



Identification and purity test of drotaverine HCl

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Abstract: Pain is an ill-defined, unpleasant sensation, usually evoked by an external or internal noxious stimulus. Pain may be acute or chronic, renal colic pain and labour pain is most common and chronic pain generally not controlled by Non Steroidal Anti-inflammatory Drugs (NSAIDs) and more potent drug needed to control pain drotaverine HCl is one of the antispasmodic drug acts by phosphodiesterase-IV inhibition to reduce the pain sensation. The purity and potency of drotaverine is a major factor to reduce the dosing frequency, toxicity and other related side effects. The potency of drotaverine HCl is found to be 98.8% and major peaks obtained in IR spectra at same frequencies as that of standard.

Key words: Phosphodiesterase-IV, Drotaverine HCl, Colic pain, Labour pain

Introduction

Pain is a warning signal, primarily protective in nature but causes discomfort and suffering, may even be unbearable and incapacitating, i.e. pain is an ill-defined, unpleasant sensation, usually evoked by an external or internal noxious stimulus (Tripathi, 2004). Excessive pain may produce other effects like sinking sensation, apprehension, sweating, nausea, palpitation, rise or fall in BP or tachypnoea, analgesics relieve pain as a symptoms without affecting its cause (Singh and Jain, 2004; Amin and El-Sheikh, 2007).

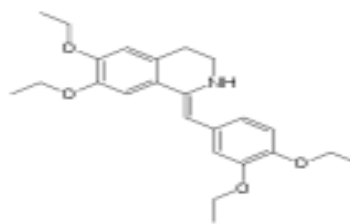
Pain caused by kidney stones (Renal colic pain) and labour pain is most common and chronic pain. Renal colic pain typically begins in the kidney area or below it and radiate through the flank until it reaches the bladder (Drach, 1998). Renal colic pain tend to remain constant whereas colic implies pain that is somewhat intermittent & often comes in the waves such as in biliary colic. Depending on the type and size of kidney stones moving through the urinal tract, the pain may be stronger in the renal or bladder or equally strong in both. Childbirth (Labour or parturition) is culmination of a women pregnancy or gestation period with birth of infant from uterus (Drach, 1998; Lennon *et al.*, 1993). Hormones and enzymes work together to produce ligamentous relaxation and widening of the pubis symphysis, mostly girdle pain occurs before birthing and is known as diastasis of the pubic symphysis, pain levels reported by labouring women vary widely which seem to be influenced by fear, anxiety levels and experience with prior childbirth (Lennon *et al.*, 1993; Morse and Resnik, 1991). Drotaverine HCl is an antispasmodic drug that suppress the pain associated with spasm caused by smooth muscle contraction, specially in tubular organs like stomach, intestine, ureter, urinary bladder, cholecystalgia, chronic cholecystitis, neck of uterus spasm during delivery (Kapui, 1998; Vargay, 1989).

Materials and Methods

Drotaverine HCl gift sample was provided by Aurochem Pharmaceuticals (I) Pvt Ltd. Mumbai -India, all other chemicals,

solvents and reagents were of the analytical grade available from local sources.

Description: Drotaverine HCl [(Z)-1-(3,4-diethoxybenzylidene)-6,7-diethoxy-1,2,3,4-tetrahydroisoquinoline]



Empirical formula- $C_{24}H_{31}NO_4$;

Molecular weight- 397.507 g mol⁻¹

Colour- Pale yellow colour crystalline powder

Taste- Bitter

Odour- Odourless

Solubility- Soluble in ethanol (96%), easily soluble in chloroform and moderately soluble in water.

