



February 6, 2006

SUBJECT: Presence of Azithromycin Sesquihydrate (Form G) in Azithromycin 250 mg, 500 mg and 600 mg Tablets Manufactured by Sandoz, Inc, USA

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SUMMARY

Commercial samples of azithromycin 250 mg, 500 mg and 600 mg tablets manufactured by Sandoz, Inc. were purchased in the United States and forwarded to the Special Testing & Analytical Development Lab at Pfizer, Groton, CT for analysis to determine the form of azithromycin in the product. A combination of ¹³C Solid State NMR (ssNMR), Fourier Transform Infrared Spectroscopy (FTIR), Powder X-Ray Diffraction (PXR), and headspace gas chromatographic (GC) analyses were performed on the samples. Results from the spectroscopic tests were compared to reference spectra of azithromycin Form G (azithromycin sesquihydrate), Form A (azithromycin dihydrate) and other forms recorded in US Patent No. US 6,977,243. Results from FT-IR, PXR, and ssNMR demonstrated the absence of detectable Form A in the three tablet strengths. The PXR results indicated that the samples contained azithromycin in a crystalline form within Family I, which is comprised of Forms F, G, H, J, M, N, O and P. The PXR results also provided evidence for absence of Form Q and those in Family II, which is comprised of Forms C, D, E, and R.

Further analysis by ssNMR and headspace GC provided for differentiation between the Family I isomorphs. The ssNMR results obtained for the three tablet strengths demonstrated excellent agreement (45 of 49 peaks matched) with the ssNMR spectrum of our Form G reference material. The ssNMR spectra for the samples also showed absences of diagnostic signals that indicated absence of five Forms (i.e., F, H, J, M, N) in the Family I isomorphs. Headspace GC analysis found no detectable n-butanol and n-propanol in the tablet samples and supported absence of Forms O and P in the Sandoz Azithromycin tablets. The headspace GC analysis also found absence of detectable levels of solvents that are components of azithromycin Forms D, E, J, M, and N. Ethanol (0.001-0.002% by weight relative to total azithromycin) was found in each of the tablet strengths. If all of the ethanol was assumed to be present as azithromycin monohydrate hemi-ethanolate (Form F), the contribution of Form F to total azithromycin content would be less than 0.1%. Based on the collective results from headspace GC, FT-IR, PXR, and ssNMR analyses, the Sandoz tablets are concluded to contain azithromycin in sesquihydrate form only.

OBJECTIVES

Testing was performed on Sandoz azithromycin 250 mg, 500 mg and 600 mg tablets to determine the form of azithromycin present in the sample. A combination of ssNMR, FT-IR and PXR spectroscopic techniques were used for the analysis. Additional testing by headspace gas chromatography was used to verify presence or absence of solvents associated with various known crystal forms of azithromycin.

SAMPLE DESCRIPTION

The 250 mg, 500 mg and 600 mg tablets used in these analyses were obtained by Pfizer from the distributor (AmerisourceBergen) and sent to the Special Testing & Analytical Development Laboratory at Pfizer GQAR, Groton, CT for testing. All samples were stored at all times at controlled room temperature. Photographs and other details for the 250 mg, 500 mg, and 600 mg tablet samples are presented in **Figures 1, 2 and 3**, respectively.

ANALYTICAL RESULTS

1. Fourier Transform Infrared Spectroscopy (FTIR)

A Nicolet model Magna-IR 550 Fourier Infrared (FT-IR) spectrometer was used to analyze the Azithromycin tablet samples using method described in Pfizer Standard Test Procedure (STP) I 3.94. Each sample was analyzed as a potassium bromide pellet preparation. Resulting spectra for the 250, 500 and 600 mg samples along with overlays with azithromycin dihydrate reference, are shown in **Figures 4, 5, and 6**, respectively. Diagnostic IR bands of 3559cm^{-1} , 3495cm^{-1} , 1343cm^{-1} , $1282/1270\text{cm}^{-1}$ (doublet) and 1083cm^{-1} that are unique to azithromycin dihydrate were not found in any of the three tablet strengths. These data indicate absence of azithromycin dihydrate in the samples (within estimated detection limit of 25% by weight relative to total azithromycin content).

2. Analysis by Powder X-Ray Diffraction (PXRD)

PXRD diffractograms were collected for the Sandoz 250, 500 and 600 mg azithromycin tablets using a Siemens D4 X-Ray Diffractometer. A portion of each tablet was gently ground to a fine powder in a mortar and pestle for the analysis. Resulting diffractograms were compared to those obtained previously for azithromycin dihydrate (Form A) and azithromycin Form G (azithromycin sesquihydrate, lot 51047-21-4H) reference samples.

Comparisons of the diffractogram for azithromycin dihydrate (Form A) with those obtained for the Sandoz 250, 500, and 600 mg tablets are shown in **Figures 7, 8, and 9**, respectively. The most diagnostic peaks for azithromycin dihydrate in the region from 7 to 22 degrees in 2-theta were not present in a pattern indicative of Form A. These data provide evidence for the absence of detectable azithromycin dihydrate in the tablets. Estimated detection limit for azithromycin dihydrate by the PXRD technique is 5% by weight relative to total azithromycin content.

The PXRD results for the Sandoz samples also provided evidence that Family II forms of azithromycin are not present in the sample. Family II includes Form D (monohydrate/monocyclohexane solvate), Form E (azithromycin monohydrate/mono-tetrahydrofuran solvate), Form C (azithromycin monohydrate, as described in US 6,977,243), and Form R (azithromycin hydrate/methyl tert-butyl ether solvate). The most diagnostic PXRD signals for the isomorphs in this family occur at 3.9, 10.1, 10.6 and 21.4 2-theta. All three spectra in **Figures 7, 8, and 9** were found to be missing the most easily discernible signals (i.e., those with highest intensity) at 3.9, 10.1 and 10.6 2-theta. One additional form, Form Q (azithromycin hydrate/hemi-tetrahydrofuran solvate) was also found to be absent in the three Sandoz tablets. This result was demonstrated by absence of diagnostic signals for Form Q at 6.8 and 8.4 2-theta in the sample spectra shown in **Figures 7, 8 and 9**.

Diffractograms of the 250 mg, 500 mg, and 600 mg tablets are shown with overlays of the Form G diffractogram in **Figures 10, 11, and 12**, respectively. Each of the sample spectra are found to contain peaks that match both position and relative intensity of those found in the reference spectrum of Form G. Form G is one form in a family of eight azithromycin isomorphs

(Family I) that have similar x-ray diffraction characteristics. In addition to Form G, the other isomorphs in this family are Form F (azithromycin monohydrate/hemi-ethanol solvate), Form H (azithromycin monohydrate/hemi-propylene glycol solvate), Form J (azithromycin monohydrate/hemi-n-propanol solvate), Form M (azithromycin monohydrate/hemi-isopropanol solvate), Form N (azithromycin water/ethanol/isopropanol solvate), Form O (azithromycin hemi-hydrate/hemi-n-butanol solvate), and Form P (azithromycin hemi-hydrate/hemi-n-pentanol solvate). Because the PXRD spectra are essentially identical for each of the forms in this family, additional analysis (e.g., ssNMR) was needed to distinguish which is present in the samples.

3. Analysis by ^{13}C Solid State NMR (ssNMR)

Under direction of our laboratory, the ^{13}C -ssNMR spectral analyses were conducted at the Pfizer Global Research and Development NMR Laboratory in Groton, CT, USA. Results of these experiments are summarized below. For the analysis, an individual tablet was ground gently to a powder and an approximate 270 mg portion was packed into the NMR tube for analysis. A one-dimensional ^{13}C -ssNMR spectrum was collected for each of the samples using a ^1H - ^{13}C carbon cross-polarization magic angle spinning (CPMAS) technique. Full details of the NMR analyses are reported in research reports CP62993_IP06009_19Jan2006 and CP62993_IP05054a.27JAN2006.

The resulting ^{13}C CPMAS spectra (ssNMR) of each sample were compared to the spectra of azithromycin Form G and Form A that had been previously documented (see PharmSci NMR report CP62993.061401, prepared by A. Medek and L. Lohr on May 28, 2002). No azithromycin Form A was found with the detection limit of approximately 1.5% (relative to the total azithromycin content). In the sample analyzed, azithromycin was found to be present as Form G. Spectral data for the sample, Form A, and Form G are shown in **Figure 13** (250 mg and 600 mg tablets) and **Figure 14** (500 mg tablet).

