Dissolution profile of phenylephrine hydrochloride pellets

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Abstract:

A Simple and rapid dissolution test method for Phenylephrine Hydrochloride Pellets - 20%W/W has been developed and validated. Based on the stability and nature of the drug, dissolution experiments were conducted in different mediums in various time intervals with Basket at 100 rpm(resolution per minute). Dissolution was found to be NMT 25% over a period of one hour, 30-50% in 2^{nd} hour, 50-70% in 4^{th} hour, at 8^{th} hour NTL 75%. The quantitative recoveries of the drug from semi formulations were established indicating non interference of excipients. The dissolution profile for pellets were considered satisfactory and this could be utilized for the Quality control Analysis of Phenylephrine Hydrochloride Pellets 20%W/W.

Key Words: Phenylephrinehydrochloride pellets, Dissolution, UV method, Drug Release.

Introduction:

A survey of literature reveals, methods [1],[2], HPLC and UV spectrophotometric [3] are reported, for determination of paracetamol, phenylephrine Hydrochloride, and chlorpheniramine maleate in pharmaceutical dosage forms and also Determination of phenylephrine hydrochloride, chlorpheniramine maleate, and methscopolamine nitrate in tablets or capsules. Quantitative analysis of chlorpheniramine maleate and phenylephrine hydrochloride in nasal drops by differential-derivative spectrophotometric, zero-crossing first derivative UV spectrophotometric and absorbance ratio methods is also reported. Determination of Phenylephrine Hydrochloride by Flow Injection Analysis with Chemiluminescence Detection is also known. How ever there is no U.V method reported so for the determination of the Phenylenephrinehydrochloride Pellets in commercial dosage forms. Hence a U.V In-House method for the determination of the Phenylenephrinehydrochloride Pellets in Pharmaceutical dosage forms is described.

Experimental Section

Instrument: UV-VIS spectra, Shimadzu 2010. LC solution computer based data station.

Chemicals and reagents: Reference standard Phenylephrine.Hydroclhoride is procured from M/S.RA Interchem, Water (Distilled water), KCl, KH_2PO_4, AR grade.

Standard preparation: Weigh and transfer accurately 50mg of Phenylephrine Hydrochloride working standard (WS) into a 100 ml volumetric flask add 70ml of methanol. Sonicate for 10 minutes and dilute with methanol to volume Mix and filter Transfer 1ml of this solution to a 50ml volumetric flask, dilute with medium to the volume and mix.

Buffers Preparations:
1.5 Buffer: 3.57g of KCl dissolved in 1000ml of D.M Water and adjust the pH to 1.5 with Conc. HCl
4.5 Buffer: 6.8 g of KH_2PO_4 dissolved in 1000ml of D.M Water and adjust the pH to 4.5 with Sodium Hydroxide
6.9 Buffer: 6.8 g of KH_2PO_4 dissolved in 1000ml of D.M Water and adjust the pH to 6.9 with Sodium Hydroxide
7.2 Buffer: 7.2 g of KH_2PO_4 dissolved in 1000ml of D.M Water and adjust the pH to 7.2 with Sodium Hydroxide

Drug release:
Apparatus: 1; 100 rpm

Time	Medium	volume
1st hour	1.5 Buffer	750ml
2nd hour	4.5 Buffer	1000ml
4th hour	6.9 Buffer	1000ml
8th hour	7.2 Buffer	750ml

Time: 1,2, 4, 8th hours

Place the stated volume of dissolution medium in the vessel of apparatus specified in the individual monograph, assemble the apparatus. Equilibrate the dissolution medium to 37 ±0.5°C, and remove the thermometer. Place the 6 samples equivalent to 10 mg of Phenyleneprinehydrochloride pellets in the apparatus, taking care to exclude air bubbles from the surface of dosage-form unit, and immediately operate the apparatus at the rate specified in the individual monograph. with in the time interval specified, withdraw a 10ml of specimen from a zone midway between the surface of dissolution medium and the top of rotation blade, not less than 1cm from the top of the rotation blade, not less than 1cm from the vessel wall. After replacing the medium with medium specified in monograph Equilibrated at 37 ±0.5°C,determine the amount of Phenylephrine Hydrochloride Pellets dissolved using the following procedure.

Procedure:
Measure the absorbance of Standard and sample preparations in 1cm cell on suitable U.V spectrometer at 214 nm. Using medium as blank record the absorbance.

