

The worrying trend of antibiotics marketed in west Africa

(Quality Assurance and safety issues of Pharmaceutical products
marketed in developing countries).

Ndjamawe Bah-Traore

THE DRUG PEDDLING MENACE



Drug peddlers in the open on a market day



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Introduction

A drug quality assurance system relies on the ability to identify counterfeit or poor quality medicines.

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Introduction

Some packets and blisters of antibiotics have been bought in local drug stores, hawkers, and pharmacies of 6 countries (Benin_[BN], Burkina Faso_[B.F], Ghana_[GH], Cote d'Ivoire_[CI], Nigeria_[NGA], Togo_[TG]) in period of January 14th, to March 16th, 2010.

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Introduction

These products have been store in low humidity away from sunshine under 25°C until they reach laboratories. The quality survey has started by XRD analysis in Bonn and the NIR Raman spectroscopy from Servantech in Rosbach v.d.höhe.

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Methods

Description

1-XRPD (X Ray Powder Diffraction) is a key analytical technique that looks at the table/capsule itself and gives a unique fingerprint of the contents .

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Method 1

X-ray Diffraction

Is a non-destructive technique that reveals information about the chemical composition and crystallographic structure of manufactured and natural materials.

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Method 1

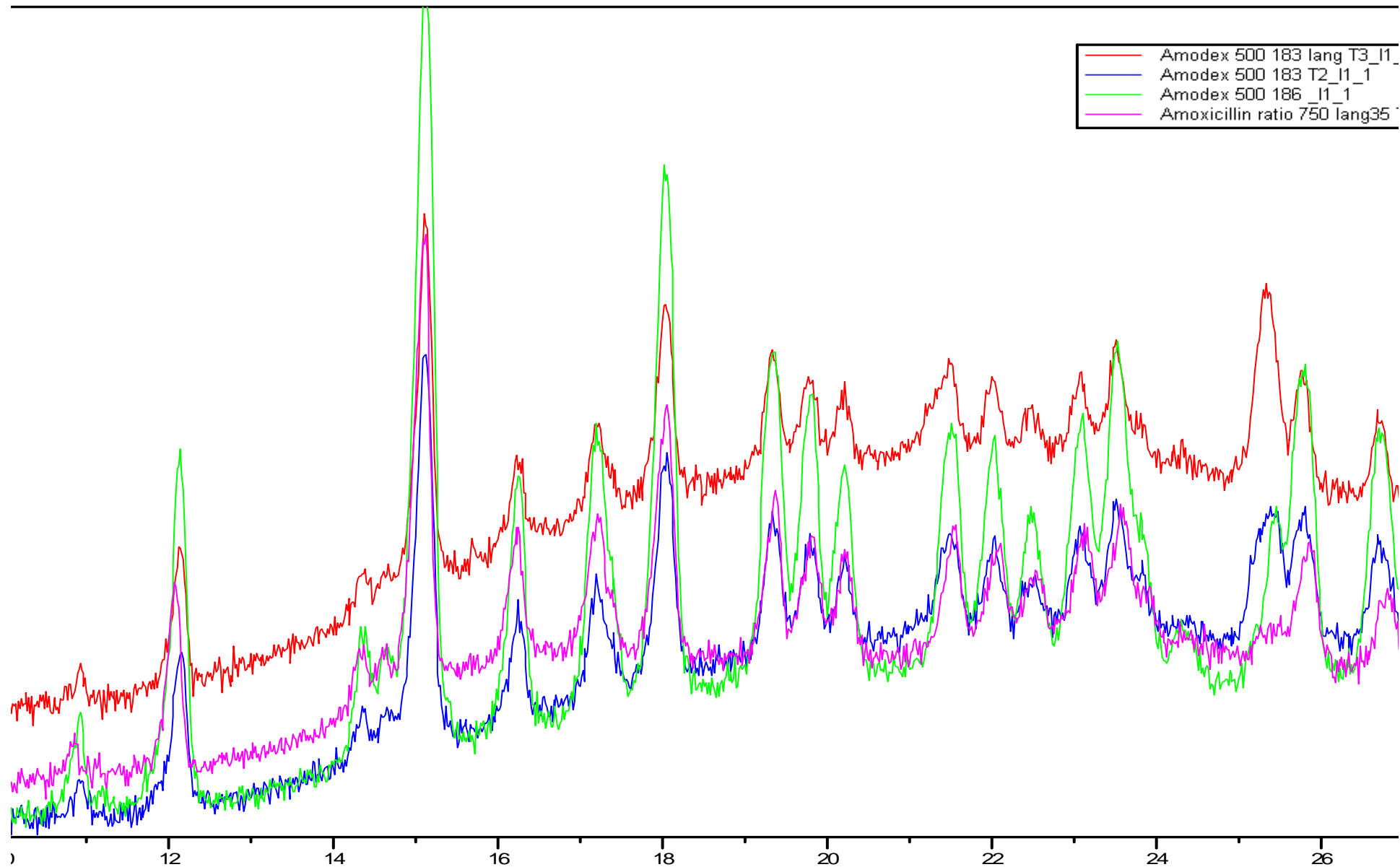
X-ray-diffraction is used to:

