Accepted Manuscript

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

Authors: Zhaoxia Hu, Sanguo Gao, Jue Gao

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

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



ACCEPTED MANUSCRIPT

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

Zhaoxia Hu1*, Sanguo Gao1, Jue Gao1

¹Process optimization department, Teva Pharmaceutical and Chemical (Hangzhou) Ltd, Hangzhou,311228, China

Corresponding author:

Zhaoxia Hu

Tel:+86-571-82106032; e-mail: zhaoxia.hu@teva.cn

Postal address: Process optimization department, Teva Pharmaceutical and Chemical (Hangzhou) Ltd, Hangzhou 311228, China

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

Download English Version:

https://daneshyari.com/en/article/5137800

Download Persian Version:

https://daneshyari.com/article/5137800

<u>Daneshyari.com</u>