The ssNMR results in **Figures 13 and 14** demonstrate that the azithromycin in Sandoz 250 mg, 500 mg, and 600 mg tablets is present as the sesquihydrate Form G. Within Family I isomorphs, each of the other Forms F, H, J, M, N, O, and P may be eliminated by absence of ssNMR signals corresponding to the crystalline solvent components in each form. Form F is excluded by absence of the signal for crystal-bound ethanol at 58.0 ppm. Form J is excluded by absence of detectable signals in the sample for crystal-bound n-propanol at 11.5 ppm and 25.2 ppm. Forms M and N are excluded by absence of detectable signals for crystal-bound isopropanol at 26.0 ppm. Form H is not present since its characteristic peaks at 103.2, 82.7, 66.9, 46.8, 33.3, 15.4 and 7.0 ppm are missing. Headspace GC analysis (discussed in Section 4) demonstrated absence of n-butanol and n-pentanol and provides evidence for excluding the remaining two forms (Forms O and P) in Family I.

Table 1 shows the comparison of carbon chemical shifts observed on the sample with those of azithromycin Form G disclosed in the example section of US 6,977,243 patent. Of 49 peaks listed in the patent, 45 were identified (within the ± 0.2 accuracy limits) in each of the tablet samples. Exceptions were noted for peaks at 75.7 ppm (weak signal in Form G standard was not detected in samples), at 73.5 ppm and 30.0 ppm (peak positions in 600 mg tablet spectrum fell just outside the ± 0.2 ppm accuracy criterion for reference peaks), and at 65.2 ppm (peak exhibited as shoulder with no defined maximum in 250 mg tablet and 600 mg tablet spectra). These variations from the Form G reference spectra are to be expected when the material is formulated into a dosage form with other excipients. Signal interferences from crystalline excipients and solid-solid interactions between the azithromycin and excipient materials leading to line width broadening can each contribute to these variations. Overall, the variations are minor and do not preclude a positive identification of Form G in the samples.

4. Analysis by Headspace Gas Chromatography (GC).

Headspace GC analyses were performed using a Tekmar 7000 Headspace Autosampler and Agilent 6890 Gas Chromatograph with flame ionization detection. Each tablet was dissolved in water (250 mg into 50 mL, 500 mg or 600 mg into 100 mL) and then 5 mL aliquots were placed into a 20 mL headspace vial containing 1 g of anhydrous sodium sulfate. Sealed vials were incubated at 85 C for 10 min and then 2 mL of headspace was injected into the chromatograph. Separation was performed using a 30 m x 0.32 mm i.d. RTX-624 (1.8 μ m film) capillary column. Oven temperature program was 40 C (5 min hold) – ramp 2 C/min to 90 C (0 min hold) – ramp 30 C/min to 225 C (2 min hold).

Retention times for various solvents on the chromatographic system were established by analyzing various aqueous solutions containing solvent reference materials. A summary of solvents and retention times is presented in the table below.

Solvent	Retention time
Ethanol	3.54
Isopropanol	4.33
Methyl tert-butyl ether	5.25
n-Propanol	6.52
Tetrahydrofuran	8.18
Cyclohexane	8.72
n-Butanol	12.21
n-Pentanol	19.80

Headspace GC profiles obtained for the 250 mg, 500 mg and 600 mg Sandoz Azithromycin tablets are presented in **Figure 15**. A small response for ethanol was detected in each of the tablet samples. None of the other seven solvents was detected in the samples. Based on a signal to noise analysis of responses from an external standard solution, limits of detection for n-propanol, isopropanol, 1-butanol, 1-pentanol, and tetrahydrofuran were each found to be 10 ppm (0.001%) or less. The limits of detection for cyclohexane and methyl tert-butyl ether were not specifically measured in this analysis, but would have lower detection limits as a result of relatively lower solubility in water (hence greater concentration in headspace) than the other solvents.

The quantity of ethanol detected in the samples was estimated by comparing response from the sample to that from an external standard solution of ethanol. The amount of ethanol in the three Sandoz samples ranged between 0.001-0.002% (weight relative to total azithromycin). Azithromycin Form F (monohydrate hemi-ethanolate) contains a theoretical 2.9% ethanol by weight. Even if the 0.002% ethanol in the Sandoz tablet was present as Form F (rather than as free solvent), this would contribute only a negligible level (i.e., <0.1%) of Form F to the total azithromycin. The absence of a significant level of ethanol and detectable responses for the other seven solvents provides evidence that the Sandoz Azithromycin tablets do not contain significant amounts of Forms D, E, F, H, J, M, N, O, P, and R.

CONCLUSIONS

Results from these analyses provide conclusive evidence that the Sandoz Azithromycin 250, 500 and 600 mg tablets tested in this study contained azithromycin in sesquihydrate form (Form G) only.

REFERENCES

1. Notebook B108526 pp. 9-10
2. Pfizer Standard Test Procedure I 3.94 (4/22/98) – Identification of azithromycin dihydrate by Infrared spectroscopy.
3. PGRD Report CP62993_IP05054_06Dec2005, prepared by Tim Hanser
4. PGRD Report: CP62993_IP0009_19Jan2006, prepared by Ales Medek
5. PGRD Report CP62993_IP05054a.27Jan2006, prepared by A. Medek
6. PGRD Report CP62993.061401, prepared by A. Medek and L. Lohr on May 28, 2002
7. United States Patent No. 6,977,243 (issued Dec. 20, 2005, Certificate of Correction issued Feb. 7, 2006)



A –Packaging



B- blister



C- tablets

- **Manufacturer:** Sandoz Inc., Broomfield, CO 80020, USA
- **Claimed active ingredient and strength (from package label):** Azithromycin monohydrate equivalent to 250 mg azithromycin
- **Test sample details:** 250 mg tablets in individual blister packaging, Lot No. V05026, expiration date August 2007. Oval, white tablets debossed with “GG D6” on one side and no markings on opposite side. Weight of one representative tablet recorded in laboratory as 411.9 mg.
- **Chain of custody:** The samples were purchased from AmerisourceBergen, 101 Norfolk Street, Mansfield, MA 02048, USA and sent directly to Pfizer GQAR, Eastern Point Road, Groton, CT 06340, USA for testing.

Figure 1. Sandoz Azithromycin (azithromycin) 250 mg tablets - Photographs and details of samples received at Pfizer GQAR laboratory in Groton.



A – Bottle (front)



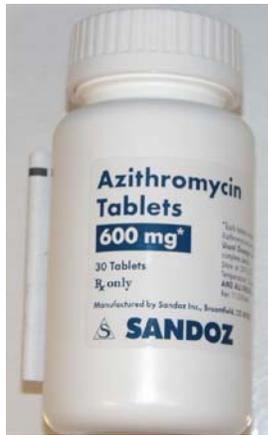
B- Bottle (back)



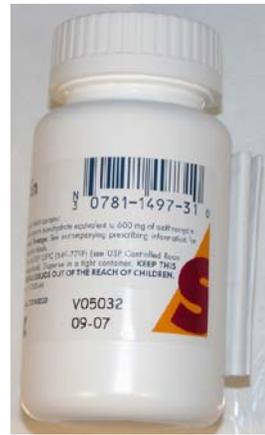
C- Tablets

- **Manufacturer:** Sandoz Inc., Broomfield, CO 80020, USA
- **Claimed active ingredient and strength (from package label):** 500 mg tablets: Azithromycin monohydrate equivalent to 500 mg azithromycin
- **Test sample details:** 500 mg tablets in bottle, Lot No. 159579, expiration date December 2007. Oval, white tablets debossed with “GG D8” on one side and no markings on opposite side. Weight of one representative tablet recorded in laboratory as 808.5 mg.
- **Chain of custody:** The samples were purchased from AmerisourceBergen, 101 Norfolk Street, Mansfield, MA 02048, USA and sent directly to GQAR, Eastern Point Road, Groton, CT 06340, USA for testing. The bottle was received in the laboratory with safety seal intact.

Figure 2. Azithromycin Sandoz (azithromycin) 500 mg tablets - Photographs and details of samples received at Pfizer GQAR laboratory in Groton.



