Investigation of the Effectiveness of Medicines Imported from Turkey in Benghazi: Customer Satisfaction and Quality Assessment

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Investigation of the Effectiveness of Medicines Imported from Turkey in Benghazi: Customer Satisfaction and Quality Assessment

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Outlines:

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2. Research Question.
3. Methodology.
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Introduction:

The effectiveness of medications used across all national healthcare facilities, is the most important factor in assessing the health system, especially in developing countries that depend on the import of medicines, such as Libya.

Brand medications. [1]

Generic medications. [1]

The Libyan pharmaceutical market suffers from problems related to quality of generic medicines as a result of the diversity of importing sources.

Introduction:

Turkey exports a large amount of the medicines produced in-country to Middle Eastern countries.[2]

Some of these pharmaceutical products are believed to be below-value generics.

where, community pharmacists observe that customers intend to avoid medicines imported from Turkey, claiming that they are not effective.

Research Aim:

In this study, we aim to:

- Test customers' perceptions of the quality of the most traded generic-branded medicines in the Libyan pharmaceutical market in Benghazi.
- Investigate the quality of the generic-branded medicines imported from Turkey, considering that they are the most traded in the Benghazi-Libyan drug market.

Are medicines imported from Turkey below-value generics/branded?

Methodology:

- A survey was conducted in the form of three sets involving doctors & nurses, clinical & community pharmacists, and patients. [4]

To gather the opinions of healthcare providers and consumers about imported medicines.

- Qualitative and quantitative comparative research method.[4]

To assess the quality of generic-branded drugs, in order to evaluate their quality against the innovator product (branded tablet) as standard.

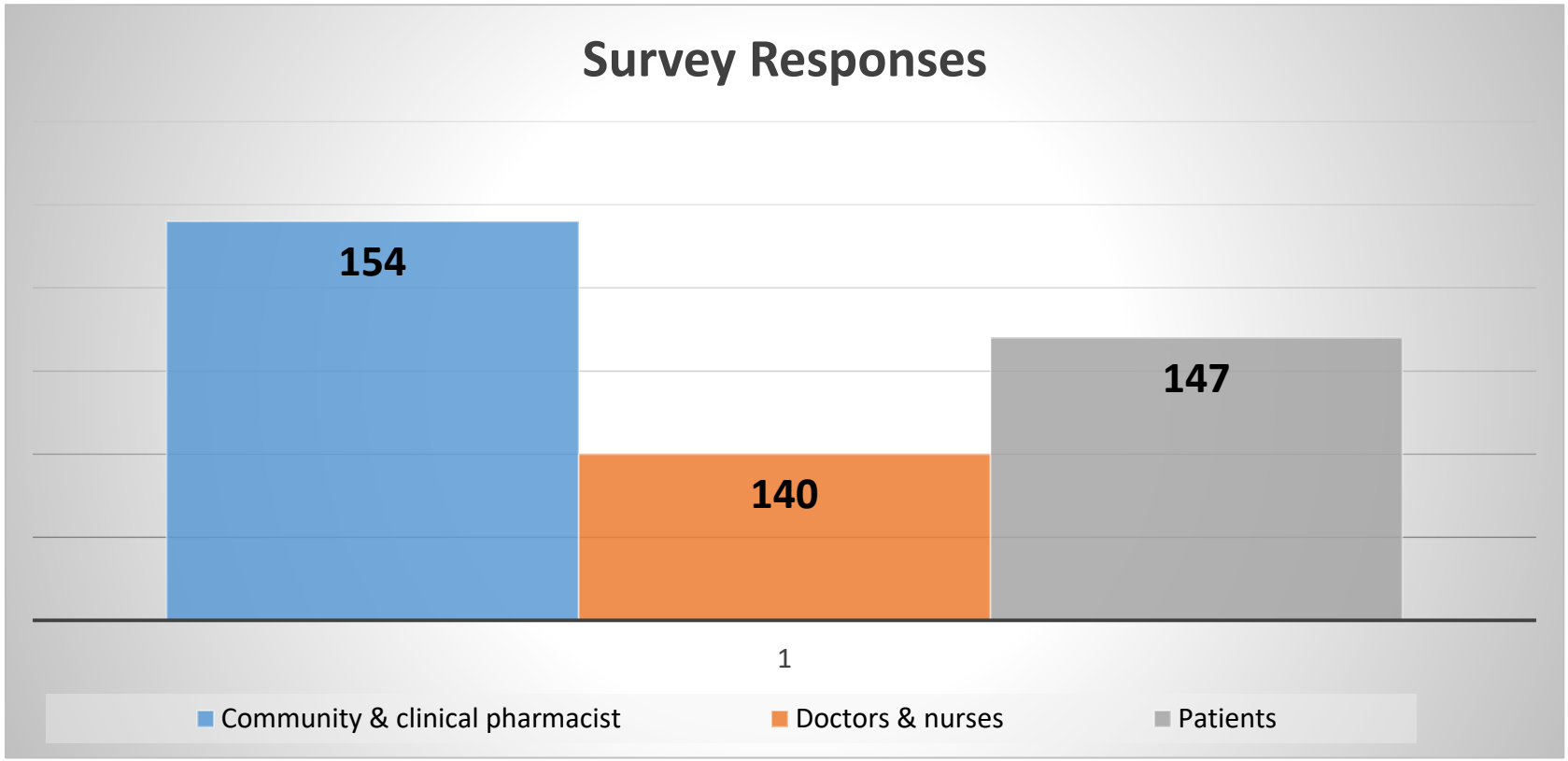
Methodology:

