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# ANALYSIS OF PANTAPRAZOLE NA MONOHYDRATE AND SESQUIHYDRATE BY POWDER X-RAY DIFFRACTION (PXRD)

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## Abstract

Pantaprazole Na monohydrate and sesquihydrate were characterized by PXRD. PXRD shows significant difference in the diffraction patterns of Pantaprazole Na hydrates. The sesquihydrate contains all the diffraction peaks of monohydrate in addition to its significant characteristic peaks.

## Introduction:

Polymorphism and its variation in the degree of crystallinity in a pharmaceutical substance may exhibit physicochemical differences that impacts therapeutic, manufacturing, commercial, and legal levels [1-4]. The abrupt change in the crystalline form during the manufacturing or storage can threaten process development, which may lead to serious consequences. Therefore, quantification of polymorphic forms due to stringent quality control measures of these different solid forms in active pharmaceutical ingredients (API) and drug product is a challenging task for analytical chemists associated with pharmaceutical business. Pantaprazole Sodium (figure 1), a FDA approved drug. is a white to off-white crystalline powder and is racemic [5-12].

In the present work, PXRD analysis of Pantaprazole Sodium (5-(Difluoromethoxy)-2-(((3,4-dimethoxy-2-yridinyl)methyl) sulfinyl)-1H-benzimidazole sodium) has been performed.

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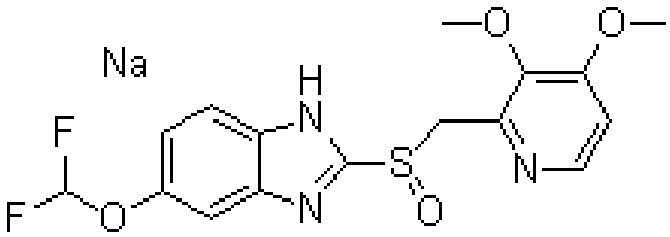


**Figure 1.** Pantaprazole Sodium (5-(Difluoromethoxy)-2-(((3,4-dimethoxy-2-yridinyl)methyl) sulfinyl)-1H-benzimidazole sodium) used in present work

**Experimental section:** The known quantities of pure polymorphic forms of pantaprazole Na monohydrate and sesquihydrate were weighed separately on a Mettler Toledo micro analytical weighing balance with an accuracy of 0.01 mg. The components were ground gently to obtain the homogeneity. The total weight of the samples was kept constant (100 mg) for each set of spiked sample preparation. Several set of spiked samples of concentrations 2, 3, 5, 10, and 15 wt% of monohydrate in sesquihydrate were prepared for the calibration plot of method development. The test samples of polymorphic ratios 6 and 13 wt% of monohydrate were also prepared for the comparison study [5-12].

**Results and discussion:** Pantaprazole Na monohydrate and sesquihydrate were characterized by PXRD. Fig. 2 shows significant difference in the diffraction patterns of Pantaprazole Na hydrates. The sesquihydrate contains all the diffraction peaks of monohydrate in addition to its significant characteristic peaks. Therefore, noninterfering peak of monohydrate was not observed to establish the calibration plot for the quantification of monohydrate in sesquihydrate.

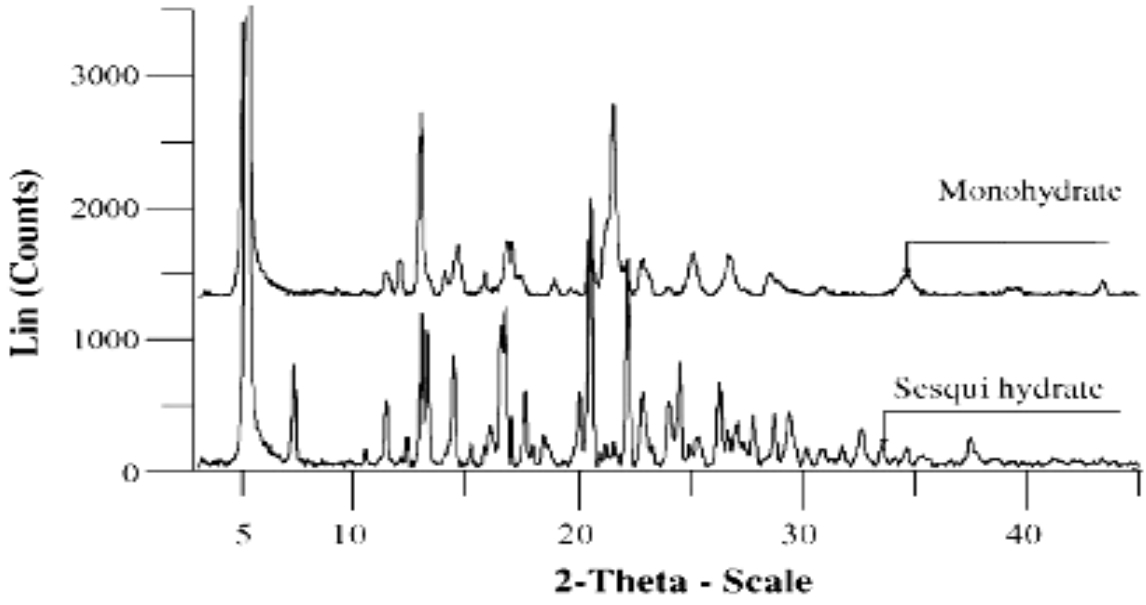


Fig. 2. Overlaid diffraction patterns of pantaprazole Na monohydrate and sesquihydrate.

Conclusion: PXRD was successful in distinguishing the monohydrate and sesquihydrate polymorphic forms of Pantaprazole Sodium.

**References:**

[1] B. Bechtloff, S. Nordhoff, J. Ulrich, Cryst. Res. Technol. 36 (2001) 1315–1328.

[2] H.G. Brittain, Polymorphism in Pharmaceuticals Solids, Marcel Dekker Inc., New York, 1999.

[3] B.Yu. Shekunov, P. York, J. Cryst. Growth 211 (2000) 122–136.

[4] J. Haleblian, W.C. Mc Crone, J. Pharm. Sci. 58 (1969) 911–929.

[5] J. Bernstein, Polymorphism in Molecular Crystals, Oxford University Press, 2002, 410.

[6] D. Singhal, W. Curatolo, Adv. Drug Deliv. Rev. 56 (2004) 335–347.

[7] C.J. Strachan, P.F. Taday, D.A. Newnham, K.C. Gordon, J.A. Zeitler, M. Pepper, T. Rades, J. Pharm. Sci. 94 (2005) 837–846.

[8] D. Giron, J. Thermal Anal. Calorimetry 64 (2001) 37–60.

[9] J. Bauer, S. Spanton, R. Henry, J. Quick, W. Porter, J. Moris, Pharm. Res. 18 (2001) 859–866.

[10] H.G. Brittain, J. Pharm. Sci. 91 (2002) 1573–1580.

[11] G. Chawla, A.K. Bansal, Express Pharma Pulse 9 (2003) 10.

[12] G. Chawla, A.K. Bansal, Express Pharma Pulse 9 (2003) 8, 20.