A –Bottle (front)



B- Bottle (back)



C- tablets

- **Manufacturer:** Sandoz Inc., Broomfield, CO 80020, USA
- **Claimed active ingredient and strength (from package label):** 600 mg tablet: Azithromycin monohydrate equivalent to 600 mg azithromycin
- **Test sample details:** 600 mg tablets in bottle, Lot No. V05032, expiration date September 2007. Oval, white tablets debossed with “GGD7” on one side and no markings on opposite side. Weight of one representative tablet recorded in laboratory as 964.1 mg.
- **Chain of custody:** The samples were purchased from AmerisourceBergen, 101 Norfolk Street, Mansfield, MA 02048, USA., and sent directly to GQAR, Eastern Point Road, Groton, CT 06340, USA for testing. The bottle was received in the laboratory with safety seal intact.

Figure 3. Sandoz Azithromycin (azithromycin) 600 mg tablets - Photographs and details of samples received at Pfizer GQAR laboratory in Groton.

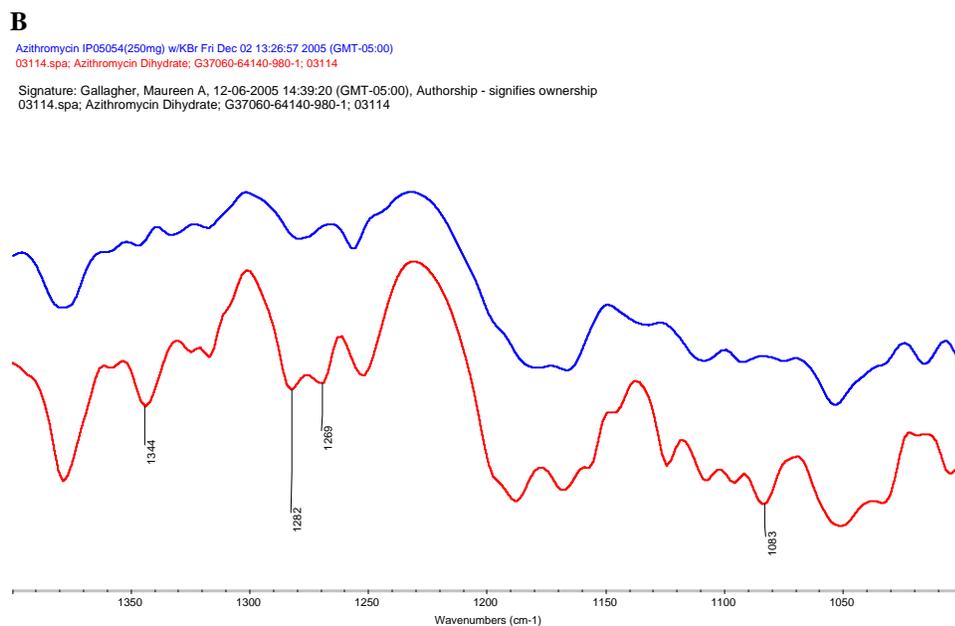
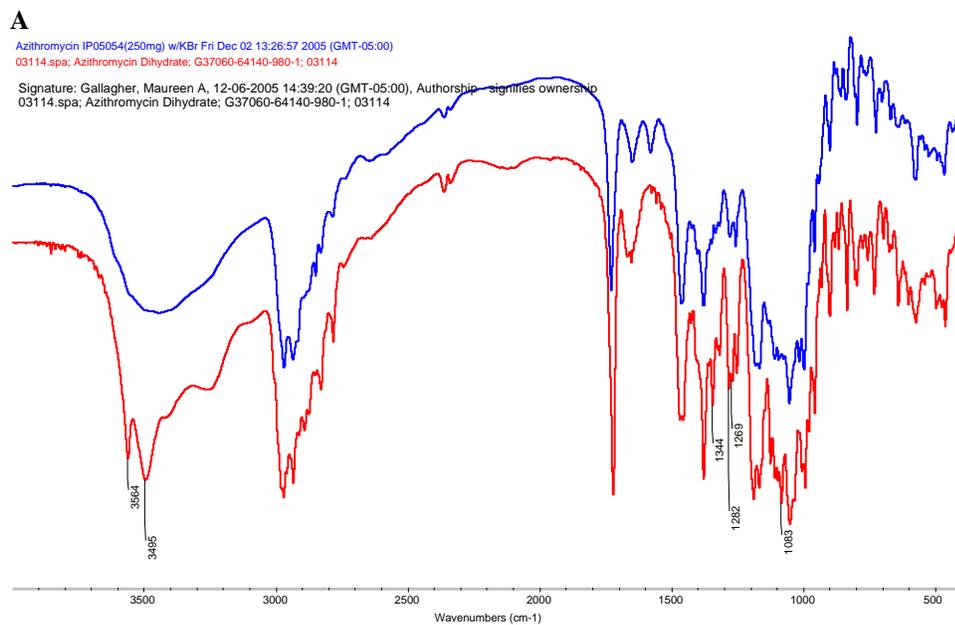
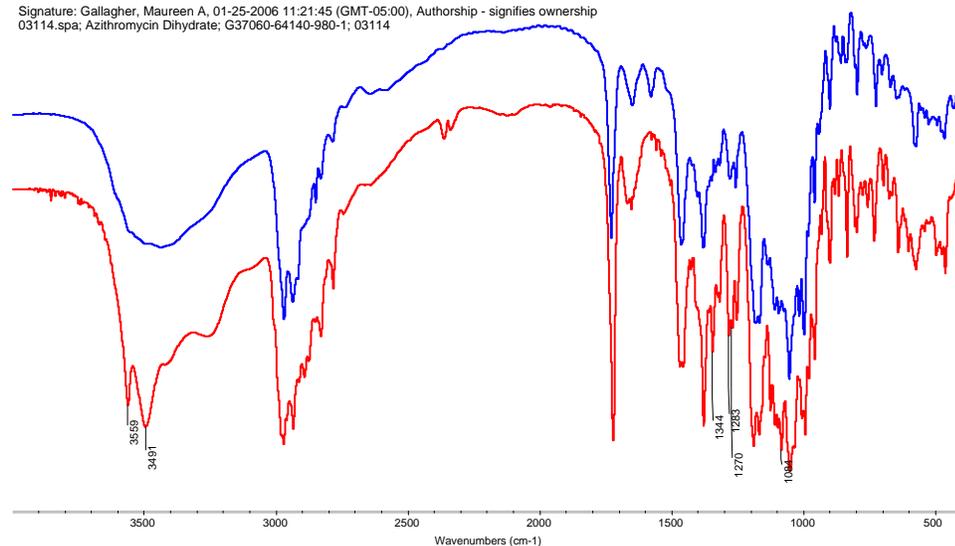


Figure 4. FTIR spectra of Sandoz azithromycin 250 mg tablet (upper trace, blue) and azithromycin dihydrate lot G37060-64140-980-1 (lower trace, red) shown: (A) full scale from 4000 cm^{-1} – 400 cm^{-1} and (B) expanded scale from 1400 cm^{-1} - 400 cm^{-1} range. The analysis indicated that azithromycin dihydrate was not detected in the sample.

A

Azithromycin (Sandoz) IP06009 KBr Wed Jan 25 11:09:57 2006 (GMT-05:00)
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114

Signature: Gallagher, Maureen A, 01-25-2006 11:21:45 (GMT-05:00), Authorship - signifies ownership
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114



B

Azithromycin (Sandoz) IP06009 KBr Wed Jan 25 11:09:57 2006 (GMT-05:00)
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114

Signature: Gallagher, Maureen A, 01-25-2006 11:21:45 (GMT-05:00), Authorship - signifies ownership
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114