Quality control assessment includes:

- ✓Weight variation test. [5]
- ✓Friability test. [6]
- ✓Hardness test. [6]
- ✓Disintegration test. [6]
- ✓Determination of Maximum UV Absorbance Wavelength.[7]
- ✓Content Uniformity test. [6][8]
- ✓Dissolution test. [7]

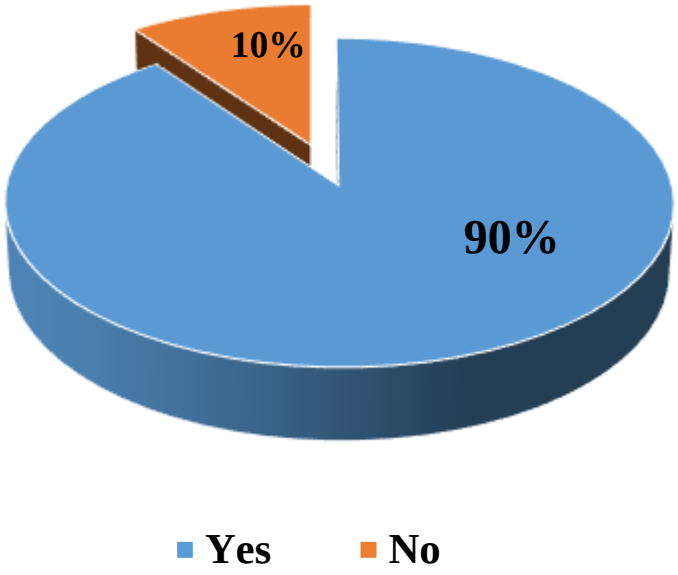
Results/ Discussion:

As per the survey results, the sample size was 441 participants response were collected.

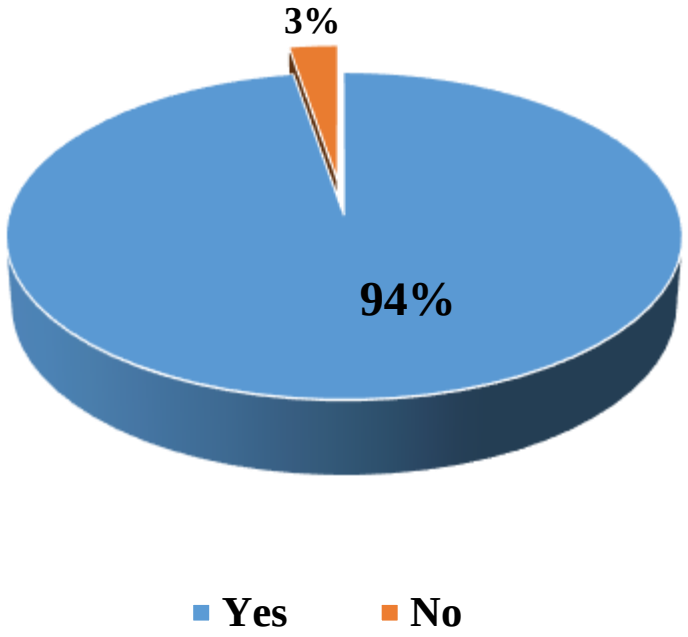


Healthcare providers survey results

90% prioritize prescribing/ administering medicines imported from countries other than Turkey.

