MOXIFLOXACIN HYDROCHLORIDE COMPOUND IMPURITIES MICROSCOPIC IMAGING STUDY

Spaulding, V.E. *

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Abstract: The methodology and formula for producing moxifloxacin hydrochloride compounds and having very low levels of impurities are provided in Pharmaceutical US Patent # 20130059880. Which initiates claims that the impurities in and ending result when produced is less than 0.1%, per total volume of this pharmaceutical when in its moxifloxacin tosylate crystal powder form. We contend that moxofloxacin related impurities not only pose some of the already known side affects such as rash, and slight fever, but that these impurities may have other deficiencies, however, may also have unknown other benefits deep within the compound properties as well. However, the problem is that whether it be an optical, electron, and even the world's most powerful Atomic Force Microscope (AFM), they all have limitations in being able to attain deep enough microscopic measurement scale levels, in order to determine what other impurities, deficiencies, and benefits this drug may have. Therefore, a much deeper microscopic imaging study is needed to see if other important discoveries could be made.

Key words: Moxifloxacin, Hydrochloride, Pharmaceutics, Infection.

1 Introduction and Background

The methodology used is to start with a micrograph, depicting a sample of moxifloxacin tosylate crystal powder at approximately 200 μm in diameter. Two microscopic imaging technologies known as IMMI [4] and will attain one

*PhD, Member of the Board of Directors at International Consortium on Microscopic and Macroscopic Research (Gonzales TX, USA) e-mail: vspauldingphd@gmail.com

continuous microscopic imaging view starting at 200 μm, attaining a continuous microscopic imaging video view of much deeper and smaller microscopic measurement scale sizes into this pharmaceutical. Eventually attaining a microscopic measurement scale size of approximately 1.0 nm or smaller. Which will expose this drug at its atomic level or even smaller. The ending result (to one degree or another) will be to find similarities, resemblances, outlines, connections, or microscopic imaging recognition patterns in the drug. Between the known and unknown impurities, deficiencies, and benefits that this pharmaceutical may yet have to offer by the discoveries made within it. Secondly, the video made will take up where this paper leaves off at. Therefore, it is not only important to read this paper to watch the video to it as well.

This paper's foundation is based upon aspects of moxifloxacin is an antibacterial medication used to treat patients with certain types of bacterial infections, such as pneumonia, bronchitis, and also has been an alternative pharmaceutical in the treatment in other types of infections such as *Mycoplasma gentialium*. However, a concise, deeper, comprehensive and detailed micro-imaging study is needed to determine not only attain new data, but to also help scientists, researchers, and the pharmaceutical industry to attain deeper understandings and insights into the compositional aspects of this pharmaceutical. Which would also add new enlightenment as to what additional possible impurities, deficiencies, and benefits this drug may have. This medication is part of a class of drugs called fluroroquinolones, which work by destroying bacterial pathogens in the body. However, as with any drug, side affects may occur as well. Therefore, the intent and purpose of this paper is to discuss some of the side affects caused by this drug, and then introduce the microscopic imaging/video study. Looking at this pharmaceutical starting at a diameter of about 200 μm eventually attain a microscopic measurement of 1.0 nm Which should reveal new data that will provide new data. proving new knowledge, understandings, insights, and enlightenment into this drug never attained before.

2 Headache and Dizziness

Treatment with this antibiotic can cause headache or dizziness in patients, health reports [5] at PDR Health. Which is a, a medical information web site associated with the Physicians' Desktop Reference. Headache pain or sensations of dizziness can affect a patient's ability to remain alert and attentive while at work or school. Patients can manage headache side effects by using an over-the-counter pain medication, such as acetaminophen. During

episodes of dizziness, affected patients should remain seated until the sensation passes in order to prevent injury from tripping or falling down. However, any symptoms should be followed up with a person's physician as soon as possible.

3 Gastrointestinal Upset

After taking a dose of moxifloxacin, patients can develop gastrointestinal side effects. Affected patients can experience stomach discomfort, nausea, vomiting or heartburn, warns at MedlinePlus [5], a health information resource established by the U.S. National Library of Medicine. Additional side effects can include constipation or diarrhea, which may cause abdominal gas or bloating. Gastrointestinal upset symptoms can be uncomfortable and may contribute to a decreased appetite in certain patients. Patients who experience severe diarrhea or notice blood within the stools should contact a medical professional immediately. This side effect can occur up to 2 months after completing treatment and indicates a severe reaction to moxifloxacin.

4 Currently Known Impurity Ratio Per Total Volume

This impurity having the number CAS 721970-37-2 was identified and published for the first time by Dr. Reddy's Laboratories Ltd. [3]. It was observed to be present in amounts above 0.1% in industrially produced moxifloxacin,where it is called Impurity-1.

Second, in the United States Pharmacopedia-India Private Ltd. publication [1], this impurity referred to as Imp-1 was correctly defined as a process impurity. The samples used by USP-India, once again were to carry out the study were provided by Dr. Reddy's Laboratories Ltd. The developed HPLC method allows detecting such impurity in moxifloxacin with a 0.016% delectability limit.

Persons and institution(s) involved in filing US Patent # 20130059880 such as Gottardo [2] also did their own experimentation confirming that the impurities of formula VII is a typical process impurity of moxifloxacin. Its formation appears to be due to the action of hydrofluoric acid, released during the coupling of the two syntons on the methoxy group. Which next releases the methyl carbocation which in turn alkylates a second moxifloxacin

molecule. This impurity is particularly difficult to remove from the product using conventional re-crystallization methods. Therefore, this molecule also needs to be looked for as well.

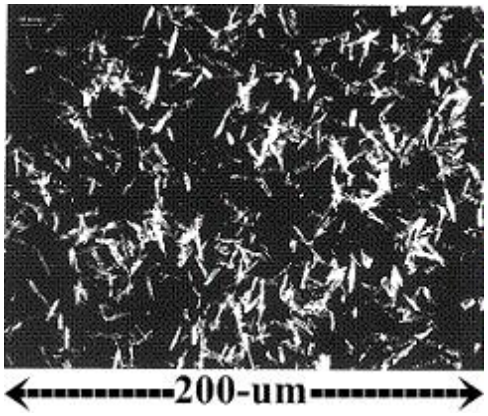

Figure 1: **Visualization of moxifloxacin (Source: Fabbrica Italiana Sintetici S.p.A [2])**

Based upon US Patent # 20130059880 shows an image acquired with an optical microscope of moxifloxacin tosylate crystal powder and indicative impurities at an approximate microscopic measurement scale level of 200 μm (Figure 1).

5 Supplemental Material

Available at: http://www.stewart-research-consulting.com/medical-r–d.html.

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