

CYCLOLAB



The Cyclodextrin Company



**Surfactant and
cosolvent free
diclofenac injection
(generic Dyloject)**



Marketed diclofenac-Na injections

Problems of approved diclofenac-Na injections (containing at least 25 mg/ml active)

- Akis[®]:** use of sensitizing polysorbate 20 (TWEEN[®])
- Dynapar[®] AQ:** use of cosolvent (tetrahydrofurfuryl propyleneglycol)
- Voltarol[®]:** use of cosolvent (benzyl alcohol)
- Dyloject[®]:** withdrawn due to stability problems



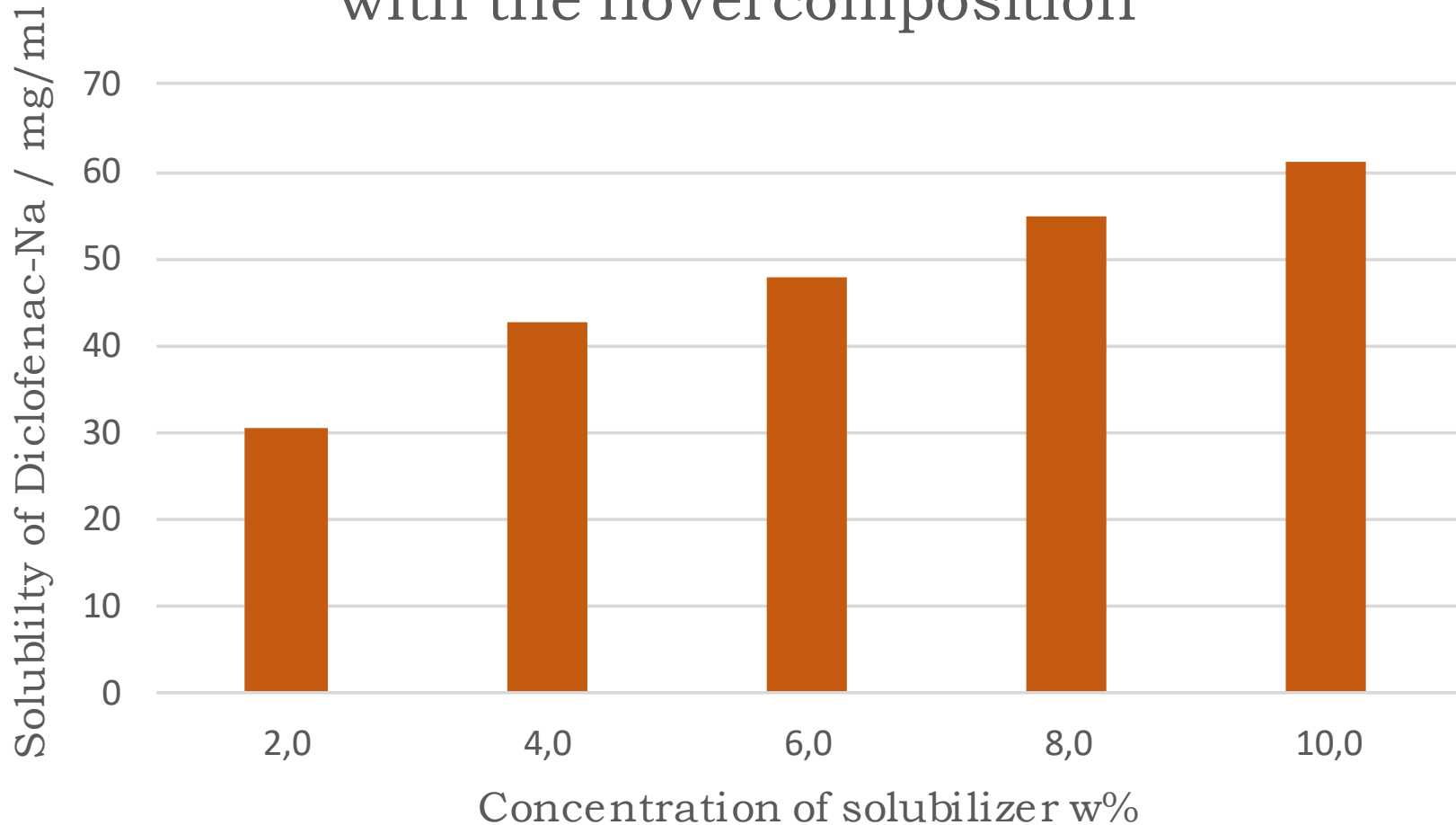
Cyclolab's proprietary diclofenac-Na composition

- Novel (no prior art), inventive → **patentable**
- Aqueous
- Syringeable (suitable viscosity)
 - Acceptable osmolality
 - **Well tolerable components**
(no cosolvent or surfactant!)
- Preliminary data suggests appropriate stability
 - **Low production cost**
 - High concentration (>37.5 mg/ml)



Cyclolab's proprietary diclofenac-Na composition

Equilibrium concentrations attainable with the novel composition





Aqueous diclofenac-Na solution

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