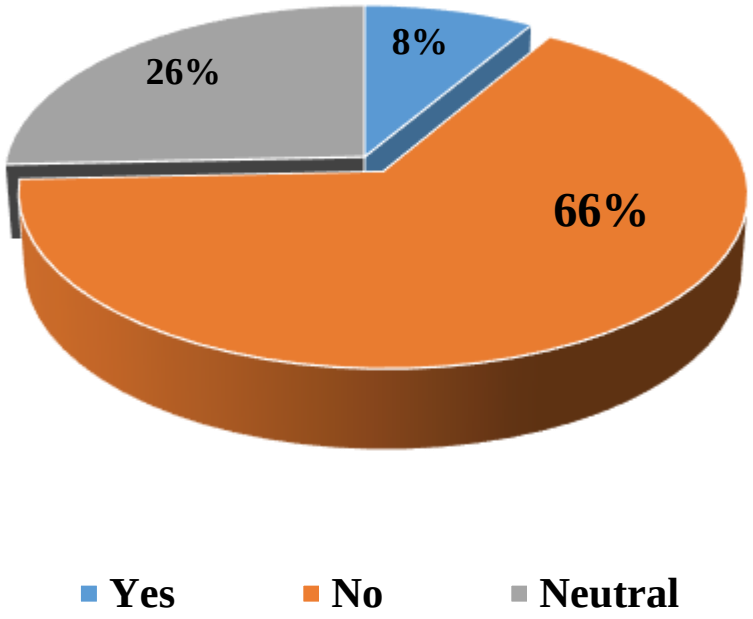


94% of pharmacists prioritize dispensing medicines imported from countries other than Turkey.

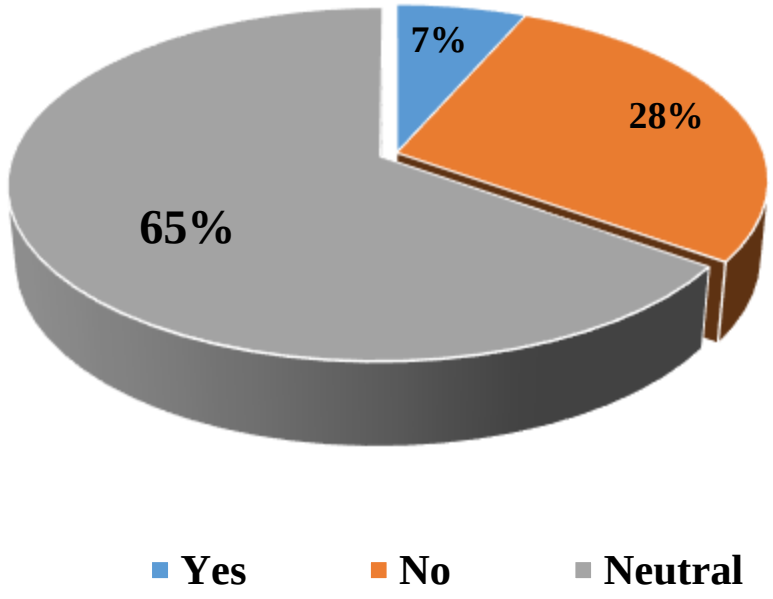


Healthcare providers survey results

66% of doctors did not recommend medicines imported from Turkey.

