

Specification for Chlorine Tablets and Granules

1. Product Description

Name	Description/Scope
Chlorine Tablets and Granules	Chlorine releasing tablets and granules for disinfecting within a healthcare environment and includes but shall not be limited to; <ul style="list-style-type: none">• Chlorine releasing tablets;• Chlorine releasing granules; and• Diluters

2. Standards/ Directives/ Legislative requirements

Base raw material active ingredient

NaDCC (Trosclosene Sodium) (CAS:2893-79-9)

NaDCC (Sodium Dichloroisocyanurate Dihydrate) (CAS:51580-86-0)

Both must conform to: ECHA Article 95 list BPR, Regulation (EU) 528/ 2012

Product Manufacturing Environment and Standards

Manufacturing facilities and production environments for the tablets and granules must be verified (e.g. having a Medicine's Licence or a successful external audit) as conforming and operating to "Pharmaceutical Good Manufacturing Practice" (GMP) standard

Tablets Specifications

With the exception of product "Chlorine Releasing Tablets 4.5g NaDCC" all tablets must contain NaDCC (Trosclosene Sodium) as the active ingredient.

Product "Chlorine Releasing Tablets 4.5g NaDCC" must contain NaDCC (Sodium Dichloroisocyanurate Dihydrate) as the active ingredient.

All specific tablet specifications are to be listed as:

- Total gross weight,
- Weight of NaDCC contained in the tablet.

All tablets must be supplied in a re-sealable container.

The weight stated on the container must be the gross weight of the Troclosen Sodium or Sodium Dichloroisocyanurate Dihydrate, as appropriate.

Granules Specifications

Product "Chlorine Releasing Granules" must contain NaDCC (Troclosen Sodium) as the active ingredient.

All specific granules specifications are to be listed as:

- Total gross weight of granules,
- % of NaDCC within granules.

All granules must be supplied in a re-sealable container.

The weight stated on the container must be the gross weight of the granules.

STANDARD / CERTIFICATION
<i>NaDCC (Troclosen Sodium) absorbent must conform to;</i> ECHA article 95 list BPR, Regulation (EU) 528/2012)