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PII: S0731-7085(17)30624-6
DOI: http://dx.doi.org/doi:10.1016/j.jpba.2017.06.019
Reference: PBA 11325

To appear in: *Journal of Pharmaceutical and Biomedical Analysis*

Received date: 11-3-2017
Revised date: 11-6-2017
Accepted date: 12-6-2017

Please cite this article as: Zhaoxia Hu, Sanguo Gao, Jue Gao, Investigation and structural elucidation of a new impurity in bulk drug of cilostazol by LC/MS/MS, FT-IR and NMR, Journal of Pharmaceutical and Biomedical Analysishttp://dx.doi.org/10.1016/j.jpba.2017.06.019

Investigation and structural elucidation of a new impurity in bulk drug of Cilostazol by LC/MS/MS, FT-IR and NMR

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Graphical abstract

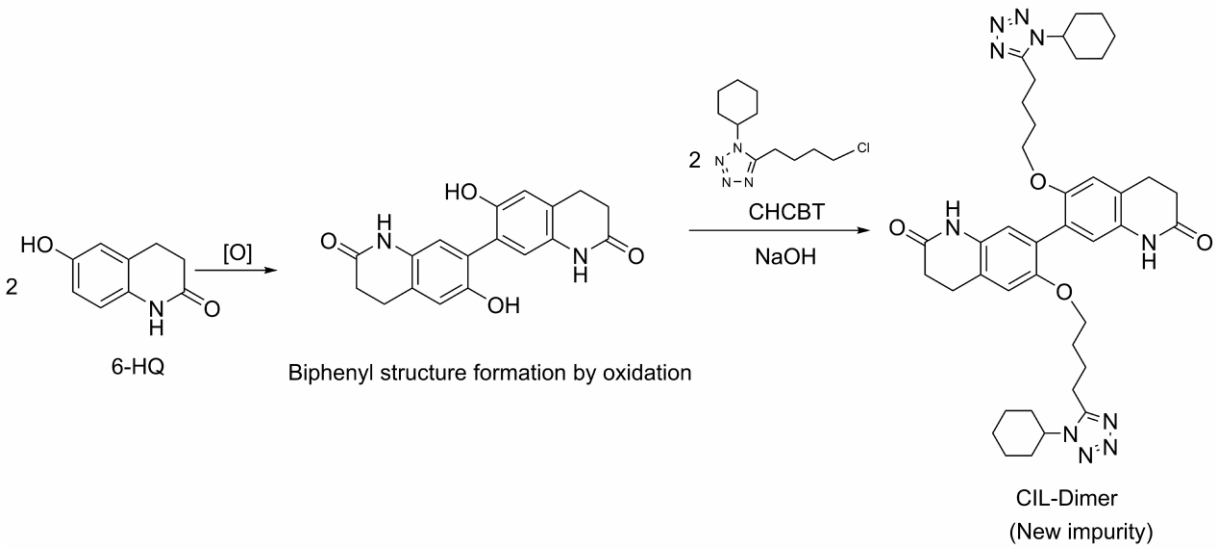

Fig.1. Graphical abstract

Highlights

· A new cilostazol impurity has been identified using MS, NMR, and IR.

. Quantification of the impurity by HPLC was studied.

.The mechanism for the impurity formation was proposed and confirmed by comparison experiments.

·Nitrogen inerting can effectively control the formation of the impurity in cilostazol bulk production.

ABSTRACT

A new impurity was detected in bulk cilostazol (CIL) crude during routine analysis. The impurity (~4%, the specification for unknown impurity in crude is not more than 0.20%) has a relative retention time of 1.46. Based on MS, NMR and IR spectral data, the impurity was identified as