Calculation. For 1st and 8th hours

$$\frac{AT \times WS \times 1 \times 750 \times Px \times 100}{AS \times 100 \times 50 \times WT \times \text{Label claim in\%}} = \%$$

Calculation. For 2nd and 4th hours

$$\frac{AT \times WS \times 1 \times 1000 \times P \times 100}{AS \times 100 \times 50 \times WT \times \text{Label claim in\%}} = \%$$

Where
AT=Absorbance of Phenylephrine Hydrochloride in sample solution
AS= Absorbance of Phenylephrine Hydrochloride in standard solution
WS=Weight of Phenylephrine Hydrochloride Working standard Taken in mg
WT=Weight of sample taken in mg
P=Purity of Phenylephrine Hydrochloride Working standard used.

The result are tabulated as follows

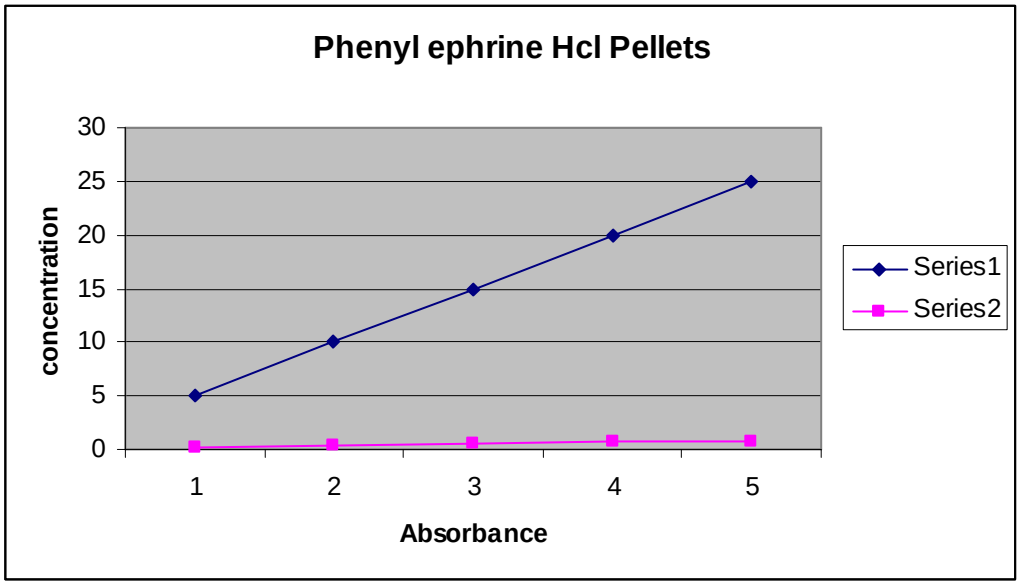
Semi formulations	Media	Ti interval	Bowl no's	Release	Average	Limits	S.D	RSD
PELLETS	1.5 Buffer 750ml	1st Hour	1,2,3,4, 5and 6	20.3%,20.5% 20.4%,20.2%,20.1%,20.4%	20.31%	NMT25 %	0.147	0.724
	4.5 Buffer	2nd hour	1,2,3,4,5 and 6	45.1%,45.3%, 45.2%,45.4% 45.2%,45.3%	45.25%	30-50%	0.1048	0.2317
	6.9 Buffer	4th hour	1,2,3,4,5 and 6	65.7%,65.6%,65.5%,65.4%,65.6%,65.4%	65.51%	50-70%	0.1169	0.1784
	7.2 Buffer	8th hour	1,2,3,4,5 and 6	77.8%.77.6%, 77.7%,77.5%, 77.6%,77.4%	77.6%	NLT 75%	0.1414	0.1822

Recovery studies:
To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out .Known quantities of standard at two different levels were added to the pre-analyzed sample and the recovery was estimated to be more than 99%

Results and Discussion

Linearity: The linearity of PHENYLEPHRINE HYDROCHLORIDE is established by plotting a graph of absorbance of standard solution versus concentration. The linearity is found to be between 5-25mg/ml

Concentration	Absorbance
5	0.163
10	0.327
15	0.490
20	0.654
25	0.817



The reproducibility and reliability of method has been tested by performing recovery studies which showed good results.

Conclusion

The proposed method is very simple, rapid and no where involves use of complicated sample preparation. High percentage of recovery shows that the method is free from interference of the excipients used in the semi formulations. There fore the method can be useful in routine quality control analysis.

References

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