

STABILITY ASSESMENT OF EXTEMPORANEOUS LOSARTAN 0,8 MG/ML EYE DROPS

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BACKGROUND AND IMPORTANCE

Losartan is an angiotensin II receptor antagonist used off-label as eye drops for corneal haze and is being investigated for corneal scarring and other eye disorders. Establishing a period of validity is essential to ensure the quality of an extemporaneous preparation and patient safety.

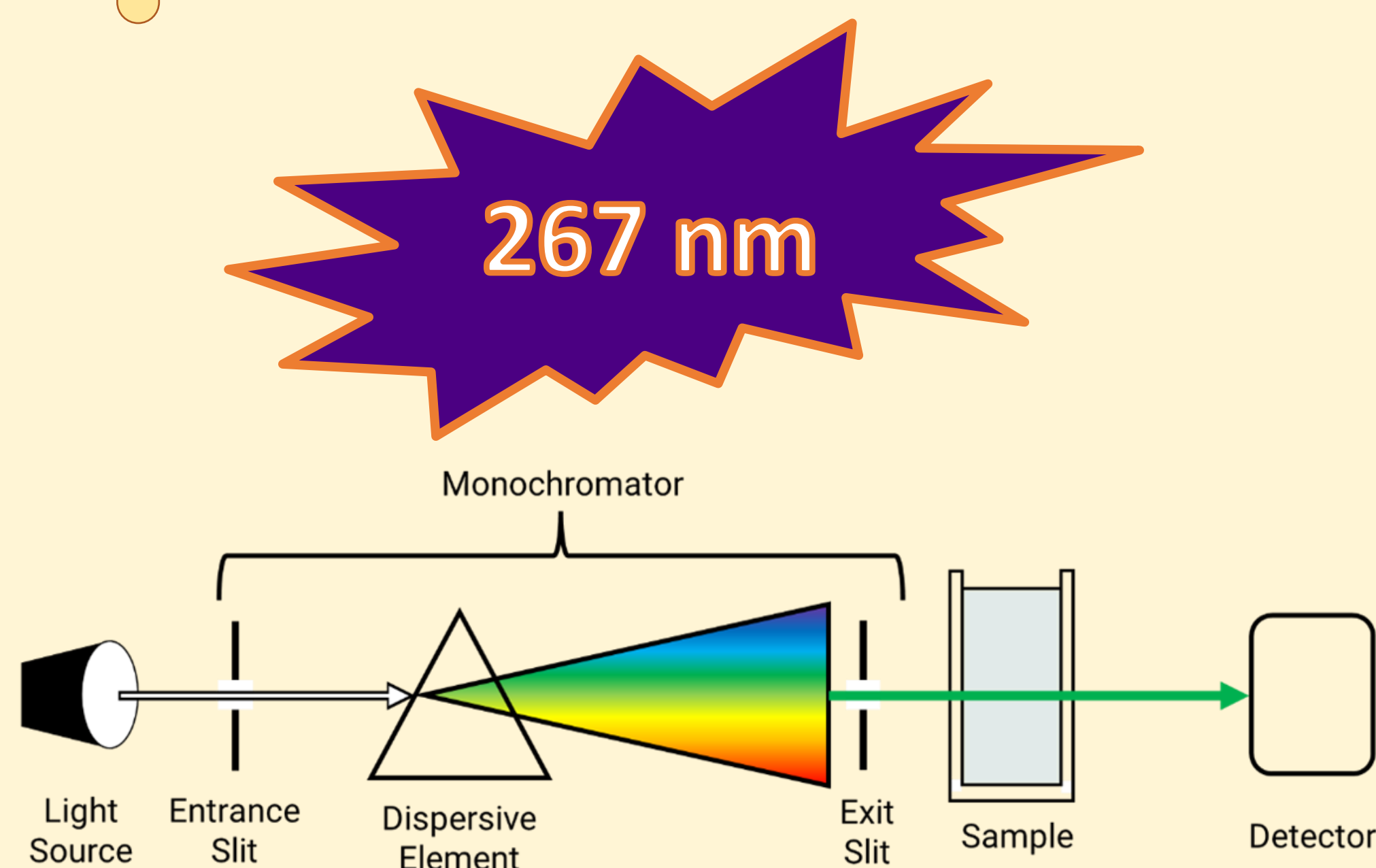
AIM AND OBJECTIVES

To evaluate the physicochemical stability of Losartan 0,8 mg/mL eye drops over a 56-day period under refrigerated storage (2-8 °C) and establish a period of validity for its use in clinical practice.

