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**<u>Review Article</u>** 

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# A REVIEW ON ANALYTICAL METHODS FOR ESTIMATION OF DOXOFYLLINE AND TERBUTALINE SULPHATE IN PHARMACEUTICAL DOSAGE FORM

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## ABSTRACT

This review article is intended to highlight the analytical methods of Doxofylline and Terbutaline sulphate in individual as well as combined pharmaceutical dosage form. Doxofylline and Terbutaline sulphate play an important role in Asthma. Doxofyline is a new generation long acting oral methyl xanthine derivative. Terbutaline sulphate selective short acting  $\beta_2$  adrenergic receptor agonist. Now these days these drugs are easily available in the market in their individual form as well as in their combined dosage form. Various analytical methods have been reported for the estimation of these drugs in their individual form as well as in their combined dosage form. **KEYWORDS:** Terbutaline sulphate, Doxofyline, Asthma.

## INTRODUCTION TO ANALYTICAL METHOD

There are various analytical methods are used now these days for the estimation. Various analytical methods like potentiometer, HPLC, aqueous and non-aqueous titrations are used in the field of analysis. Aqueous and non-aqueous titrations are also used in the field of analysis. But now these days HPLC plays an important role in the field of analysis for the quantitative determination. HPLC is referred as high pressure liquid chromatography which is a separation technique based on the solid stationary phase and liquid mobile phase. Chromatography is mass transfer process involve adsorption. The active component of the column is adsorbent which is granular material of solid particles (silica, polymers). The principle of separation in the normal phase mode and reverse phase mode is adsorption in which the substances travel /separate according to their relative affinities. Now these days

HPLC plays an important role in the field of pharmaceutical analysis for the separation of various substances from the mixture of substances.

**Introduction to Drug Profile** 

#### Doxofylline

Structure



- IUPAC name: 7-(1,3-dioxolan-2-ylmethyl)-1,3-dimethylpurine-2,6-dione
- Molecular formula: C11H14N4O4
- Molecular weight: 266.257 g/mol
- Category: Bronchodilator
- Solubility: trichloromethane, soluble in water and acetone, slightly soluble in acetic acid and ethyl alcohol.
- Melting point:141-144°c

#### **Terbutaline sulphate**

#### Structure



- IUPAC name: 5-[2-(tert-butylamino)-1-hydroxyethyl]benzene- 1,3-diol; sulfuric acid
- Molecular formula: C<sub>12</sub>H<sub>21</sub>NO<sub>7</sub>S
- Molecular weight: 323.36 g/mol

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- Category: Bronchodilator.
- Solubility: Water, Acetonitrile.
- Melting point :119-122°c

# **Reported Methods of Doxofyline**

Sr.No.	Drug	Method	Brief introduction	Reference
1	Doxofylline	RP- HPLC	Mobile phase: Acetonitrile:Phosphate buffer(50:50%v/v) pH:3 Column: HiQSil C18 Flow rate:1ml/min Wavelength:272nm	[5]
2	Doxofylline & Sertraline	RP- HPLC	Mobile phase: Acetonitrile:Water (30:70% v/v) pH:3 Column:Kromosil C18 Flow rate:1ml/min Wavelength:234nm	[6]
3	Doxofylline	RP- HPLC	Mobile phase: Acetonitrile:Formic acid (90:10% v/v) pH:3 Column:Kromosil C18 Flow rate:1ml/min Wavelength:274nm	[7]
4	Doxofylline & Montelukast sodium	RP- HPLC	Mobile phase: Methanol:Sodium phosphate buffer(75:25%v/v) pH:6.5 Column: Inertsil C18 Flow rate:1ml/min Wavelength:230nm	[8]
5	Doxofylline & Ambroxol	RP- HPLC	Mobile phase: Potassium dihydrogen orthophosphate buffer: Acetonitrile(25:75% v/v) pH:6.8 Column: Kromosil C18 Flow rate:1ml/min Wavelength:257nm	[9]
6	Doxofyline, Montelukast, Levocetrizine dihydrochoride	RP- HPLC & UV	Mobile phase: Ammonia acetate buffer: Acetonitrile(75:25% v/v) pH:3.5 Column: Agilent C18 Flow rate:1ml/min Wavelength:230nm	[10]