- determine the crystallite size of a compound
- analyze and optimize final dosage forms
- detect and analyze the used fillers in capsules/tablets.

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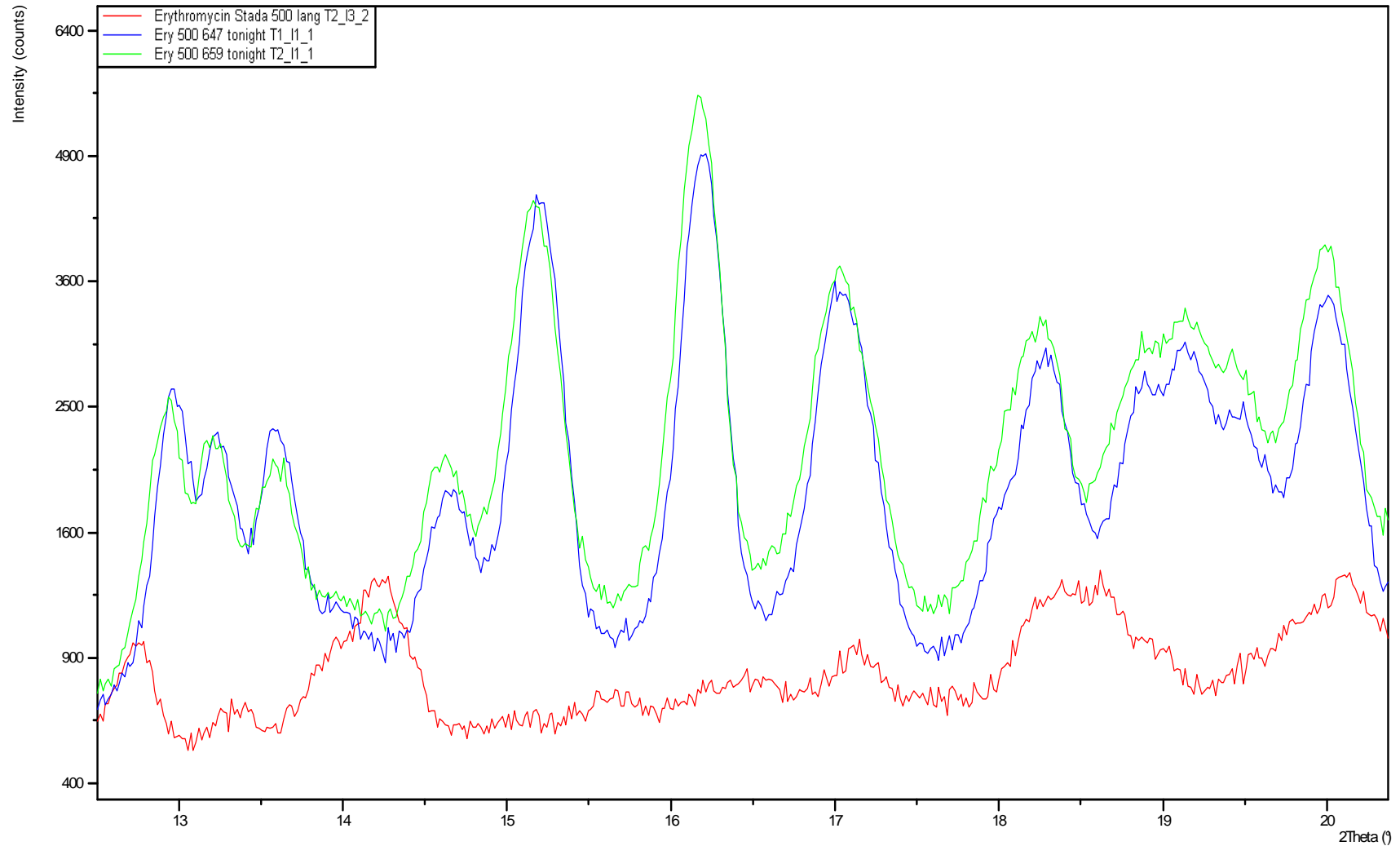
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Method 1 (X-Ray diffraction ;Amodex 500 mg /Cl. Feb.2010)



Method 1(X-ray diffraction.)