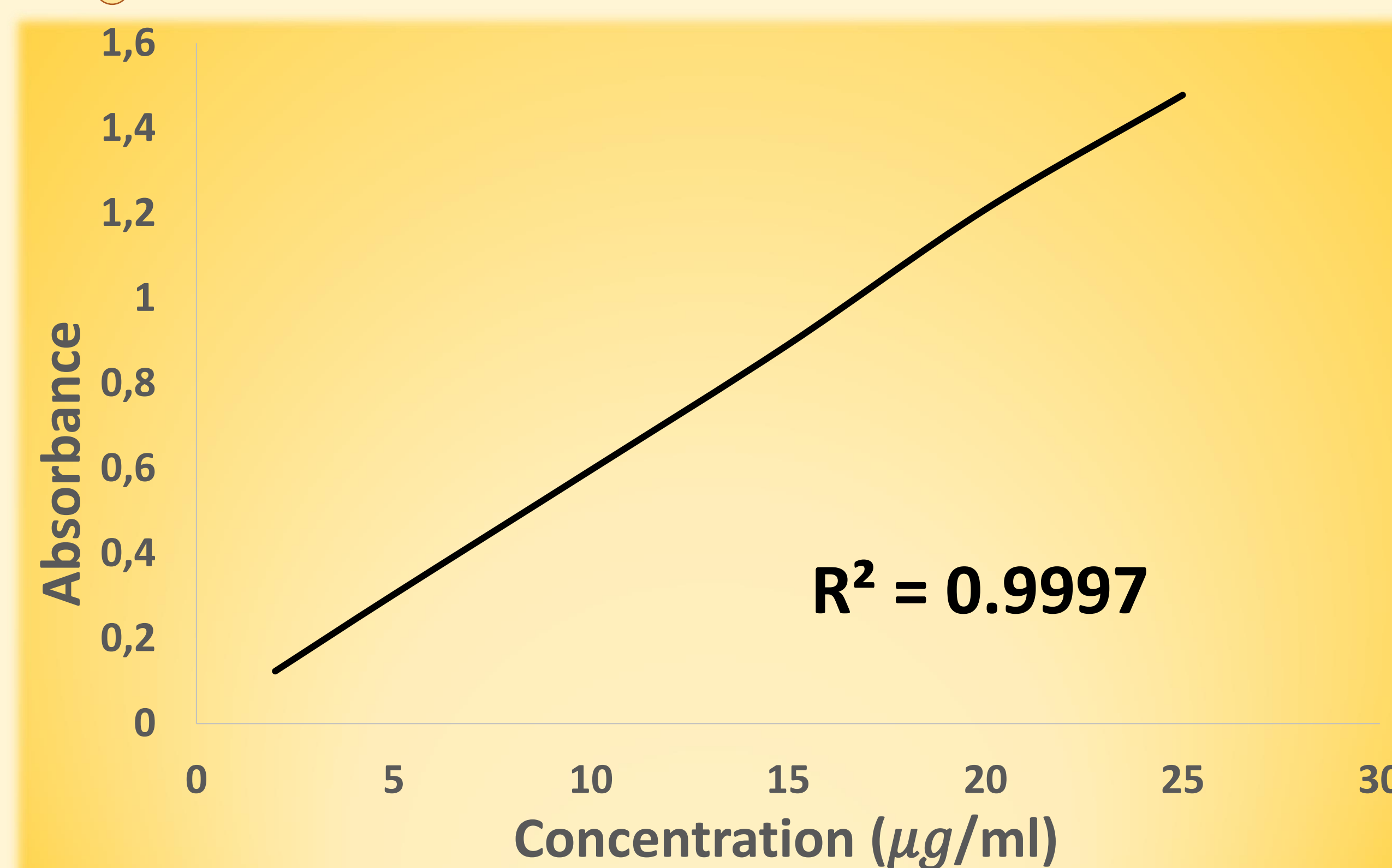
MATERIALS AND METHODS

Losartan was determined using an Ultraviolet-Visible spectrophotometric method at a wavelength of 227 nm by designing a calibration curve from a stock solution. Then, three batches (A, B, C) were prepared and triplicate samples (1, 2, 3) from each were analyzed on Days 0, 7, 14, 28, 42, 56.

