**NUMBER 5255-3** (Supersedes 5255-2)

# Aqualon™ CMC BET sodium carboxymethyl cellulose

Aqualon CMC BET sodium carboxymethyl celluloses are high-purity grades of the polymer produced and tested to meet low levels of bioburden and endotoxins.

## Functionality

Excellent suspending agent and viscosity modifier
Easily dispersed in water
Compatible with most active ingredients

## Available in the following grades

- Aqualon CMC 7MF PH BET sodium carboxymethyl cellulose
- Aqualon CMC 7LF PH BET sodium carboxymethyl cellulose
- Aqualon CMC 7L2P BET sodium carboxymethyl cellulose

## Bioburden and endotoxin limits

Aqualon CMC BET sodium carboxymethyl cellulose is tested to meet the following limits:

| Specification | Limits | Test Method |
|---|---|---|
| TAMC | <100 CFU/g | USP<61>, <62>, EP 2.6.12, 2.6.13 |
| TYMC | <100 CFU/g | USP<61>, <62>, EP 2.6.12, 2.6.13 |
| Salmonella | Absent/10g | USP<61>, <62>, EP 2.6.12, 2.6.13 |
| E. coli | Absent/1g | USP<61>, <62>, EP 2.6.12, 2.6.13 |
| Endotoxin | <10 EU/mg | USP<85>, EP 2.6.14 |

## Packaging

Each package of Aqualon CMC BET contains 10 kg of powder in a single polyethylene (PE) bag of 4 mil thickness, twisted closed and secured with a zip tie. The PE bag is inserted into an 8-gallon HDPE Euro Open Head Drum with a rubber gasket inserted into a galvanized steel locking ring cover. A safety seal is installed to ensure package integrity. The drum complies with FDA regulations for food and drugs.

## Regulatory/Classifications

All grades conform to the USP–NF monograph for sodium carboxymethylcellulose and are produced to meet USP <1078> and *The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2017* as published under the auspices of the International Pharmaceutical Excipient Council (IPEC, 2017). Other regulatory information is available on request.

## Product Safety

Read and understand the Material Safety Data Sheet before using this product. Ashland does not represent that these product grades, as provided by Ashland, are sterile or meet parenteral drug product requirements. It is the purchaser's responsibility to determine the suitability of each component of its own manufactured product for that product's intended use or uses.