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Development of Validated UV Spectrophotometric Method for Assay of Ozagrel

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ABSTRACT

Abstract: UV Spectrophotometric method was developed and validated for the quantitative determination of Ozagrel in bulk drug and in pharmaceutical formulations. Ozagrel shows the maximum absorbance at 270 nm. Ozagrel follows Beer's law in the concentration range of 1.0-10.0 µg/ml (r = 0.999). The detection limit (DL) and quantitation limit (QL) were 0.4629 and 1.4027 µg/ml respectively. Accuracy and precision were found to be satisfactory. The developed methods were validated according to ICH guidelines. All the validation parameters were found to be satisfactory accordance with the standard values. Therefore, the proposed method can be used for routine practice for the determination of Ozagrel in assay of bulk drug and pharmaceutical formulations.

Keywords : Ozagrel, validation, UV-Spectrophometry.

I. INTRODUCTION

Ozagrel (Ozagrel Sodium), the thromboxane A2 (TXA2) synthase inhibitor is a kind of intravenous antiplatelet agent. It can increase 6-keto-PGF1 alpha in various isolated cells and tissues perhaps via accumulated PG endoperoxides resulted by the inhibition of TXA2 synthase. Ozagrel was firstly introduced to the market in Japan in 1992, which was used to reduce airway hyperresponsiveness to acetylcholine and leukotriene D4. Ozagrel was also found to help to expend the blood vessels, and inhibit the spasms of cerebral artery despite the function of inhibiting the accumulation of platelet activation in the clinical practice. Moreover, intravenously administered antiplatelet agents offer the prospect of a much more rapid onset of antiplatelet effect. For these reasons, ozagrel was used to prevent cerebral vasospasm induced by the subarachnoid hemorrhage (SAH), and to improve the cerebral circulation after acute ischemic stroke.

Stroke is the second commonest cause of death and the leading cause of disability worldwide. Approximately 87% of all strokes are ischaemic that is due to a blockage of an artery in the brain. Platelet therefore is actived in the acute phase and releases neurotoxic and thrombogenic eisosanoids including thromboxane B2. There is as yet no routine effective, generally accepted and specific treatment for acute

ischemic stroke, except for aspirin. There is no reliable evidence on the effects of other antiplatelet drugs in acute ischemic stroke. Therefore, it is necessary to explore other promising drugs that could improve the cerebral blood flow and protect brain function.

For its potential role, ozagrel has been widely used in acute ischemic stroke, especially in China and Japan. There were some non-large-sampled clinical trials of ozagrel in the last 15 years, however, these clinical trials didn't provide the conclusive evidence of efficacy of ozagrel for AIS, meanwhile, no systematic review has been done about ozagrel for AIS till now. Therefore, ozagrel's efficacy and safety should be strictly assessed before it is recommended for routine use in patients with acute ischemic stroke. In a word, the aim of this review is to systematically evaluate all the relevant RCTs of ozagrel for acute ischemic stroke, in order to provide the latest and better available evidence for clinical practice and further research planning for acute ischemic stroke.

II. EXPERIMENTAL WORK

❖ **Standard solutions**

- **Solution A (Stock standard solution)**

Accurately weighed quantity of Ozagrel (10.0 mg) was dissolved in 10.0 ml of water. (conc.: 1.0 mg/ml).

- **Solution B (Working standard solution)**

Accurately measured 1.0 ml of solution A was diluted to 100.0 ml with water (conc.: 10.0 µg/ml).

❖ **Selection of λ_{max}**

Working standard solution was scanned in the UV range (200-400 nm) in 1.0 cm quartz cell against solvent blank to obtain the spectrum of the drug. Ozagrel showed well-defined λ_{max} at 270.0 nm and this wavelength was selected for further study.

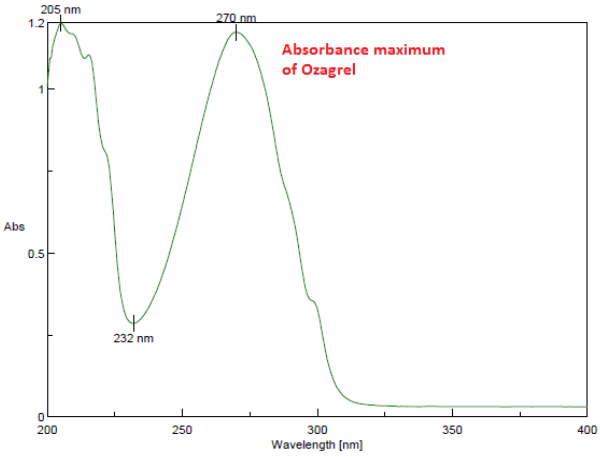

Figure 1 : UV Spectra of Ozagrel at 270.0 nm

❖ **Study of Beer-Lambert's Law**

The working standard solution of Ozagrel was diluted with distilled water to get series of concentration ranging from 1.0-10.0 µg/ml. Absorbance of these solutions were measured at 270.0 nm in 1.0 cm cell using solvent blank. A plot of absorbance vs. concentration was found to be linear.

III. CONCLUSION

This study shows that how data mining can be used in SIEM system. This paper firstly introduces the related knowledge, architecture of SIEM system and then the rule of algorithm for the correlation analysis. We have seen various association rules to detect abnormal patterns.

One of the areas we are exploring for future research is how we can use other data mining technique like classification, clustering to enhance the system capacity. In addition, we are enhancing the techniques we have mentioned to reduce false positive alerts and to reduce CPU load on system while computing data mining rules. Furthermore we are working to contribute some new modules for open source SIEM project.

