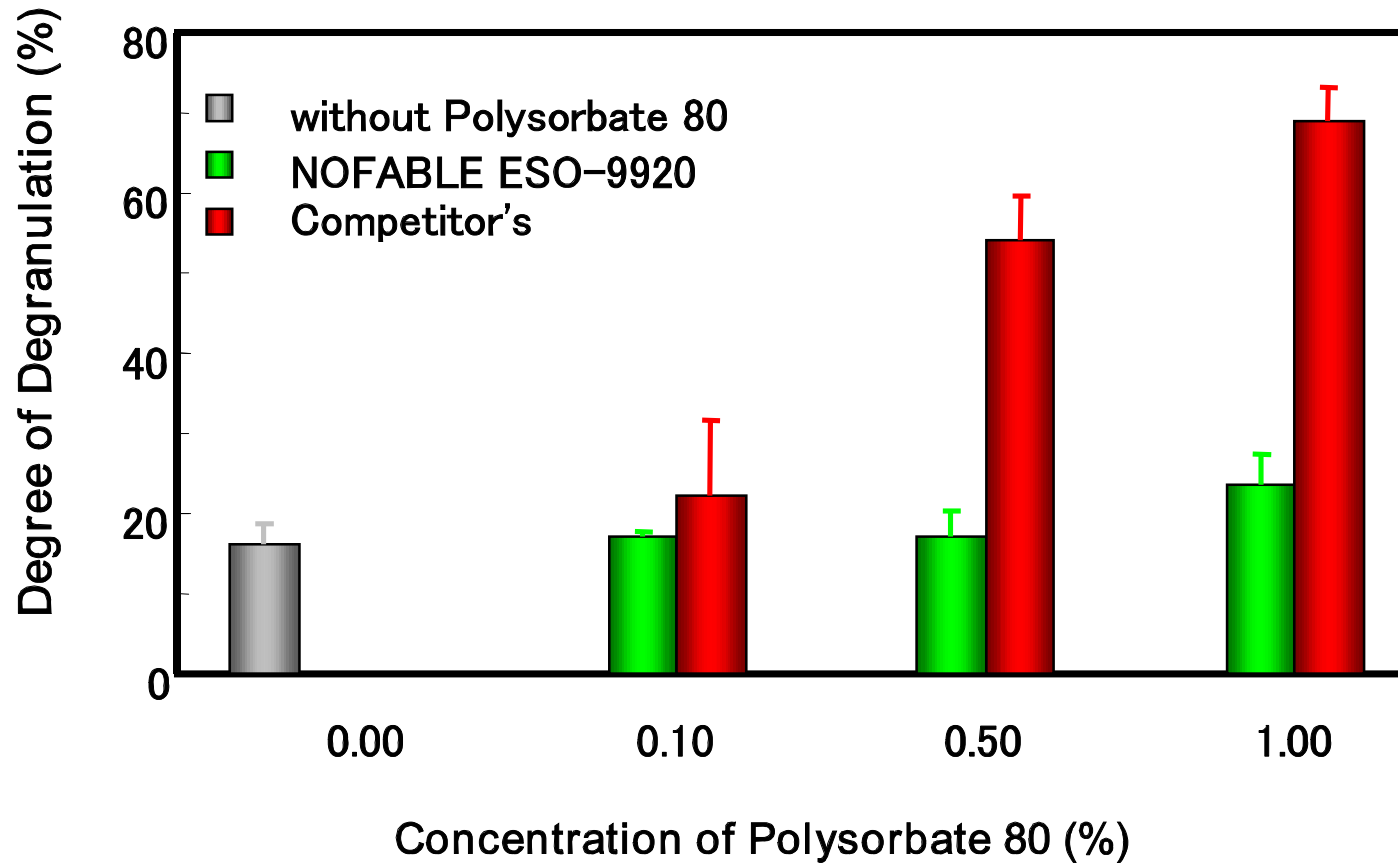
NOFABLE ESO-9920 of NOF CORPORATION is an extra highly purified Polysorbate 80 and an extremely low impurity profile based on both of a purification technology of Oleic Acid (99% up) and a noble ethoxylation technology.

NOFABLE ESO-9920 causes the least allergic reaction among several other Polysorbate 80s. New study indicates that NOFABLE ESO-9920 has a low degranulation characteristics in comparison with competitors' injectable Polysorbate 80s due to its low impurity profile.

The cap of the purity of Oleic Acid(85%max)has been eliminated in EP 5.4th Edition through negotiations between European Medicals Agency (EMA) and NOF CORPORATION.

