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PHARMACEUTICAL SCIENCES

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METHOD OF SYNTHESIS OF THE ETOPROPAZINE

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Abstract: an experimental synthesis of Etopropazine substance was carried out in laboratory conditions so that to develop further standardized methods for studies on quality of the substance described and to obtain the pharmacopoeia standard sample in the amount required for developing the quantitative determination methods that would be alternative to the pharmacopoeial ones.

Key words: Ethopropazine, Prophenamine, Parsidol, Parsidan, Parkin, phenothiazine, etopropazine hydrochloride.

Prophenamine (INN; also known as etopropazine (BAN; trade names Parsidol, Parsidan, Parkin) is a phenothiazine derivative in which the hydrogen attached to nitrogen is replaced by a 2-(diethylamino)propyl group; is applied as an antiparkinsonian agent with anticholinergic, antihistamine and antiadrenergic effects. It is also used to relieve extrapyramidal syndrome caused by drugs such as other phenothiazine compounds, however, as well as other compounds with antimuscarinic properties, it has not value in tardive dyskinesia [1, p. 115; 2, p. 281-288].

Etopropazine, 10-(2-diethylaminopropyl)phenothiazine, was synthesized by alkylation of phenothiazine with 1-diethylamino-2-propyl chloride or bromide in the

presence of sodium amide according to the scheme shown in Figure 1 [3, p. 2-4; 4, p. 592-593].

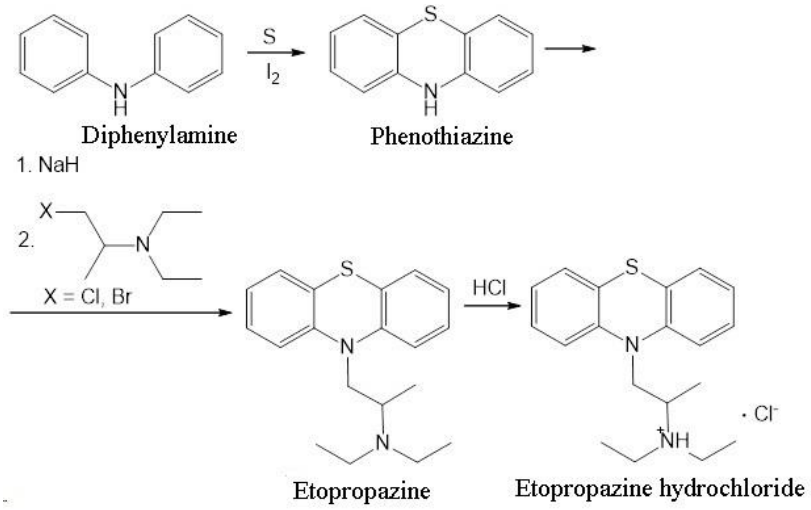

Fig. 1. Scheme of the etopropazine hydrochloride obtaining

The following substances were used as raw materials: phenothiazine, methyl iodide, 2-chloro-1-diethylaminopropane, magnesium, hydrogen chloride.

The production process was as follows: to a Grignard reagent prepared from 1 g of magnesium, 6.2 g of methyl iodide and 20 ml of dry ether, 6.2 g of phentiazine in 100 ml of warm dry benzene were added over 1 hour with stirring and under a hydrogen atmosphere. After 30 minutes boiling, a solution of 6.6 g of 2-chloro-1-diethylaminopropane in 10 ml of dry benzene was added to the boiling solution for 1 hour, and heating was continued for another 1.5 hours.

Then the reaction mixture was cooled and treated with an aqueous ammonium chloride solution, and chloroform was added to dissolve the oil at the interface between the benzene and aqueous layers. The chloroform-benzene extract was extracted with 2 M hydrochloric acid and the acidic extract was made basic at 5-10°C with 50% aqueous sodium hydroxide solution.

A mixture of N-(2'-diethylamino-2'-methylethyl)phenthiazine and N-(2'-diethylamino-1'-methylethyl)phenthiazine was obtained as a viscous oil of yellow color with a boiling temperature 202°-205°C / 2 mm.

This oil was treated in ethereal solution with hydrogen chloride to obtain a white solid which was fractionally crystallized from ethylene dichloride. The less soluble fraction, N-(2'-diethylamino-2'-methylethyl)phentiazine hydrochloride, forms

colorless rhombuses with melting temperature 223-225°C. The more soluble N-(2'-diethylamino-1'-methylethyl)phenthiazine hydrochloride was obtained as colorless prismatic needles, m.p. 166-168°C.

The physicochemical and spectral parameters comply with the international standards [5, p. 373]. The substance which have been obtained was standardized as an intralaboratory pharmacopoeial standard, so that to be applied further for alternative methods developing of quantitative determination described in the corresponding pharmacopoeia.

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