Sr.No.	Drug	Method	Brief introduction	Reference
1	Terbutaline sulphate	RP-HPLC	Mobile phase: Ammonia acetate	
			: Methanol( $(0:30\% V/V)$ pH:3.5	[11]
			Column: Aglient C18	
			Flow rate: Imi/min	
			wavelength:220nm	
2	Terbutaline sulphate, Bromohexin, Guaifenesin	RP-HPLC	Mobile phase: Phosphate	
			buffer: Acetonitrile(80:20% V/V)	[12]
			pH:3 Column: Wakosil	
			Flow rate: Iml/min	
			Wavelength:248nm	
3	Terbutaline sulphate, Guaiphensin, Ambroxol hydrocholride	RP- HPLC,UV	Mobile phase: Mixture of Water	
			and Acetonitrile containing	[13]
			sodium hexane sulphonate	
			pH:3 Column: 5 Micron water	
			symmetry C18	
			Flow rate:1ml/min	
			Wavelength:280nm, 250nm	
4	Terbutaline sulphate, Guaiphensin	RP-HPLC	Mobile phase: Methanol :	
			Water( $60:40\%$ v/v) adjusted with	[14]
			phosphate buffer	
			Column: Agilent C18	
			Flow rate:0.8ml/min	
			Wavelength:275nm	
5	Terbutaline sulphate, Bromhexinene hydrochloride	RP-HPLC	Mobile phase:Perchloric acid:	[14]
			Acetonitrile(60:40%v/v)	
			Column: Phenomenex luna C18	
			Flow rate:1.5ml/min	
			Wavelength:254nm	

#### Mechanism of action

A fixed dose combination of doxofylline and terbutaline sulphate is available for the treatment of asthma. Terbutaline sulphate stimulates the  $\mathcal{A}^{-}$  adrenergic receptors of the sympathetic nervous system and has little or no effect on the adrenergic receptors.

#### REFERENCES

- 1. Maulik Oza, Chirag Oza, Jagdish Kakadiya. development and validation of solvent extraction spectrophotometric method for simultaneous estimation of Doxofylline and Terbutalinesulphate in their combined dosage form, American Journal of Pharmtech Research.
- 2. M Bhavani, D Sireesha, M Akiful haque, S Harshini, Vasudha Bakshi, A Padmanabha rao. analytical method development and validation of Doxofylline and

Terbutalinesulphate by RP – HPLC method, International Journal of Pharma Research and Health Science.

- 3. Deepali Nanaware, Vidhya Bhusari, Sunil Dhaneshwar. Validated HPLC method foe simultaneous quantitation of Doxofylline and Terbutalinesulphate in bulk drug and formulation. Asian Journal of Pharmaceutical and Clinical Research.
- 4. Gananadhamu Samathula, Krishnaveni Yadiki, Shantikumar Saladi, Sreekant Gutala, K V Surendranath. Stability indicating RP – HPLC method for the simultaneous estimation of Doxofylline and Terbutaline sulphate in pharmaceutical formulations. Department of pharmaceutical analysis, National Institute of Pharmaceutical Education and Research.
- Ashu Mittal, Shikha Parmar, Development and validation of RP-HPLC for determination of Doxofylline in bulk drug and pharmaceutical dosage forms, Journal of Analytical Chemistry, 2010; ol-65(3): 293-297.
- B.Victoria Rani, C. Parthban, M. Sudhakar, Method development abnd validation for simultaneous estimation of Sertralineand Doxofylline in pharmaceutical dosage form by RP-HPLC, International Journal of Pharmaceutical sciences, 7: 465-468.
- Revathi R, Ethiraj T, Themozhi P, Saravanan VS, Ganesan V, HPLC method development for simultaneous analysis of Doxofylline and Montelukast sodium in combined form, Pharm Methods, Oct-Dec; 2(4): 223-228.
- Sonia M. Nappinnai, K. Manikandan, Simultaneous estimation of Doxofulline and Ambroxol in tablet dosage form by RP-HPLC, International Journal of pharmaceutical science and research, 2016; 7(9): 3721-3727.
- Nitish kumar, Durgadas Anghore, Ravindra K Rawal, Abhay pandey, RP-HPLC and UV method development for simultaneous estimation of Doxofylline, Montelukast and Levocetrizine in pharmaceutical dosage form. Analytical Chemistry letters, 2018; 8(2): 195-204.
- B. Subhandana, K Sushmita, Buchi N. Nalluri, RP-HPLC-PDA method for the analysis of Terbutaline sulphate in bulk dosage form and in dissolution samples, Journal of applied pharmaceutical sciences, 3(03): 126-132.
- 11. Porel A, Haty S, Kundu A, Stability indicating HPLC method for simultaneous determination of Terbutaline sulphate, Bromhexine and Guaifenesin, Indian Journal of Pharmaceutical sciences, 2011; 73(1): 46-56.
- 12. M. V, Vinod, I, Vasundhara, K. S. Krishnamurthy, RP-HPLC UV method development and validation for simultaneous determination of Terbutaline sulphate, Ambroxal

hydrochloride and Guaifenesin in pure and dosage form, Indian Drugs, 2001; 38(8): 428-432.

- 13. Jaiprakash N, Sangshetti, Gayatri Takate, Rana.Z Ahmed, Zahid Zaheer, Method development and validation of RP-HPLC method for simultaneous estimation of Terbutaline sulphate and Guaifenesin in bulk and dosage form, Journal of Chmical and Pharmaceutical research, 2017; 9(1): 100-107.
- 14. Sreenivasa Charan Archakam, New Stability indicating RP-HPLC method for the simultaneous estimation of Terbutaline Sulphate Bromhexine hydrochloride in tablet dosage form, international Journal of Research in pharmaceutical sciences, 2018; 9(3): 776-781.