

Isolation and characterization of two impurities of Nifedipine

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The identification and characterization of API impurities can be a long and arduous process. For this reason, when an impurity is under control and falls within acceptable specifications, its identification is not usually performed. However, there are cases where customers or regulatory agencies ask for impurity identification even though they fall within the more stringent specifications for unknown impurities. This can lead to interesting findings.

We present here a case of the isolation and identification of two unknown impurities present in the crude of Nifedipine (Figure 1), a calcium-channel blocker used in the treatment of hypertension. The findings that emerged from this work allowed us to better understand the genesis of two other impurities already characterised and identified in the past.

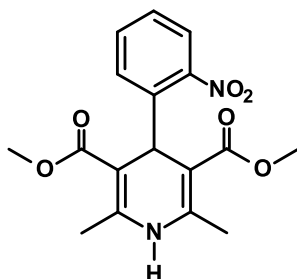


Figure 1: Nifedipine