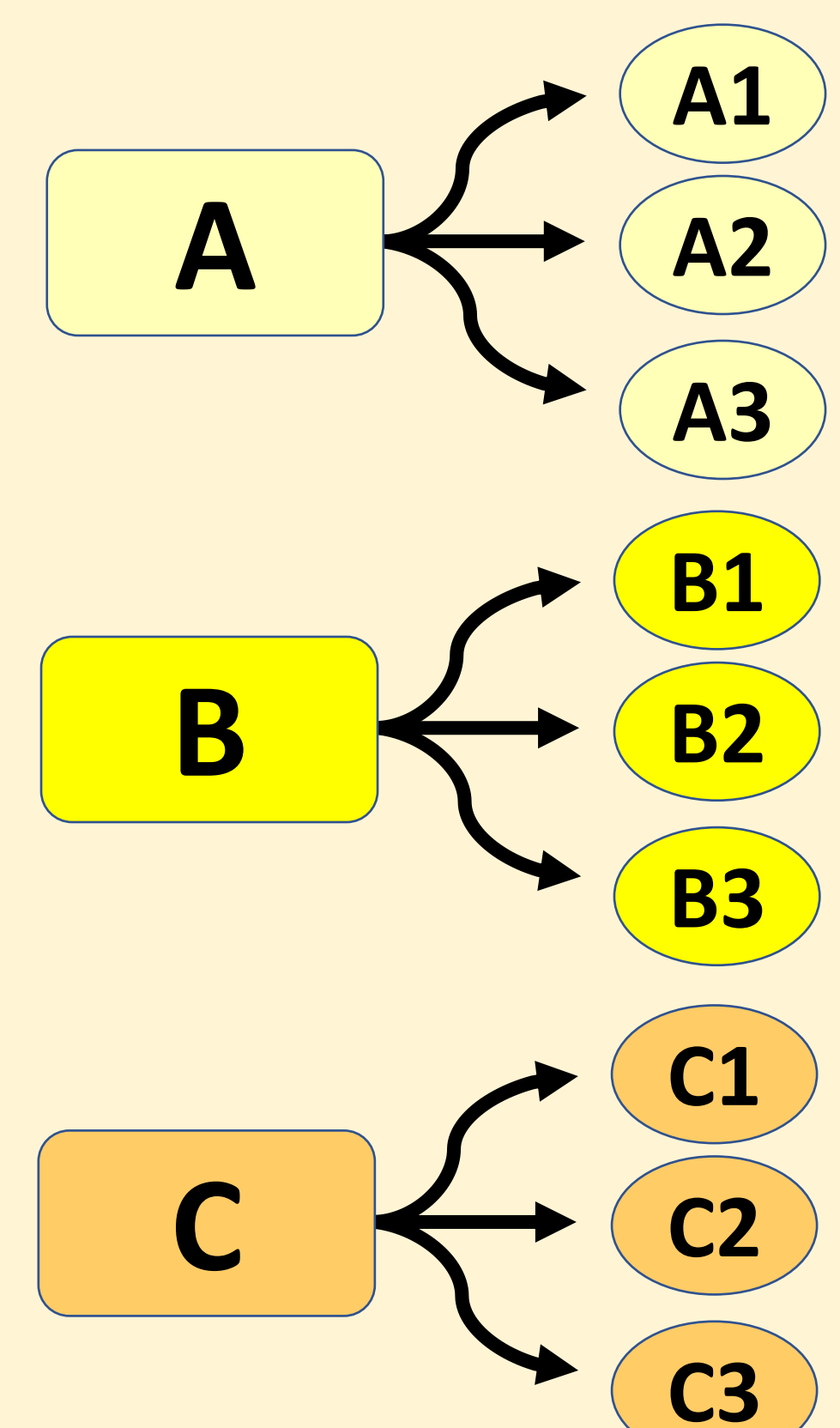
UV-VIS SPECTOFOTOMETRY



CALIBRATION CURVE



BATCHES AND SAMPLES



RESULTS

Samples	Measurements											
	Day 0		Day 7		Day 14		Day 28		Day 42		Day 56	
	Abs	Conc	Abs	Conc	Abs	Conc	Abs	Conc	Abs	Conc	Abs	Conc
A1	0,495	8,3	0,497	8,3	0,492	8,3	0,483	8,1	0,476	8	0,479	8
A2	0,494	8,3	0,487	8,2	0,496	8,3	0,485	8,1	0,495	8,3	0,488	8,2
A3	0,493	8,3	0,489	8,2	0,501	8,4	0,481	8,1	0,491	8,2	0,484	8,1
B1	0,495	8,3	0,491	8,2	0,499	8,4	0,488	8,2	0,485	8,1	0,487	8,2
B2	0,491	8,2	0,479	8,1	0,501	8,4	0,497	8,3	0,487	8,2	0,486	8,2
B3	0,501	8,4	0,501	8,4	0,497	8,3	0,495	8,3	0,488	8,2	0,497	8,3
C1	0,495	8,3	0,497	8,3	0,495	8,3	0,474	8	0,486	8,1	0,484	8,1
C2	0,493	8,3	0,491	8,2	0,496	8,3	0,475	8	0,487	8,2	0,482	8,1
C3	0,489	8,2	0,493	8,3	0,488	8,2	0,493	8,3	0,486	8,1	0,485	8,1

Concentrations are expressed in µg/mL. All measurements were performed on 1:100 dilutions of the original solution.

Day 0
8,28 µg/ml

Day 56
8,14 µg/ml

>98%
remaining

CONCLUSIONS

Losartan 0.8 mg/mL eye drops formulation demonstrated excellent physicochemical stability under refrigeration, providing strong evidence to support a 56-day period of validity. Further studies include monitoring pH and osmolarity throughout the validity period.

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