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TECHNICAL DATA SHEET

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93519-TETRACAINE HYDROCHLORIDE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation.

Name: Tetracaine hydrochloride

Bulk code: 93519

1.2 Synonyms

Tetracaini hydrochloridum; Butethanol; Amethocaine hydrochloride;

Butylaminobenzoyldimethylaminoethanol hydrochloride; Dimethylaminoethanol p-

Aminobenzoylbutane hydrochloride; Pantocaine hydrochloride; Tetracaine chloride;

Decycaine; Tetracaine hydrochloride; Pantocaine.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White.

Odour: Odourless

Slightly hygroscopic.

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_{15}H_{24}N_2O_2 \cdot HCl$

CAS: 136-47-0

Molecular weight: 300,8 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications in analysis bulletin.

Solubility: Soluble in 7.5 p. water, 40 p. alcohol and 30 p. chloroform; soluble in glycerine. Practically insoluble in acetone, benzene t ether.

Melting point: Approximately 148°C. There are two other crystalline forms, which melt at about 134°C and 139°C respectively; the mixtures melt within the range of 134–147°C.

5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT.

93519-TETRACAINE HYDROCHLORIDE

Tetracaine is a potent long-acting ester-class local anaesthetic, which acts by stabilising the neuronal membrane, preventing the onset and spread of nerve impulse, and is used in anaesthesia. Due to its systemic toxicity, it is not used for other local anaesthetic techniques.

The salt hydrochloride is generally used in solutions and creams, while the base is used in ointments.

6. DOSAGE

Topical use:

- In the form of 1% creams and 0.5% ointments, which can be used in painful anal and rectal conditions.
- In the form of a 0.25–0.5% solution for superficial anaesthesia of the mucous membranes of the nose and throat.
- In the form of sprays, tablets and pills to dissolve slowly with saliva, administered topically in the mouth.

7. REMARKS**STORAGE:**

Store at room temperature ($25\pm 2^{\circ}\text{C}$), in a cool, dry place, away from sunlight, in a tightly closed container.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).