Ery 500mg/Benin.March 2010



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Methods

Description

2-The TruScan handheld Raman analyzer is an instrument for identity tests in pharmaceutical quality control, and for counterfeit testing of pharmaceutical products.

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Method 2(TruScan)

The TruScan handheld Raman analyzer is an instrument for identity tests in pharmaceutical quality control. It compares the Raman spectrum of a sample with a stored spectrum of a reference sample with proven identity.

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Rama TruScan



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First Defender RM



Method 2 (First Defender RM)

A handheld Raman spectrometer is for forensic investigations. It has an on-board spectral library of about 8.500 chemical substances.

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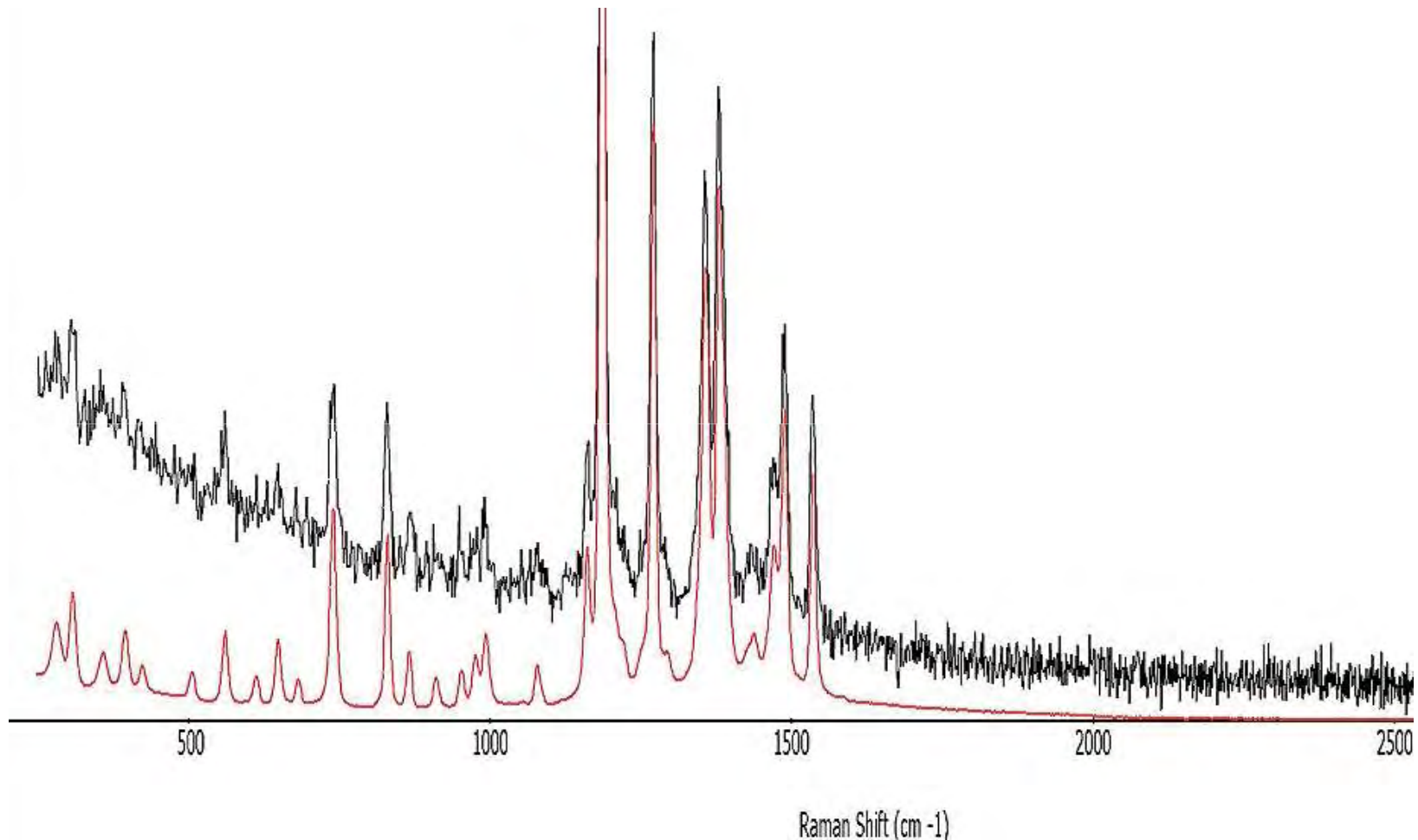
Result (First Defender RM,Truscan)
Most of the samples gave good Raman spectrum that could be analyzed, and in most cases the active pharmaceutical ingredient (API) was identified in the product (if the API was in the library).

