

Aquatabs 8680mg Technical Data Sheet

1. Name of the Product
Aquatabs 8680mg.

2. Product Type
Aquatabs 8680mg are effervescent tablets for the disinfection of water for human consumption.
Dosage Form: White/off white, flat bevelled edged, effervescent tablets.
Strength/Potency: 8.68g NaDCC (Sodium Dichloroisocyanurate/Troclosene Sodium) per tablet.

3. Dosage/Usage Instructions
One Aquatabs 8680mg tablet will disinfect 1,000-1,250 litres of clear water at a dosage of 4-5mg/l available chlorine. Leave for 30 minutes before drinking.

4. Qualitative & Quantitative Composition

Active Ingredient:

Active Substance: Troclosene Sodium (CAS No. 2893 - 78 - 9).

Excipients:

Each Aquatabs 8680mg tablet contains the following excipients:

Adipic acid

Sodium bicarbonate

Sodium sulphate

5. Aquatabs 8680mg Physiochemical Properties

Physical and Chemical Properties:

Appearance	: White/off white, flat bevelled edged, effervescent tablet
Odour	: Slight chlorine odour
Average weight	: 17.36gm
Hardness	: $\geq 107N$
Disintegration	: ≤ 9 minutes (in 1000mls water)
NaDCC content	: 7.81 – 9.55gm NaDCC per tablet (target 8.68gm)

6. Packaging
Aquatabs 8680mg tablets are packaged into polypropylene/polyethylene tubs with 60 tablets per tub. Six tubs are packaged per each cardboard outer carton.
7. Shelf-life
Aquatabs 8680mg when tub-packed have a shelf life of 3 years.

8. Certificates

To assure that Aquatabs 8680mg are manufactured to appropriate Quality Control standards for a product which is ultimately consumed, Medentech manufactures to standards of Good Manufacturing Practice (GMP) and is also an ISO9001 & ISO13485 Quality-Assured Company.

Inspections are undertaken on a regular basis by the Health Products Regulatory Authority (HPRA), which is the responsible Authority in Ireland, for GMP conformance to European Standards. This ensures that all appropriate testing is undertaken to assure that the product meets specification, that the processes have been validated to produce a consistent product, that stability studies have been undertaken to International standards, that materials are selected and tested to meet specified standards and specifications etc.

Inspections to meet ISO9001 & ISO13485 requirements are undertaken biannually by NSAI (National Standards Authority of Ireland).

Both the sodium dichloroisocyanurate (NaDCC) used in Aquatabs and the finished product (Aquatabs) are certified by NSF International to the NSF/ANSI Standard 60. NSF International conducts unannounced annual audits also for continued conformance to the NSF/ANSI Standard 60 requirements.