Melting point- 210 °C

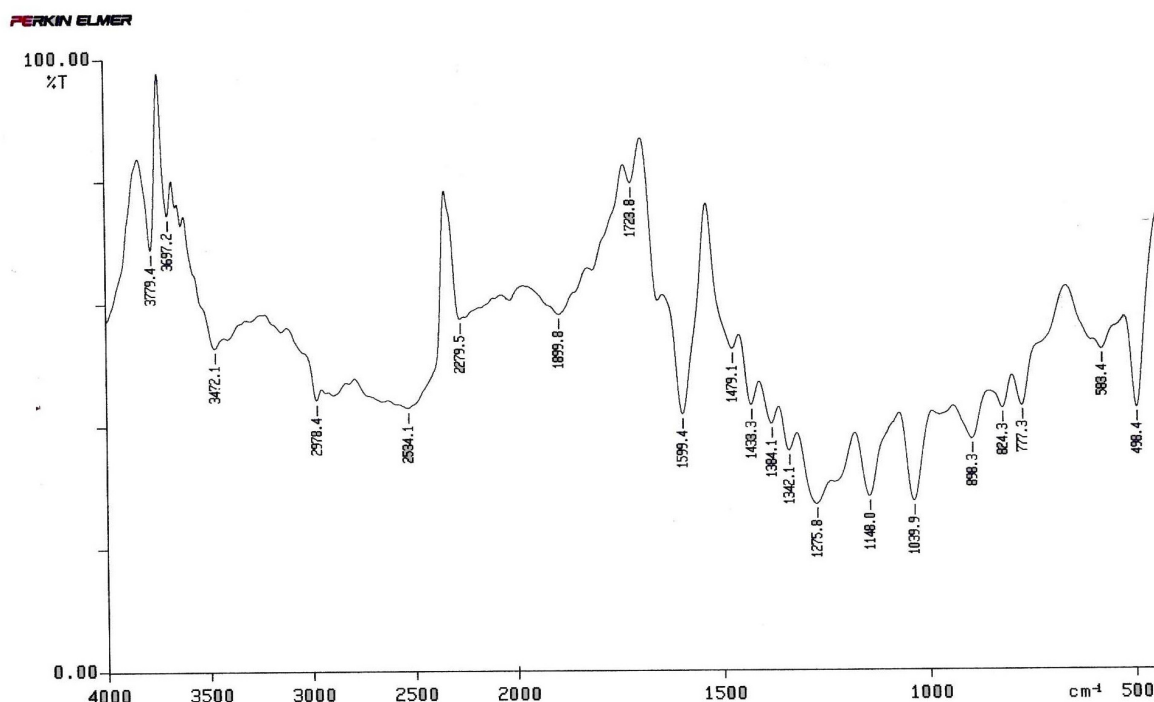
pH- 4.14

Identification:

By IR- The absorption spectrum of test sample is concordant with that of standard spectrum (Fig. 1).

By HPLC- The retention time of the major peak in the chromatogram obtained from the sample preparation matches with that of retention time of the main peak in the chromatogram obtained due to standard preparation (Lalla and Shah, 1993).

By spectrophotometer - Solution of drotaverine (0.02 mg ml⁻¹) were prepared in ethanol (96%) and serial dilution were prepared in a series of 10 ml volumetric flasks containing 1-10 mcg ml⁻¹ of drotaverine which is used for preparation of calibration curve of spectrophotometric method (Abdelltef and Ayad, 2007).



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Fig. 1: Infra red spectra of Drotaverine HCl

Results

Drotaverine HCl sample has melting point- 210°C and pH- 4.14 the major peaks obtained in IR spectra at same frequencies as that of standard and spectrophotometric evaluation gives 98.8% potency.

Discussion

Drotaverine HCl is a benzyloisoquinoline derivative, and is an analogue of papaverine (opium alkaloid) which is an antispasmodic drug acts by phosphodiesterase- IV inhibition (Kapui, 1998) to increase the intracellular level of cyclic adenosine monophosphate (cAMP) which causes relaxation of smooth muscle that suppress the pain associated with spasm caused by smooth muscle contraction, specially in tubular organs like stomach, intestine, ureter, urinary bladder, cholecystalgia, chronic cholecystitis, neck of uterus spasm during delivery and also used as a cerebral and coronary vasodilator in subarachnoid haemorrhage, coronary artery bypass surgery and microsurgery (Romics and Molnar, 2003; Kapui, 1998; Vergay, 1989; Ziyatdinova and Samigullin, 2007).

Drotaverine HCl sample passes the purity test and pure form of drug have greater efficacy to control the pain associated with ureter, urinary bladder, cholecystalgia, chronic cholecystitis.

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