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Method 2 (First Defender RM)

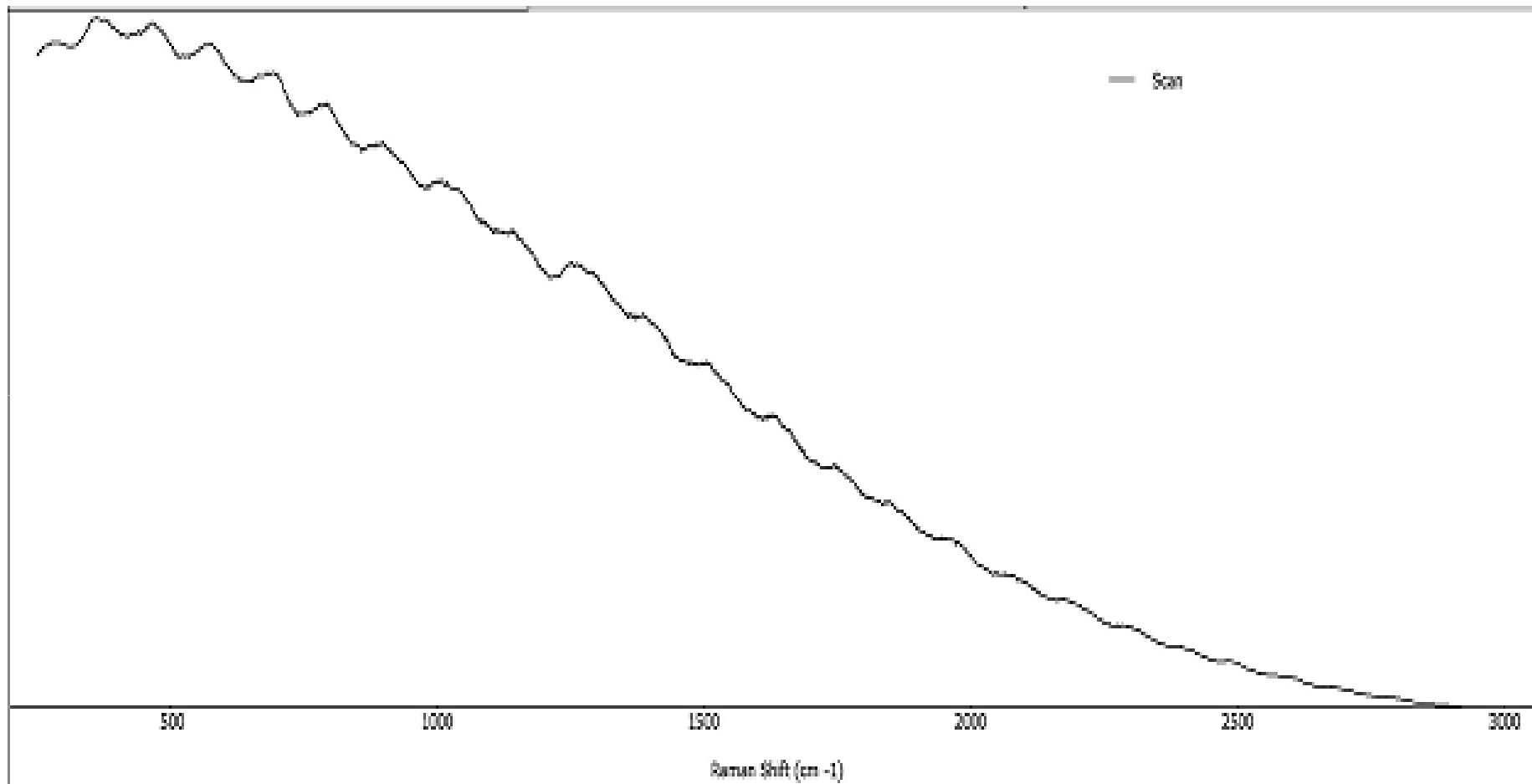
Spectrum of Metronidazole .BF /Jan.2010



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Method2 (First Defender RM; Doxycycline 100mg Letap .GH/Feb.2010)