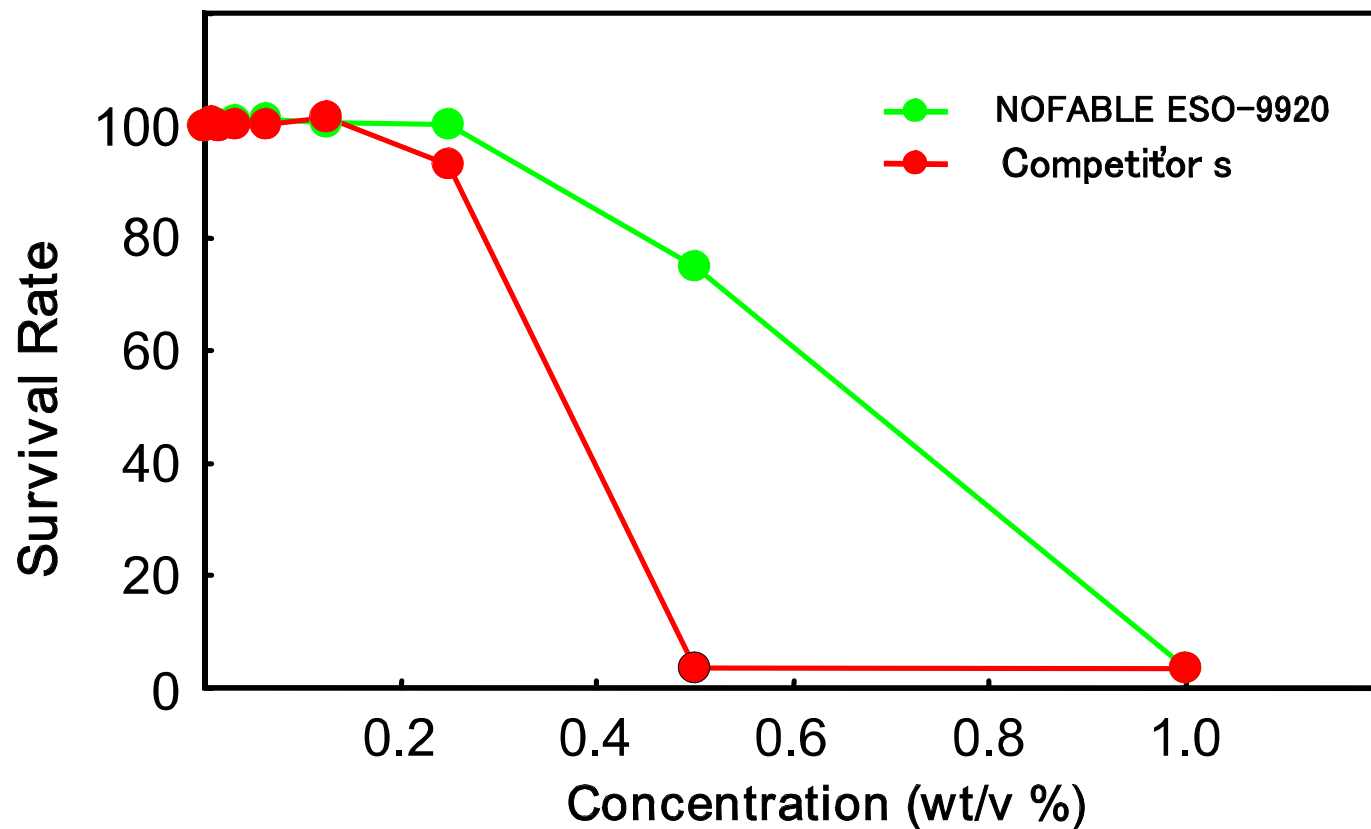
Now, NOFABLE ESO-9920 meets Multi-compendial-NF, EP and JP.

1) Degranulation Test (An allergic study model)



