



## TO Develop Method on RP-HPLC and Validate for the Determination of Plasticiser (Di-Octyl Phthalate) Content in Re-constituting Diluents and Re-constituted Solutions of Ciprofloxacin Injection

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**Abstract :** A simple, rapid, accurate and economic reverse phase HPLC method was developed and validated for determination of di-(2-ethylhexyl)phthalate (DOP) in re-constituting diluents and reconstituted solutions of Ciprofloxacin for injection. The method was applied to detect any leaching enhancement in presence of Ciprofloxacin reconstituted injections. Ciprofloxacin for injection is a widely used broad spectrum beta-lactam antibiotic. As per requirements of various regulatory authorities of different countries, DOP content needs to be monitored in the re-constituting diluents used to reconstitute injections. The proposed method is a unique method wherein DOP can be determined directly without any sample pre-treatment before analysis. The method can be used as a good quality control tool to control the leaching of DOP in the re-constituting diluents and reconstituted injections. **Method:** C18 column (250 x 4.6 mm, 5 $\mu$ ) and a mixture of methanol, Acetonitrile and water as mobile phase. DOP was detected at 225 nm. The method has low limit of quantification (0.058  $\mu\text{g mL}^{-1}$ ) which is much below the acceptance limit calculated as per USFDA tolerance criteria (3.5  $\mu\text{g mL}^{-1}$  for adults and 0.3  $\mu\text{g mL}^{-1}$  for neonates and infants).

**IndexTerms** - HPLC, DOP, PVC, FDA, Re-constituting diluents, Ciprofloxacin for injection.

**Keywords :** Desalination, Adsorption, Reverse Osmosis, Chemical Precipitation, Bio sorbent.

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