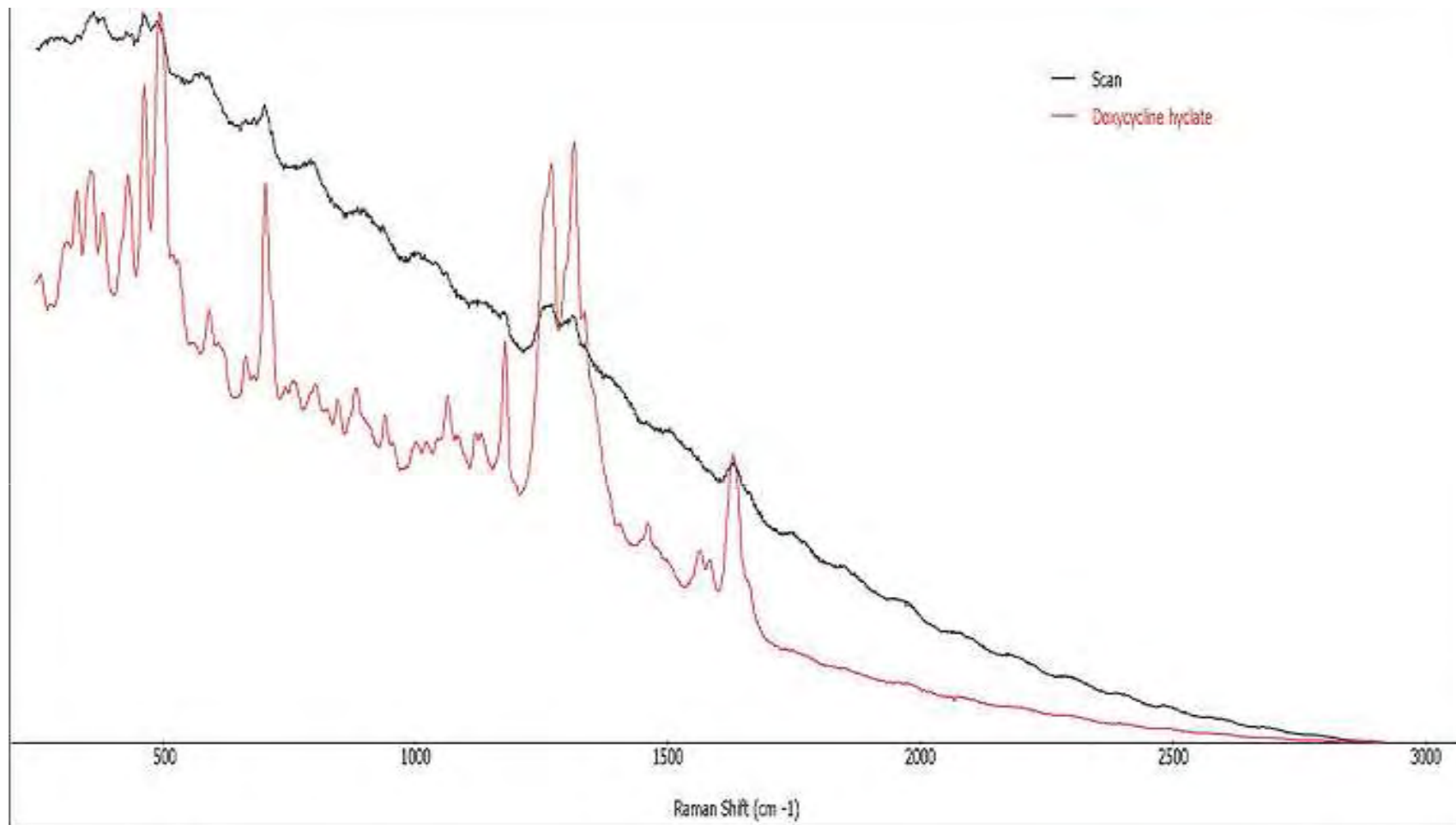
Session001 - Scan078

4/20/2010 2:47 PM

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Method 2 (First Defender RM, DOXYCAP 100 GH/Feb.2010)