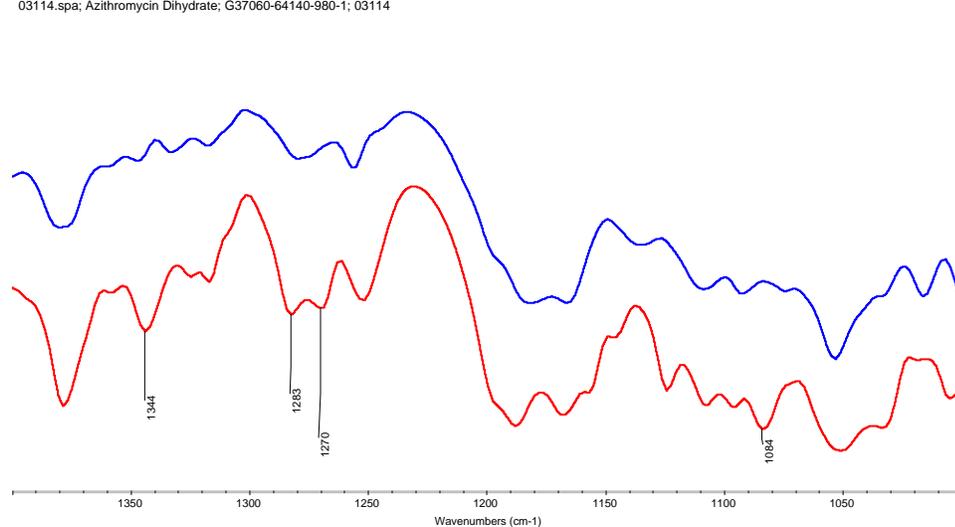
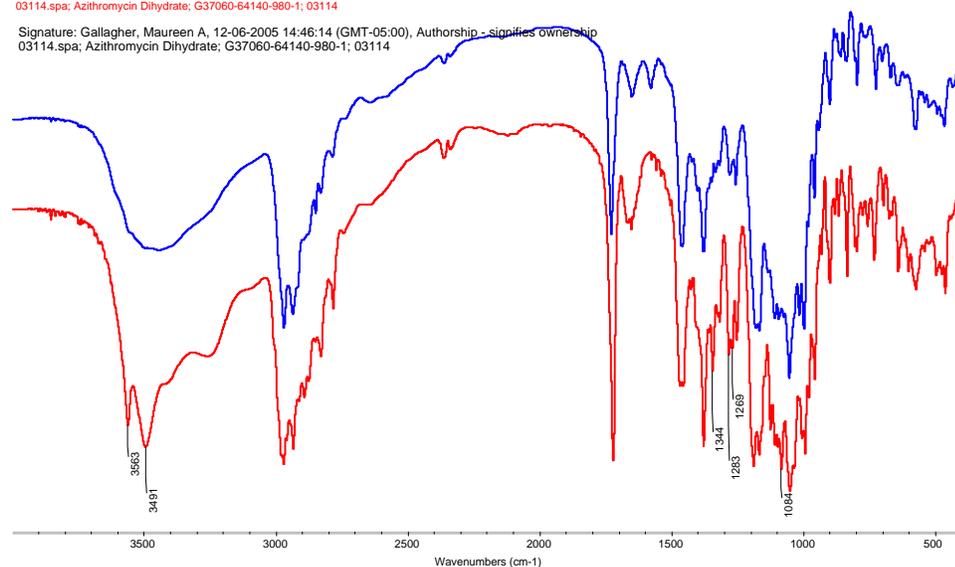


Figure 5. FTIR spectra of Sandoz Azithromycin 500 mg tablet (upper trace, blue) and azithromycin dihydrate lot G37060-64140-980-1 (lower trace, red) shown: (A) full scale from 4000 cm⁻¹ – 400 cm⁻¹ and (B) expanded scale from 1400 cm⁻¹ - 400 cm⁻¹ range. The analysis indicated that azithromycin dihydrate was not detected in the sample.

A

Azithromycin 600mg IP05054_KBr Fri Dec 02 14:29:15 2005 (GMT-05:00)
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114

Signature: Gallagher, Maureen A, 12-06-2005 14:46:14 (GMT-05:00), Authorship - signifies ownership
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114



B

Azithromycin 600mg IP05054_KBr Fri Dec 02 14:29:15 2005 (GMT-05:00)
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114

Signature: Gallagher, Maureen A, 12-06-2005 14:46:14 (GMT-05:00), Authorship - signifies ownership
03114.spa; Azithromycin Dihydrate; G37060-64140-980-1; 03114

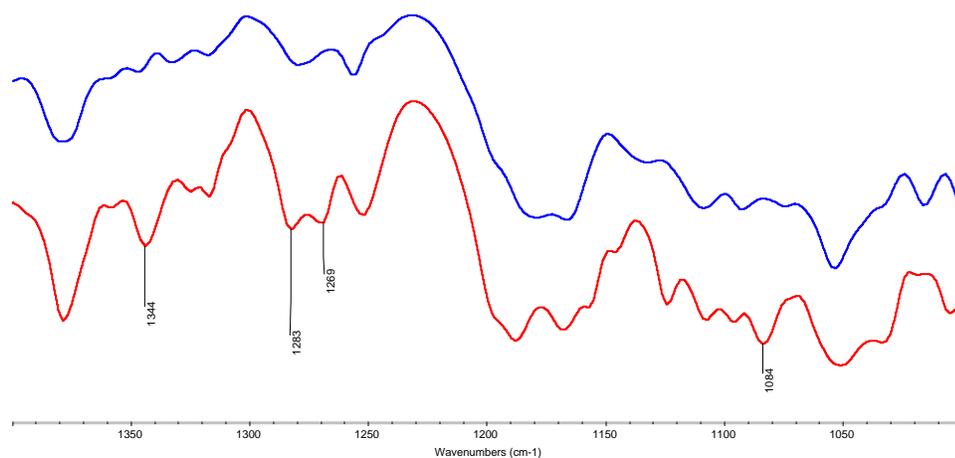


Figure 6. FTIR spectra of Sandoz Azithromycin 600 mg tablet (upper trace, blue) and azithromycin dihydrate lot G37060-64140-980-1 (lower trace, red) shown: (A) full scale from 4000 cm^{-1} – 400 cm^{-1} and (B) expanded scale from 1400 cm^{-1} - 400 cm^{-1} range. The analysis indicated that azithromycin dihydrate was not detected in the sample.

IP05054 250-mg TAB LOT V05026 vs. AZITHROMYCIN DIHYDRATE REF.

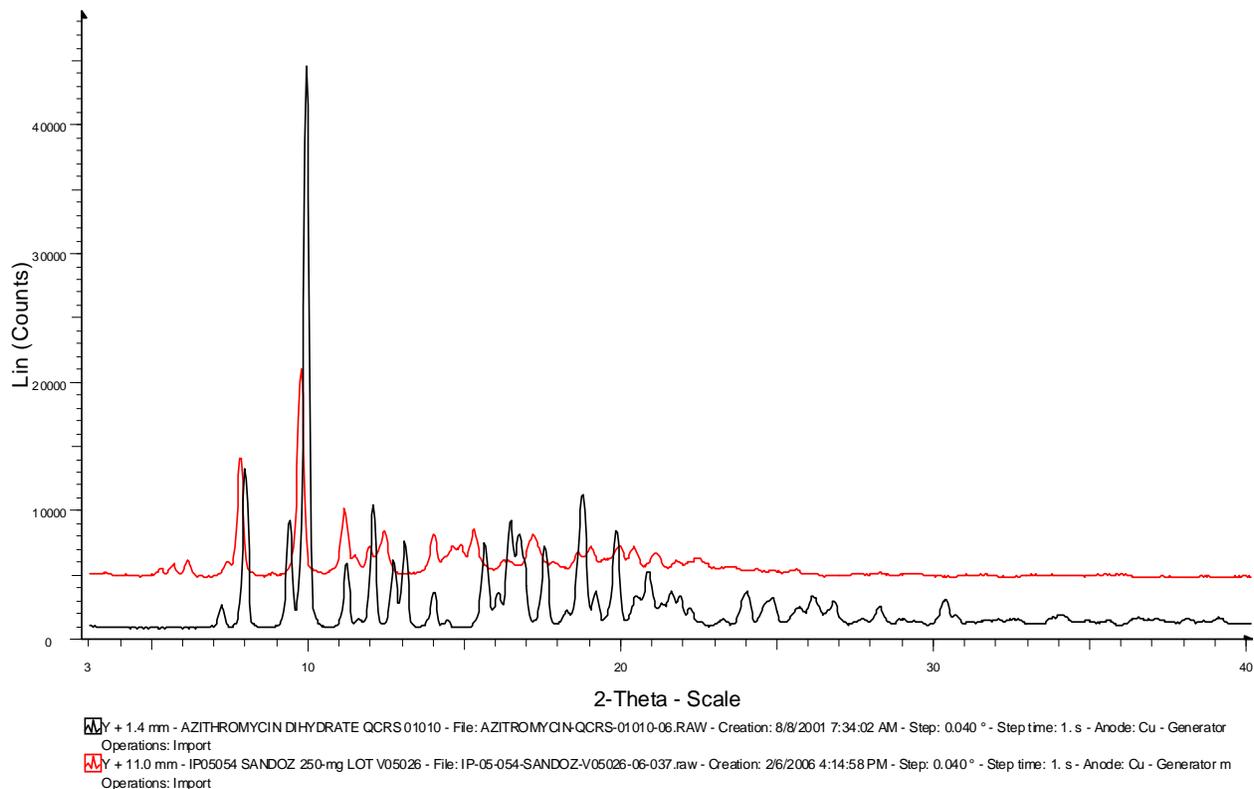


Figure 7. Overlay of diffractograms for Sandoz azithromycin 250 mg tablet and azithromycin dihydrate reference (QCRS lot 01010-QCS-06). The absence of several diagnostic peaks for azithromycin dihydrate in the sample over range of 7 to 22 degrees in 2-theta indicated that azithromycin dihydrate was not detected.