Sr. No.	Parameters	Ozagrel (at 270.0 nm)
1.	Linearity dynamic range	1-10 µg/ml
2.	Regression equation	Y= 0.124901X
2.	Slope	0.1249
4.	Correlation coefficient (r)	0.999

Table : Results of Linearity studies

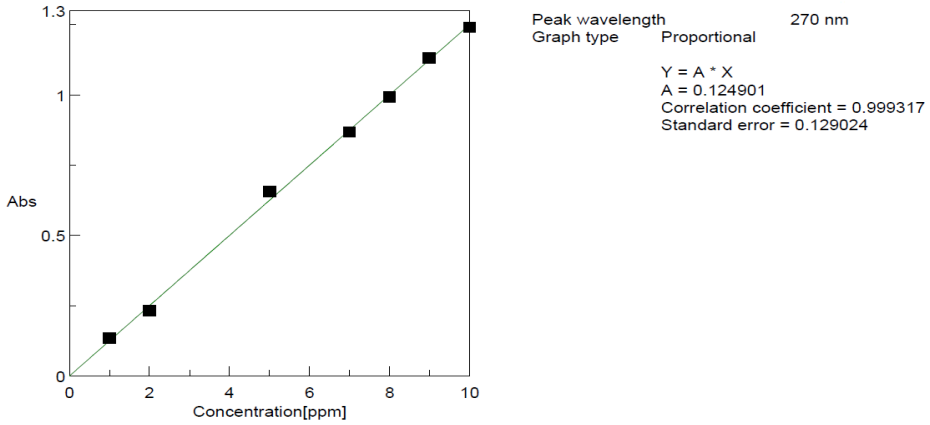

Figure : Study of Beer-Lambert's Law at 270.0 nm

❖ **Determination of Absorptivity Values at Selected Wavelength**

Five standard solutions of Ozagrel 10.0 µg/ml were prepared and the absorbance of each resulting solutions were measured at 270.0 nm in 1.0 cm cell using solvent blank. The A (1%, 1cm) values were calculated using the relation,

$$\mathbf{A\ (1\%, 1cm)} = \frac{\mathbf{Absorbance}}{\mathbf{B \times C}}$$

where,

A (1%, 1cm) = Specific Absorptivity of Ozagrel at 270.0 nm,
B = Path length (1 cm),
C = Concentration in g/100ml

Sr. No	A (1%, 1cm) at 270.0 nm
1.	1198.53
2.	1198.44
3.	1198.50
4.	1198.52
5.	1198.47
Mean	**1198.49**
±S.D.	**0.037**
% RSD	**0.003**

Table: Absorptivity Value of Ozagrel at 270.0 nm

❖ **Estimation of Ozagrel in Tablet Formulation**

- **Standard Solution:** Working standard solution was prepared (10.0 µg/ml) as described under preparation of standard solution.
- **Procedure:** Twenty tablets were weighed and average weight was calculated. Tablets were crushed to a fine powder. An accurately weighed quantity of tablet powder equivalent to about 10.0 mg of Ozagrel was shaken with about 8.0 ml of water, sonicated for 15 minutes, the volume was made up to 10.0 ml with water, and solution was filtered through Whatman Grade I filter paper.1.0 ml of the filtrate was diluted to 100.0 ml with water. The absorbance of final solution was measured in 1.0 cm cell at 270.0 nm against solvent blank. Five such replicate estimation were performed. The content of Ozagrel was calculated using formulae-

Method A

$$\% \textbf{ of Labelled claim} = \frac{\textbf{Asmp} \times \textbf{Cstd} \times \textbf{AW}}{\textbf{Astd} \times \textbf{Wsmp} \times \textbf{Lc}} \times \textbf{100}$$

where,

A_{smp} = Absorbance of sample

A_{std} = Absorbance of standard

C_{std} = Concentration of standard (µg/ml)

Lc = Labelled claim per tablet (mg)

AW = Average weight of tablet (mg)

W_{smp} = Weight of tablet powder taken (mg)

Method B

$$\% \textbf{ of Labelled claim} = \frac{\textbf{Asmp} \times \textbf{AW}}{\textbf{A (1\%, 1cm)} \times \textbf{Wsmp} \times \textbf{Lc}} \times \textbf{100}$$

where,

A_{smp} = Absorbance of sample

A (1%, 1cm) = Specific Absorptivity value of Ozagrel at 270.0 nm.

AW = Average weight of tablet (g)

W_{smp} = Weight of tablet powder taken (g)

Lc = Labelled claim of tablet (g)

Pulmoza tablet (Avg. Wt. 359.82 mg., Labelled claim: 200 mg per tablet)						
S.N.	Sample wt.(mg)	Std conc. (µg/ml)	Abs. at 270.0 nm		% of labelled claim	
			Standard	Sample	Method A*	Method B*
1	17.90	10.60	1.2704	1.1980	100.46	100.40
2	18.10	10.60	1.2704	1.2040	99.88	99.87
3	18.30	10.60	1.2704	1.2170	99.88	99.87
4	17.50	10.60	1.2704	1.1700	100.38	100.37
5	17.70	10.60	1.2704	1.1780	99.97	99.98
* Each value is mean of five observations				Mean	100.72	100.10
				±S.D.	0.838	0.268
				% RSD	0.832	0.267

Table: Results of Estimation of Ozagrel in Tablets

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