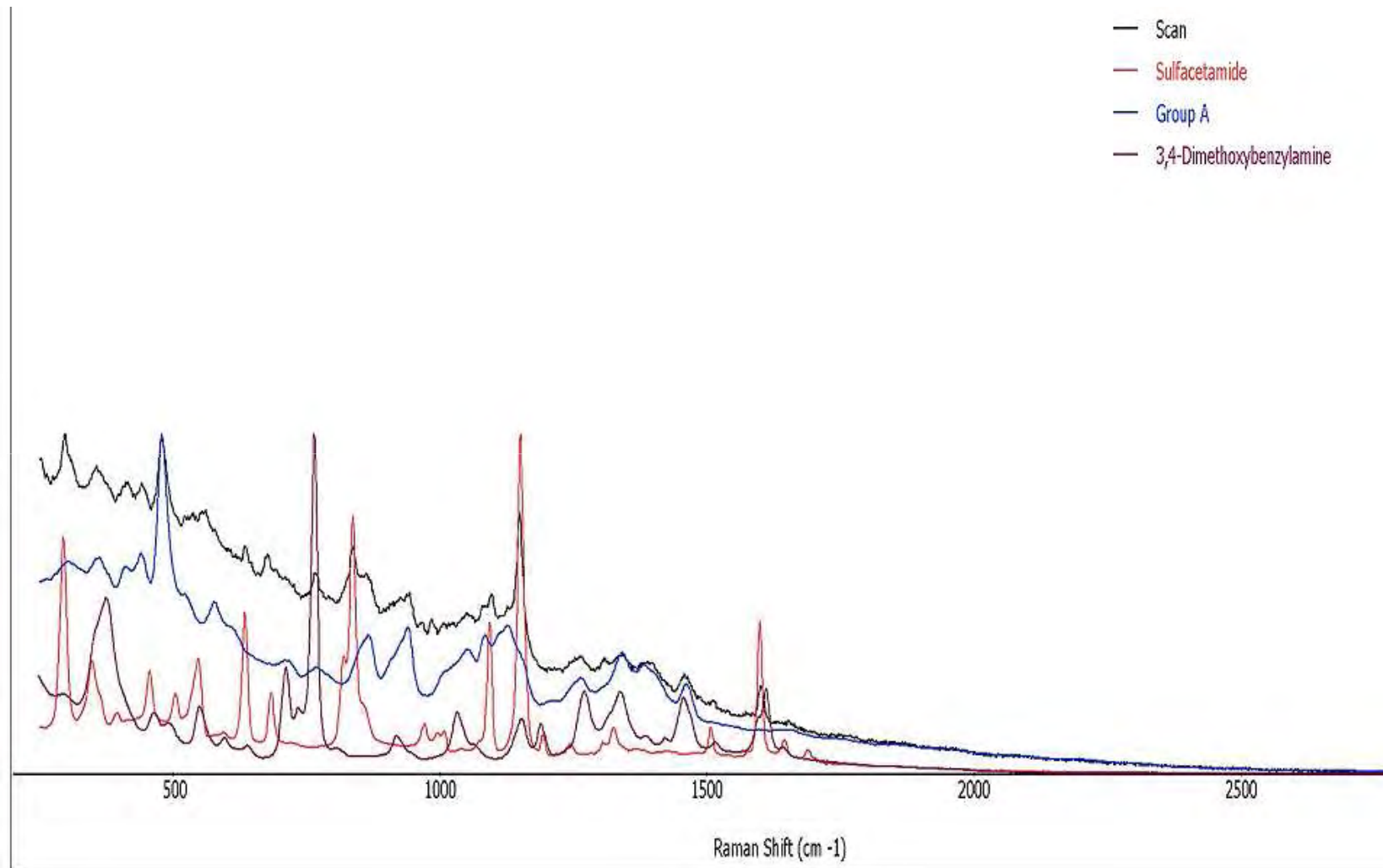
Session001 - Scan080

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Method 2 (First Defender RM; MaloxineBF/Feb.2010)