IP06009 500-mg TAB LOT 159579 vs. AZITHROMYCIN DIHYDRATE REF.

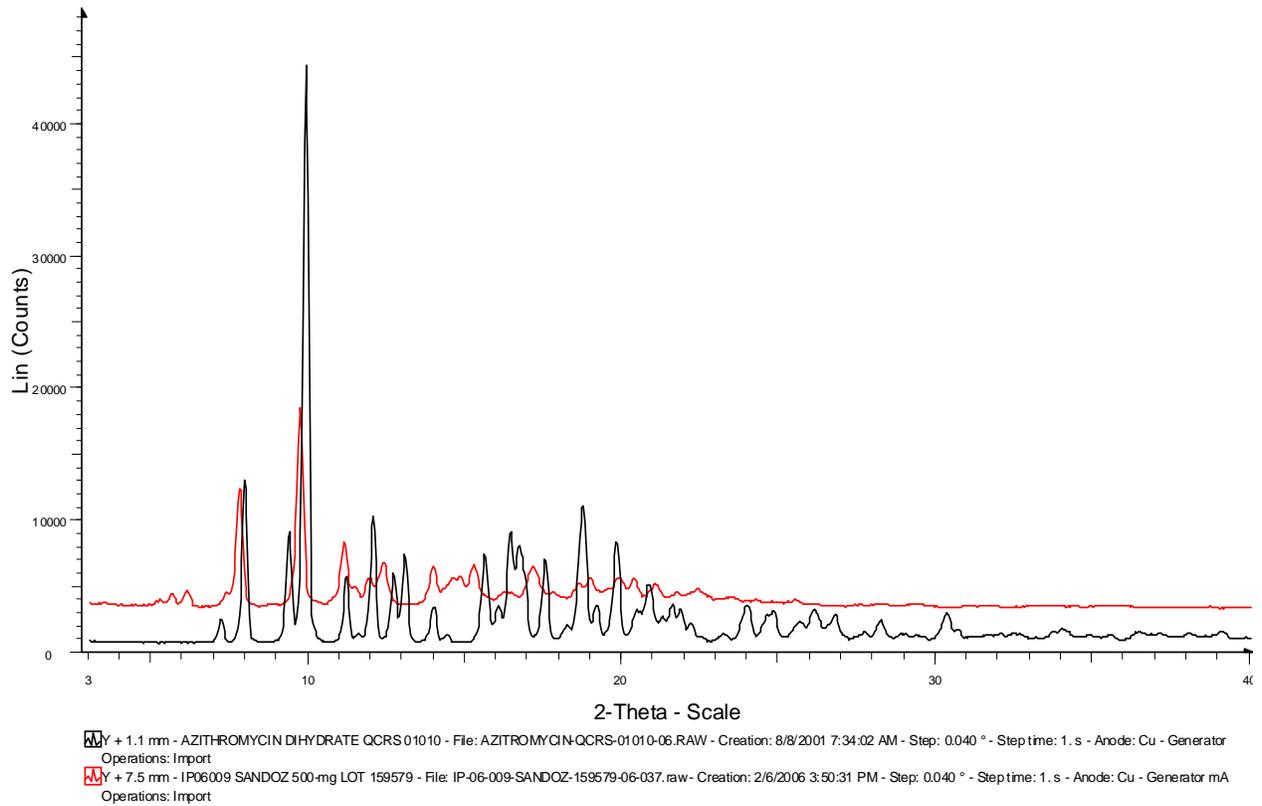


Figure 8. Overlay of diffractograms for Sandoz azithromycin 500 mg tablet and azithromycin dihydrate reference (QCRS lot 01010-QCS-06). The absence of several diagnostic peaks for azithromycin dihydrate in the sample over range of 7 to 22 degrees in 2-theta indicated that azithromycin dihydrate was not detected.

IP05054 600-mg TAB LOT V05032 vs. AZITHROMYCIN DIHYDRATE REF.

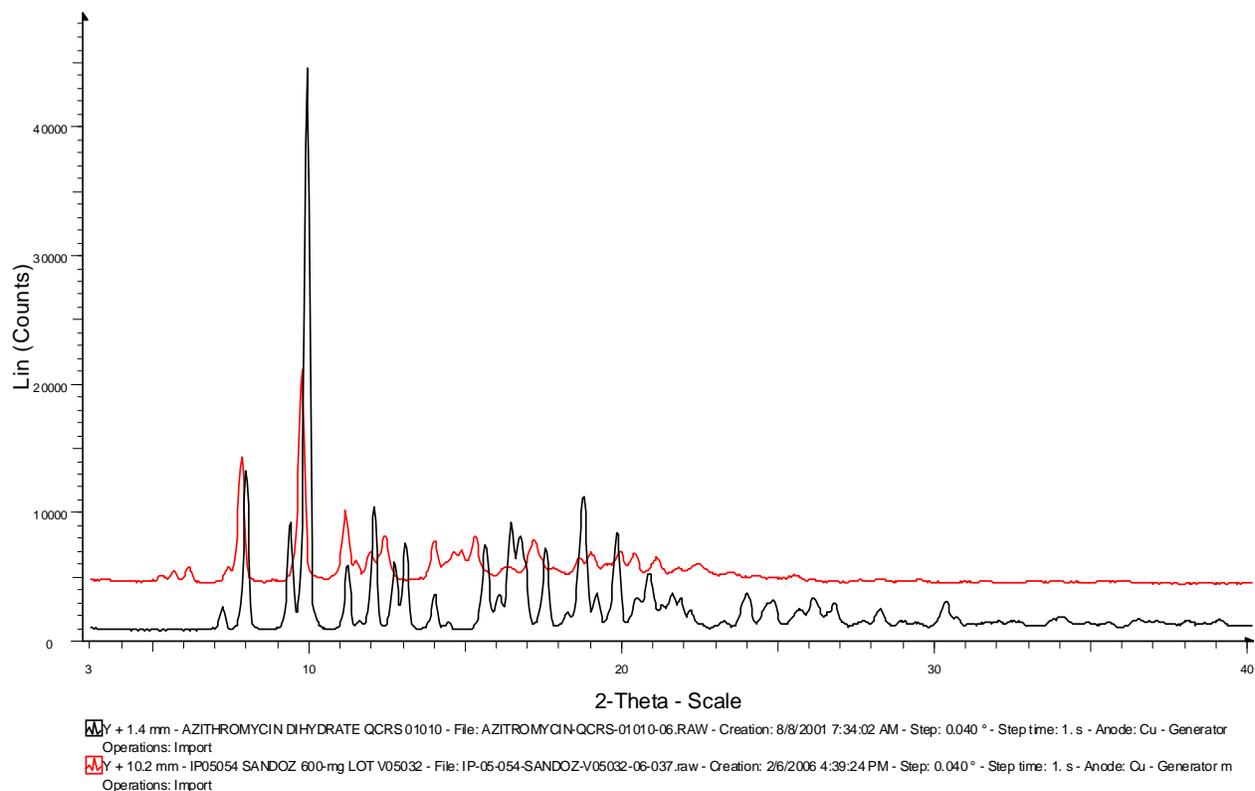


Figure 9. Overlay of diffractograms for Sandoz azithromycin 600 mg tablet and azithromycin dihydrate reference (QCRS lot 01010-QCS-06). The absence of several diagnostic peaks for azithromycin dihydrate in the sample over range of 7 to 22 degrees in 2-theta indicated that azithromycin dihydrate was not detected.

