Title: **Optimization and validation of methods for the analysis of cyclodextrin pharmaceutical drug.**

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Date: January 2019

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Cyclodextrins are a type of molecules that are widely used in the pharmaceutical industry because of their properties. Usually, they are used as excipients, since among its properties, it emphasizes the ability to increase the solubility of other molecules with therapeutic properties, as well as the biocompatibility of medications or the ability to mask the bitter taste of some pharmaceutical products.

On the other hand, some derivatives of cyclodextrins can be used as active principles directly, just in the same way the product studied in this project is used.

The main objective of this work has been to establish a definitive related substances (impurities) method of the pharmaceutical product, optimizing the original method, and, on the other hand, developing the validation of the assay method of the same product.

The analytical methods used in this report have been taken from the active ingredient supplier's developed methods of the product under study. Both are separation methods by reversed phase liquid chromatography with diode array detection, because the substances present in the pharmaceutical product have not high polarity.

In the optimization process of the related substances method, changes have been made to the general parameters of the method and some tests have been carried out to identify impurities that appear at the beginning of the chromatogram.

The validation of the assay method has been carried out according to the criteria established by Galenicum Health S.L. and in accordance with international guidelines. The method has been validated by assessing the linearity, accuracy, precision and repeatability and stability of the solutions. Although the results are not included, specificity and robustness were also evaluated.