Project Mexico: a cross-border analysis of medication content

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018

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Introduction

Each year, more people are traveling outside of the United States for their health care needs seeking lower costs and less stringent healthcare regulations.

Over 2.5 million crossings were recorded at one US/Mexico border crossing, the US Port of Entry at Andrade, CA, in 2017. Very little research has been done regarding the quality of the medications and/or services acquired by travelers.

The purpose of this study is to test the content uniformity and weight variation of five medications purchased in Mexico compared to their US counterparts.

Methods

No less than three lots each of ibuprofen, metformin, apixaban, sildenafil, and hydrochlorothiazide were purchased from pharmacies in Los Algodones, Mexico. One lot of each medication was purchased from a US pharmacy to demonstrate compliance with United States Pharmacopeia (USP) methods.

Active Pharmaceutical Ingredients (API) were donated or purchased and used to prepare standard solutions, which were serially diluted to create standard concentration curves for each product.

Weight variation and content uniformity were performed per USP <905>. Twenty tablets from each lot were selected at random, with ten weighed individually and ten weighed collectively. Each weight was recorded in triplicate and used to determine mean weight and relative standard deviation.

Content uniformity (CU) testing was performed on ten tablets from each lot. Tablets were placed in volumetric flasks and analyzed by high performance liquid chromatography (HPLC).

HPLC methods used were adapted from the corresponding monographs, when available, and developed when unavailable or insufficient.

Disclosures

The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

Results

Relative standard deviations (RSD) in weight among samples purchased in Mexico ranged from 0.45 percent to 17.39 percent, with a mean RSD of 2.17 percent.

Of every medication tested, at least one lot fell above or below the percent of label claim approved by USP guidelines. The amount of drug found in each of the 23 lots tested are shown in the table below, as well as the figure to the right.

Medication	Lot number	Weight Variation			Content Uniformity		
		Avg wt/tab, grams	Total wt/10 tabs, grams	RSD, %	Avg percent of LC, %	RSD, %	USP Limits
Ibuprofen 800 mg tablet	021018	1.0371	10.3149	1.11	105	1.70	90-110%
	021818	1.0306	10.3273	1.08	96	14.26	
	021118	1.0319	10.2740	0.59	105	0.49	
	0292	0.7928	7.8993	0.75	0	0	
	3560364B*	0.9441	9.4411	0.55	105	0.97	
Apixaban 5 mg tablet	90965240	0.2668	2.5807	18.03	0	0	N/A
	90965240/ 90965262	0.1516	1.4896	3.04	0	0	
	AAT3036	0.2087	2.0745	1.06	101	1.87	
Metformin 500 mg tablet	071017	0.5772	5.7957	0.98	81	2.06	95-105%
	031717	0.5752	5.7511	0.46	80	4.39	
	081217	0.5760	5.8185	1.59	71	24.61	
	MF17DI10	0.7949	7.9644	1.18	88	6.28	
	4500588B*	0.5328	5.3282	0.65	84	1.68	
HCTZ 50 mg tablet	HI17AB02	0.2193	2.1713	0.95	88	6.05	90-110%
	HI15AG01	0.2295	2.1474	4.65	82	16.99	
	HI17FE01	0.2140	2.1572	1.18	85	13.26	
	PW04528*	0.2191	2.1905	1.02	92	5.57	
Sildenafil 100 mg tablet	18140636	0.5925	5.8905	1.25	84	21.62	90-110%
	180120	0.6275	6.2612	1.10	97	6.38	
	172134	0.6276	6.2719	1.18	87	12.74	
	17L137	0.4088	4.1145	1.39	143	11.96	
	7K1809	0.6184	6.1797	0.95	118	11.65	
	8368097*	0.6156	6.1564	1.68	104	10.25	

* = US manufacturer; HCTZ = hydrochlorothiazide; RSD = relative standard deviation; LC = label claim; USP = United States Pharmacopeia; apixaban does not have an available USP monograph so HPLC methods used were replicated from a completed study

Table 1: Results for weight variation and content uniformity for the individual lots tested.

Results

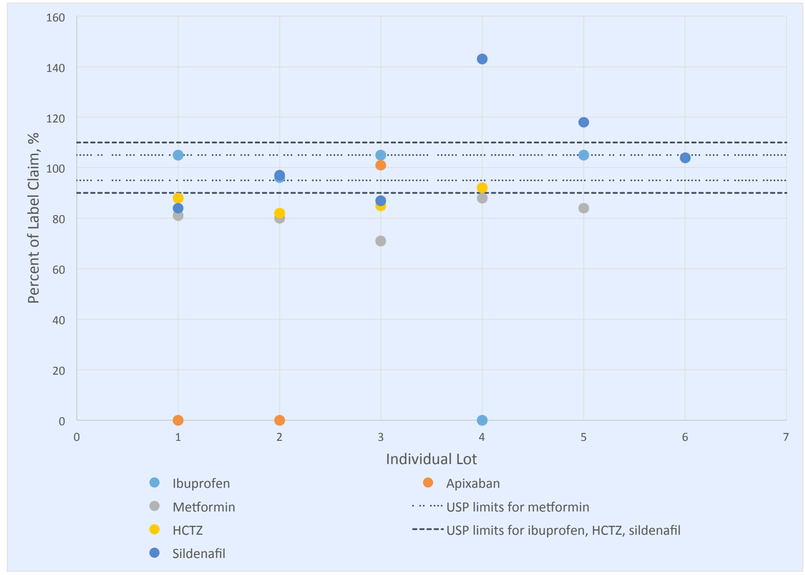

Figure 1: Content uniformity of the lot numbers listed in Table 1 with their corresponding USP limits

Discussion and Limitations

All the lots for metformin fell outside USP ranges, including the US manufacturer, indicating that there may be an error in the test method used for metformin.

Due to time constraints and funding, we could only test five medications from Mexico that were all obtained on the same day from the same town.

These findings do not demonstrate the clinical significance of the inconsistencies found in these medications from Mexico.

Conclusion

Since there are inconsistencies in the content uniformity and weight variance among medication samples tested, caution should be taken when purchasing medications from Mexico. Larger sample sizes and number of medications are needed to confirm and validate these findings.

References

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