IP05054 250-mg TAB LOT V05026 vs. AZITHROMYCIN FORM G

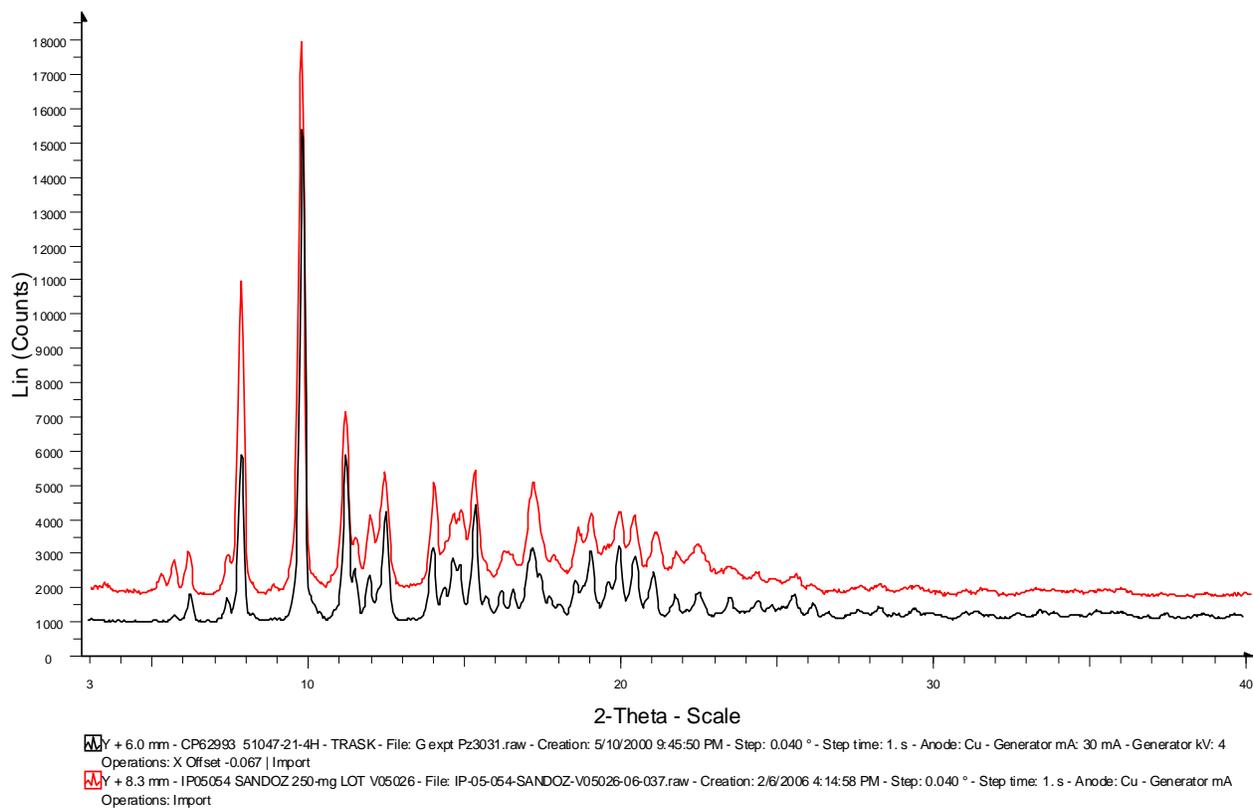


Figure 10. Comparison of diffractograms for a Sandoz 250 mg Azithromycin tablet and azithromycin Form G reference material.

IP06009 500-mg TAB LOT 159579 vs. AZITHROMYCIN FORM G

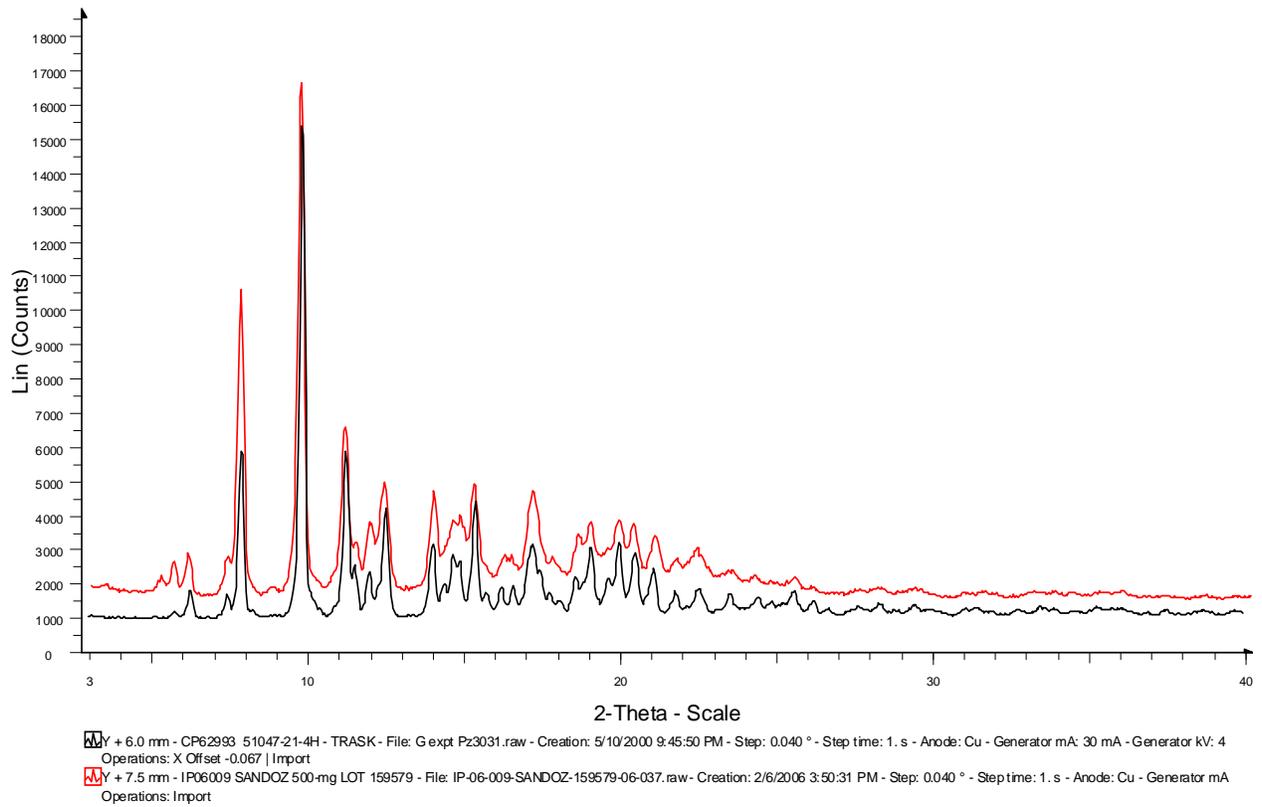


Figure 11. Comparison of diffractograms for a Sandoz 500 mg Azithromycin tablet and azithromycin Form G reference material.