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First DefenderRM, TruScan

Product, Batch/ Expir.	Manufacturer	Appearance, Form	Spectrum	ID / Interpretation
Doxynor 100, Batch:104 EXP:4, 2013	Menarini Florence Italia	Pink coated Tablets	Fluorescence, but with Raman peaks	No Match (Doxycycline hyclate in Library, but no ID, not similar)
Ampicilline 500mg, 080303 EXP 03/2011	Ubithera Le Grand- Quevilley France	Red/Yellow Capsules	Good spectrum	No Match (but very similar to Ampicilline spectrum)
ERY Gé 500mg Batch:647/659 EXP:6/11 6/12	Bouchara Recordati France	White Tablet in transparent blister	Good spectrum	No Match (but very similar to Erythromycine stearat spectrum)

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First Defender RM,TruScan

Product, Batch/ Expir.	Manufacturer	Appearance, Form	Spectrum	ID / Interpretation
Erythromycin Stearate tablets BP 500mg, 227, 7/09, Exp. 6/12	Strides Arcolab India	Red Tablets, coated	Fluorescence, but with Raman peaks	Erythromycin stearate
Amodex 500mg, Batch:186, EXP: Nov 2012	Synthelabo Sanofi Aventis	beige/ brown capsules	Good spectrum	No Match (Amoxicillin not in library)
Chloramphenicol 250mg, B:165,EXP:Oct 11	Bailly-Creat France	white capsules	Good spectrum	Chloramphenicol
Chloramphenicol Cap. 250mg	M&G Pharm.	White capsules	Good spectrum	Chloramphenicol

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Rama Truscan

Product, Batch/ Expir.	Manufacturer	Appearance, Form	Spectrum	ID / Interpretation
Piroxicam Tablets 20mg, Batch:090601, MD:2009.06.05 EXP:2012.06.04	SPGC Sine China	Light yellow tablets	Good spectrum	Piroxicam
Ciprofloxacin 500mg, EXP:03/2012	Strides Arcolab India	White tablets in transparent blister	Good spectrum	No Match (Ciprofloxacin not in library)
DOXIN Doxycycline 100mg Batch:07081 EXP: 08/11	Geneith Pharm. China	green capsules	Fluorescence, but Raman peaks	Doxycycline hyclate

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First DefenderRM, TruScan

Product, Batch/ Expir.	Manufacturer	Appearance, Form	Spectrum	ID / Interpretation
Doxycycline Capsule 100mg, Batch:1350018 EXP:01/10	LETAP Pharm. Ltd PO. Box 3346 .Accra	green capsules	Fluorescence	No Match (not evaluable)
Doxycycline HCl 100mg, Batch:7365, EXP:06-10	Pharmaquick Cotonou-Benin	Yellow tablets	Fluorescence	No Match (not evaluable)
Doxycap Doxycycline 100mg, Batch:AK02568 EXP:FEB2010	Hovid - Malaysia	pink/green capsules	Fluorescence, but Raman peaks	Doxycycline hyclate

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First DefenderRM,TruScan

Product, Batch/ Expir.	Manufacturer	Appearance, Form	Spectrum	ID / Interpretation
Erythrofil (Erythromycin stearate) 250mg Batch:50754 EXP: May 2010	Fourrts Laboratories Tamil Nadu (India)	Pink tablets	Good spectrum	Erythromycin stearate
Ampicillin-3H2O (287.5→250mg), Batch:0429 EXP:11/11	LETAPharm Ltd PO.Box 3346 Accra	red/black capsules	Good spectrum	No Match (ampicilline in library → similar)

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First Defender RM,TruScan

Product, Batch/ Expir.	Manufacturer	Appearance, form	Spectrum	ID / Interpretation
Maloxine (Sulphadoxine 500mg + Pyrimethamine 25mg), Batch:EM-396, MD:04/2008, EXP:03/2011	Shreechem Lab. India Under Licence from Expharm S.A. Belgium	White tablets (in non-transparent packaging)	Good spectrum	Sulfacetamide (Sulphadoxine not in library. Part of chem. Structure is identical, but not very probable to give the same spectrum)
Metronidazole Tabl. 0.2g, Batch:081008 EXP2011/10/30	SINE Pharmaceutical China	White tablet	Good spectrum	Metronidazole

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Conclusion

Based on the results obtained, the next step is promising with the chemical analysis for identity, Strength, and other quality characteristics designed to ensure the required levels of safety and effectiveness.

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