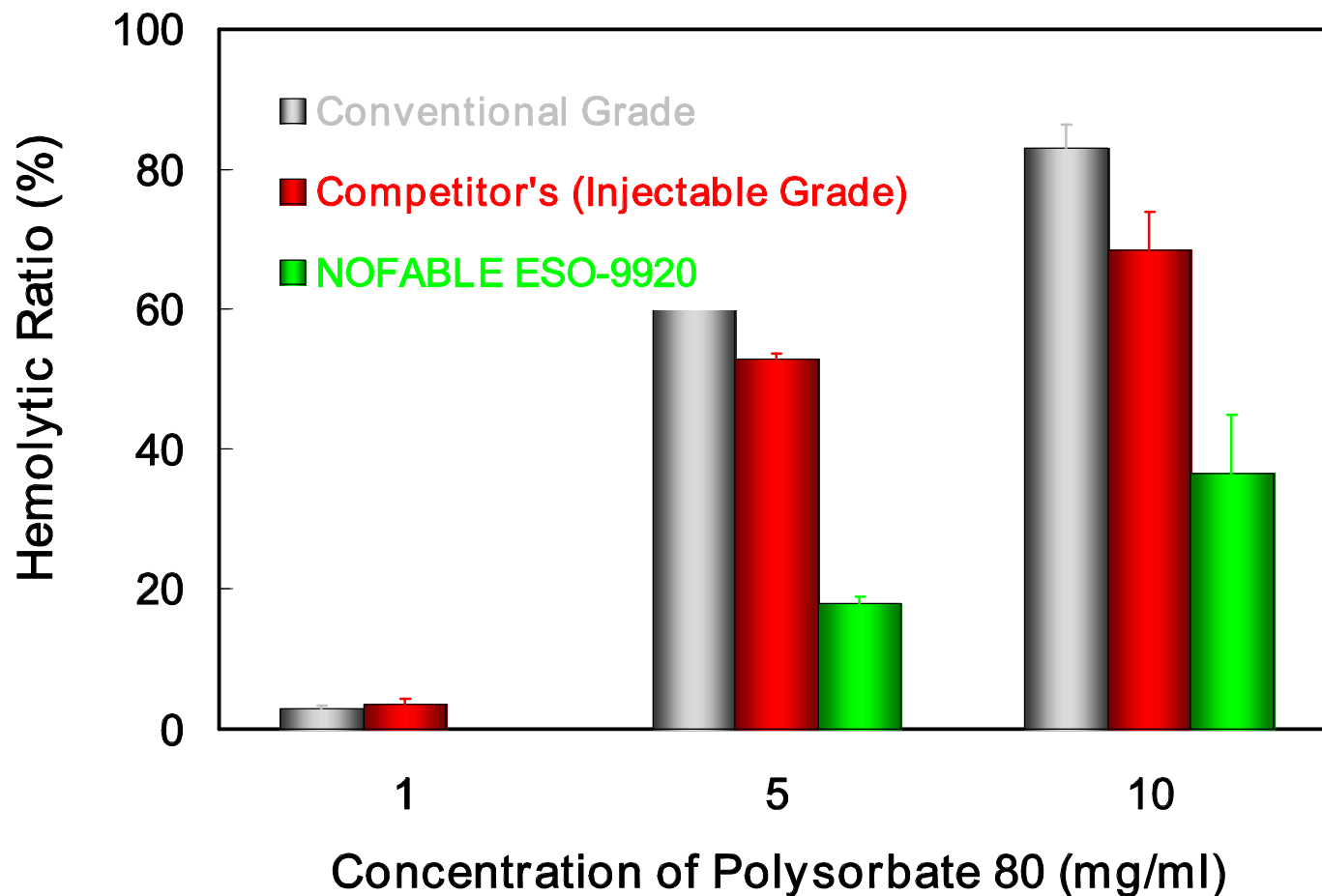
Effect of Polysorbate 80 on degranulation in RBL-2H3 mast cell. The cells were treated with different concentration of polysorbate 80 for 60 mins. The degree of Degranulation is determined by measurement of released α -hexosaminidase into supernatants.

2) Cell Toxicity Test



Effect of concentration of Polysorbate 80 on cell toxicity using SIRC Cell. The cells were treated with each Polysorbate 80 for 24 hrs. The viable cells are determined by Neutral Red Uptake method.

3) Hemolysis Test



Effect of Concentration of Polysorbate 80 on Hemolytic Ratio. Red Blood cells from guinea pig are treated with Polysorbate 80 for 60 mins. Each hemolytic ratio is determined by absorbance of 576nm in the solution.

4) Status of European Pharmacopoeia (EP)

NOFABLE ESO-9920 which consists of high purity Oleic Acid (99% up), has not met EP 5th Edition compendium due to a cap of purity (85% max.) of Oleic Acid of Polysorbate 80 in the compendium.

The cap of the purity of Oleic Acid has been eliminated in EP 5.4th Edition through negotiations between European Medicals Agency (EMA) and NOF CORPORATION.

Now, NOFABLE ESO-9920 (Polysorbate 80) meets Multi-compendial-NF, EP and JP

Summary

NOFABLE ESO-9920 (Polysorbate 80) of NOF Corporation, which consists ultra purified Oleic Acid (99%up) and extremely low impurity profile, provides the following great featured Polysorbate 80.

- i) Low Degranulation (Low Allergic Reaction)
- ii) Low Cell Toxicity
- iii) Low Hemolysis
- iv) Multi-Compendial-NF, EP, JP