IP05054 600-mg TAB LOT V05032 vs. AZITHROMYCIN FORM G

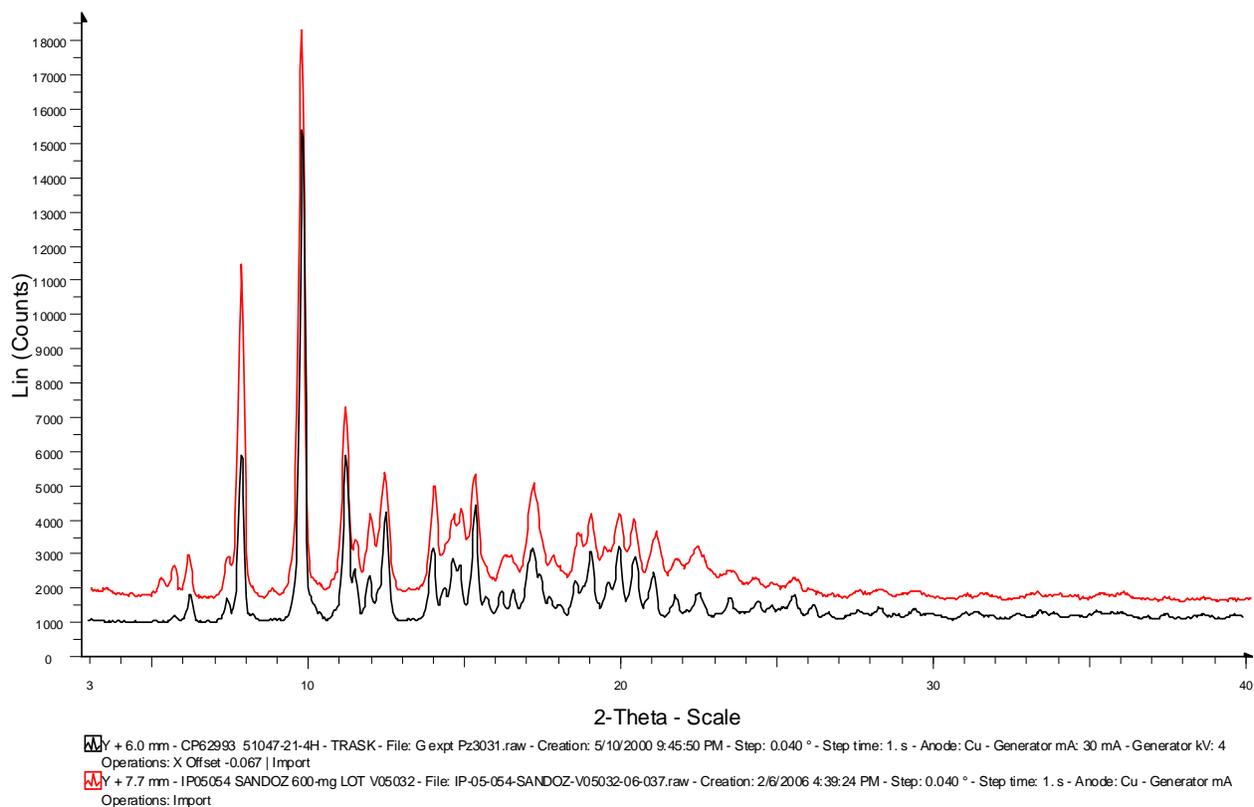


Figure 12. Comparison of diffractograms for a Sandoz 600 mg Azithromycin tablet and azithromycin Form G reference material.

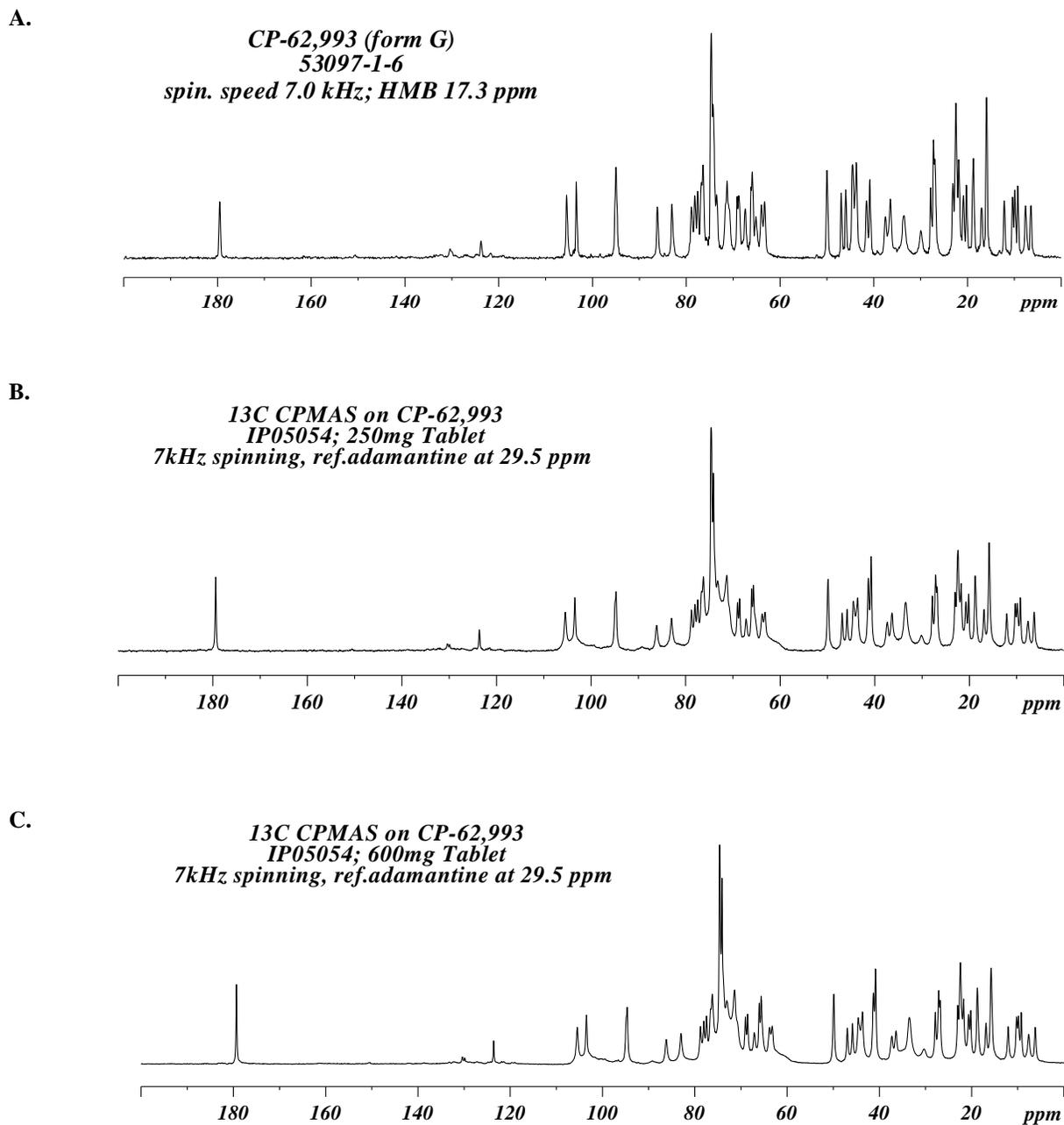


Figure 13. ^{13}C CPMAS ssNMR spectra for the Sandoz 250 mg tablet (**B**), Sandoz 600 mg tablet (**C**) and azithromycin Form G reference (**A**). A detailed comparison of the carbon chemical shifts in ppm units for azithromycin Form G (from United States Patent No. 6,977,243) and corresponding azithromycin shifts for the 250 mg and 600 mg samples is shown in **Table 1**.