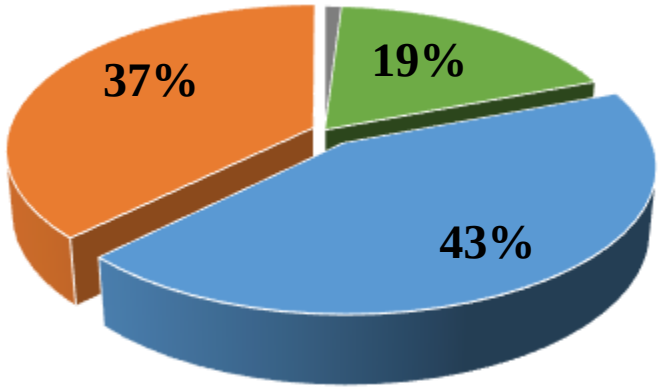


65% of the pharmacists do not dispense medications imported from Turkey.



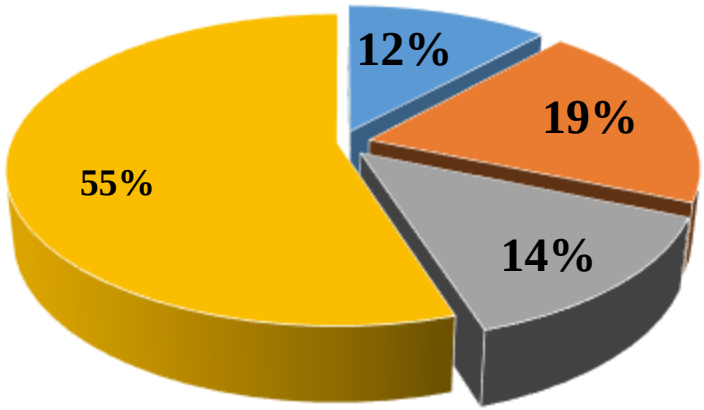
Patients survey results

43% of patients used brands imported form countries other than Turkey, **37%** used them were they not effective.



Most frequently used medications were:

- **Atacand**
- **L-thyroxin**
- **Metformen**
- **Other**



Patients survey results

- Thyroxin® quality investigation was halted as a result of the difficulty of shipping the standard, where they requires a low temperature about -20 °C.
- Glucophage® quality investigation was halted due to a shortage of metformin tablets under generic-brands manufactured in Turkey.
- Atacand® was investigated using 3 different batch numbers of (AstraZeneca/Esenyurt/Turkey) and 1 batch number of (AstraZeneca/Switzerland).

Quality control tests results

✓The **weight uniformity** test resulted in acceptable percentage deviation, complying with BP, equal 7.5% (Avg. Wt. 130 mg).

✓**Friability** of 50 tablets was accepted according to BP, were there is no crick or broken in the used tablet samples.

Weight g	CC*	CC1	CC2	CC3
% Friability	0.25%	0.15%	0.15%	0.15%

Quality control tests results

✓In the **hardness** test, the table diameter and thickness of three samples was comparable with the innovator candesartan tabs 7.5 mm & 3 mm.

Tablet No.	Tensile strength kg/cm² CC*	Tensile strength kg/cm² CC1	Tensile strength kg/cm² CC2	Tensile strength kg/cm² CC3
Mean	85.06	58.73	59.36	39.72
St. Dev.	0.75	34.97	41.13	44.34

✓The **disintegration** times of the three samples in water were comparable to the innovator time, and their means were within the limit for uncoated tablets.

Quality control tests results

- ✓UV spectroscopy was used for qualitatively investigation of candesartan tablet, and to identify the **maximum UV absorbance** wavelength (254 nm).

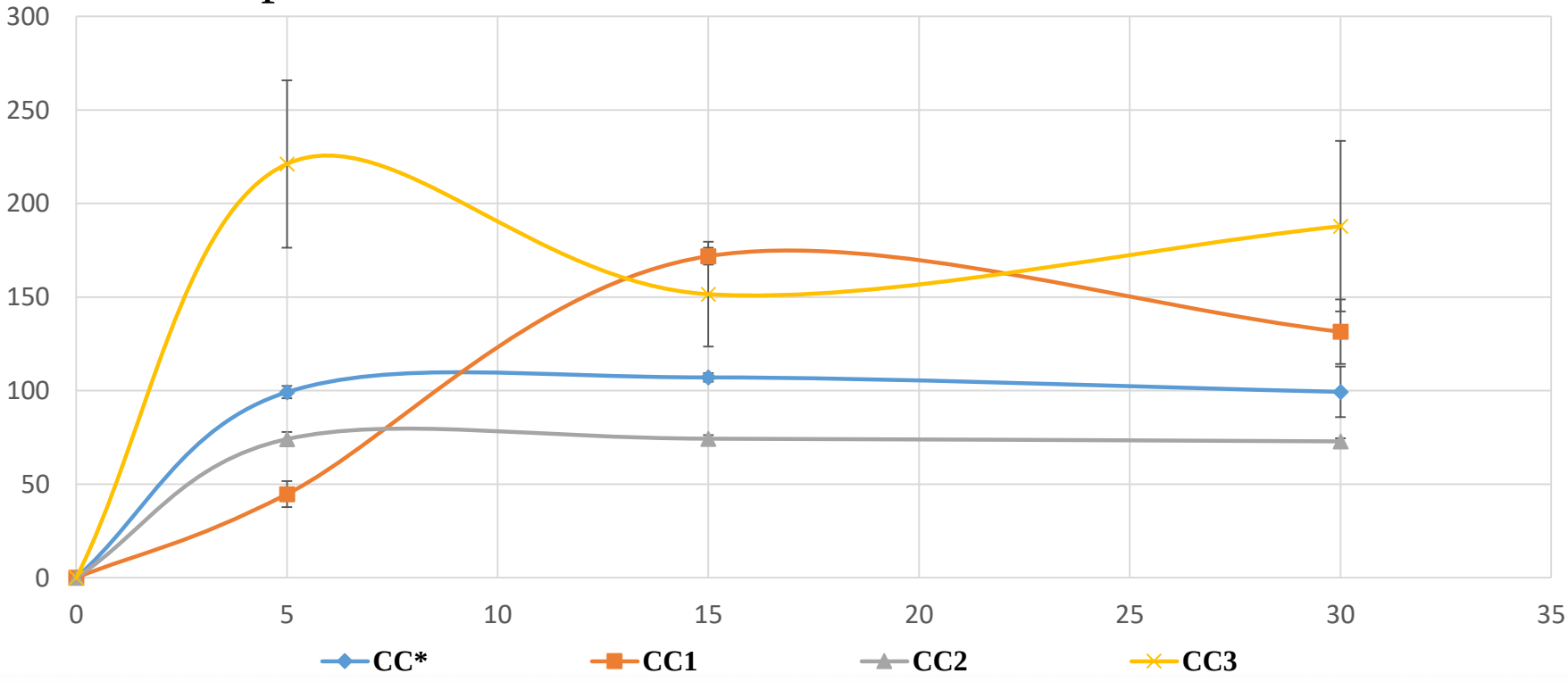
- ✓The **content uniformity** test according BP, resulted in accepted limit for the innovator as well as generic PN1, (Tab. conc. within % range 85-115).

  While PN2 and PN3 tablets lies out of the limit, and deviate from the expected innovator concentration value 0.05, with nonlinearity in the calibration curve by using (acetonitrile and water) solvent.

PN	Wt.	Conc. mg/ml	Y Absorbance	ln X=	X conc.	%(85-115)
CC*	0.127 g	0.05	0.169	-3.0785653	0.046025	92
CC*	0.130 g	0.05	0.159	-3.1639624	0.042258	84
CC*	0.131 g	0.05	0.164	-3.1212639	0.044101	88
CC1	0.128 g	0.05	0.179	-2.9982921	0.049872	100
CC1	0.127 g	0.05	0.179	-2.9982921	0.049872	100
CC1	0.127 g	0.05	0.171	-3.0666097	0.046579	93
CC2	0.129 g	0.05	0.18	-2.9897523	0.0503	100
CC2	0.130 g	0.05	0.173	-3.0495303	0.047381	95
CC2*	0.131 g	0.05	0.102	-3.6558497	0.02584	**51**
CC3*	0.129 g	0.05	0.135	-3.3740393	0.034251	**68**
CC3*	0.130 g	0.05	0.211	-2.7250213	0.065545	**131**
CC3	0.130 g	0.05	0.194	-2.8701964	0.056688	113

Release profile

- ✓**Dissolution profile** was determined using Phosphate buffer (pH 6.8) found that there is a difference in the concentration release flow compared to the innovator.