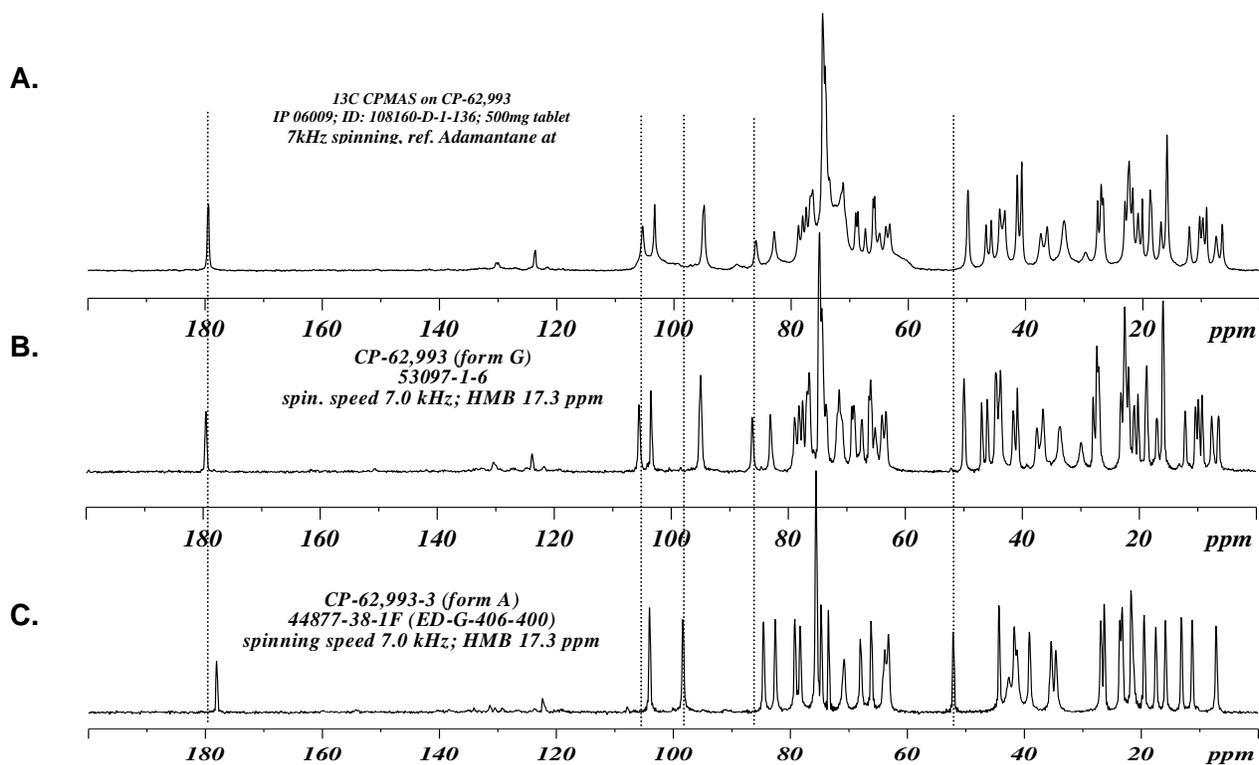
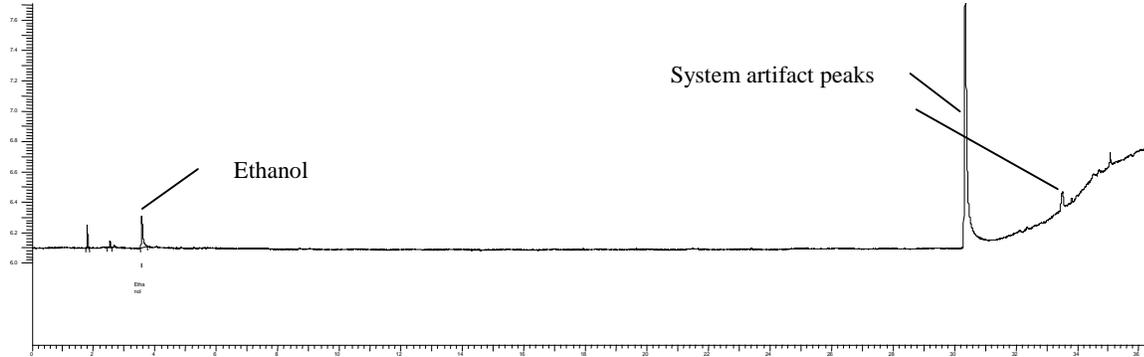
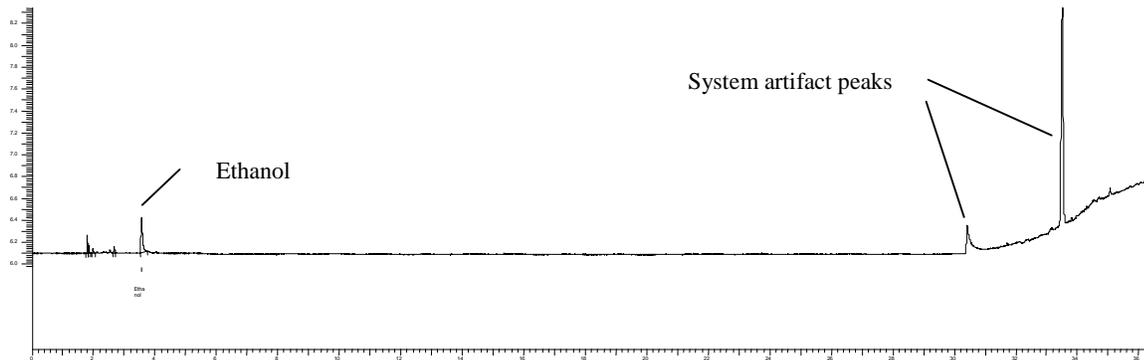


Figure 14. Comparison of ¹³C Solid State NMR spectra obtained from (A) Sandoz Azithromycin 500 mg tablet; (B) Azithromycin form G reference standard (CP-62,993, lot 53097-1-6); (C) Azithromycin Form A reference standard (CP-62,993, lot 44877-38-1F). A detailed comparison of the carbon chemical shifts in ppm units for azithromycin Form G (from United States patent US 6,977,243) and corresponding azithromycin shifts found in the 500 mg samples is shown in Table 1.

Sandoz 250mg IP05054



Sandoz 500mg IP06009



Sandoz 600mg IP05054

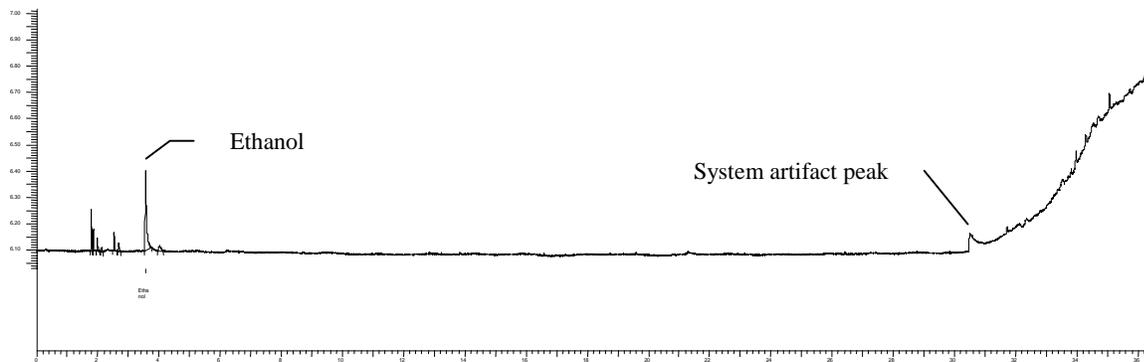


Figure 15. Headspace GC profiles for Sandoz Azithromycin tablets: (A) 250 mg tablet, (B) 500 mg tablet, and (C) 600 mg tablet. System artifact peaks eluting after 30 minutes are from high boiling solvent contamination from previous (unrelated) testing. Overall, the system artifact peaks are minor and did not impact the conclusions from the headspace GC analyses.

Table 1. ¹³Carbon ssNMR shifts of azithromycin as listed for Form G in US 6,977,243 and shifts observed in spectra of the Sandoz azithromycin samples shown in **Figure 13 and 14**. Of 49 peaks listed in the patent, 45 were identified (within the ± 0.2 accuracy limits) in each of the tablet samples. Exceptions (noted in footnotes below) were minor and do not preclude a positive identification of Form G in the samples.

250 mg tablet (ppm)	500 mg tablet (ppm)	600 mg tablet (ppm)	Form G from Patent (accurate within ± 0.2 ppm)
179.5	179.5	179.5	179.5
105.6	105.4	105.6	105.5
103.5	103.4	103.6	103.5
94.8	95.0	94.8	95.0
86.2	86.1	86.3	86.2
83.1	83.0	83.1	83.1
78.9	78.9	78.9	78.9
78.2	78.1	78.2	78.2
77.6	77.6	77.6	77.6
76.3	76.4	76.3	76.4
(a)	(a)	(a)	75.7
74.7	74.7	74.7	74.7
74.2	74.3	74.2	74.3
73.3	73.6	73.2 (c)	73.5
71.4	71.2	71.5	71.3
69.1	69.1	69.2	69.1
68.7	68.7	68.7	68.8
67.3	67.4	67.2	67.4
65.8	65.9	65.7	65.9
(b)	65.0	(b)	65.2
63.9	63.9	63.9	64.0
63.3	63.3	63.3	63.3
50.0	49.9	50.0	50.0
47.0	46.9	47.1	46.9
46.0	46.0	45.9	46.0
44.6	44.5	44.7	44.5
43.7	43.7	43.8	43.7
41.5	41.5	41.4	41.5
40.9	40.8	40.9	40.8
37.5	37.5	37.4	37.5
36.5	36.4	36.5	36.5
33.6	33.5	33.6	33.6
30.2	29.9	30.5 (c)	30.0
28.0	27.8	28.0	27.9
27.2	27.2	27.3	27.3
23.1	23.1	23.1	23.1
22.5	22.4	22.5	22.5
21.9	21.8	21.9	21.9
20.8	20.9	20.8	20.9
20.3	20.2	20.3	20.2
18.9	18.9	18.9	18.8
17.0	17.0	17.0	17.0
15.9	16.0	15.9	16.0
12.2	12.2	12.2	12.2
10.4	10.4	10.4	10.4
10.0	9.9	10.0	9.9
9.3	9.2	9.4	9.3
7.7	7.6	7.8	7.6
6.4	6.5	6.3	6.5

- (a) Low intensity peak in the standard of form G. Most likely overlapped with excipient signals in the sample
(b) Peak detected as a shoulder with no defined maximum.
(c) Peak position in sample differs from position listed in patent by more than 0.2 ppm and is likely a result of line broadening caused by interaction of azithromycin with tablet excipients.