Conclusion:

By this study it seems to be clear that:

- ✓Some of generic-branded medications imported from Turkey, are below value, based on the opinion of patients and healthcare providers.
- ✓Did not meet the limits of some quality tests as hardness & dissolution.
- ✓The leaders at the Libyan Food and Drug Control Center (LFDCC), suspect some of the investigated batches are unregistered and smuggled.

Limitations:

The limitations encountered in the present investigation was the:

- Small sample size for:
  - " content uniformity test".
  - " dissolution test".

- Unavailability of active pharmaceutical ingredient API.

Recommendations:

For the investigation of candesartan cilexetil 16 mg oral tablet, we recommend:

- Use large sample size of evaluated tablet.
- Use the API as comparator.
- Utilization of HPLC to analyze candesartan cilexetil tablet.
- …

References:

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3. Colgan, S., Faasse,K., Martin, L., Stephens, M., Grey, A., Petrie, K. (2015), 'Perceptions of Generic Medication in the General Population, Doctors and Pharmacists: a Systematic Review', *BMJ Open*, 5(12).

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5. Albratty M., Alhazmi H., Makeen H., Najmi A., Alam M., Ageeli R., et al. (2020), 'Quality Control Measurement and in vitro Bioequivalence of Candesartan Cilexetil Tablets Marketed in Saudi Arabia', *Journal of Pharmaceutical Research International, (Past name: British Journal of Pharmaceutical Research),* 32(12), pp. 155-163.

6. Prakash, G., Chandra, S., Sandhya, P., Bidur, C., Samir, D. (2020), 'Pharmacopoeial comparison of in-process and finished product quality control test for pharmaceutical tablets', *GSC Biological and Pharmaceutical Sciences,* 11(3), pp. 155-165.

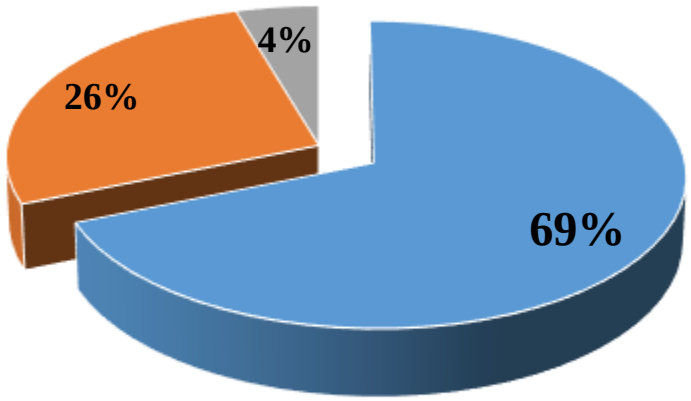
References:

7. BP. Commission, (2018), 'Consultation response: Dissolution testing in BP finished products monographs for solid oral dosage forms', *British Pharmacopoeia*.

8. European Directorate for the Quality of Medicines and Health Care EU.Ph. (2021), Candesartanum cilexetili, *European Pharmacopoeia*, 10.4.

Thank you

56% of doctors & nurses believe that medicines imported from Turkey are bad.



Weight uniformity test

Tablet	Average weight g	Average weight mg	% of average weight deviation
CC*	0.1305	130.5	0
CC1	0.1303	130.3	0.761
CC2	0.13	130	1.11
CC3	0.1294	129.45	0

Hardness variation results

Tablet No.	CC* Hardness /N.	CC1 Hardness /N.	CC2 Hardness /N.	CC3 Hardness /N.
1	294	287	55	54
2	294	298	66	76
3	294	103	294	298
4	294	297	294	46
5	294	296	294	436
6	294	296	294	35
7	294	296	40	62
8	294	54	293	17
9	294	51	427	45
10	293	91	32	297
mean	**293.9**	**206.9**	**208.9**	**136.6**

Patients survey results

Most frequently used medications were: