

The logo for A&C, consisting of the letters 'A' and 'C' in a bold, blue, sans-serif font, with an ampersand between them.

**TRANSPARENT PRACTICES**  
**PHARMA-GRADE QUALITY**  
**FLEXIBLE SOLUTIONS**

CUSTOM  
FLEXIBLE  
SOLUTIONS  
TRANSPARENT  
QUALITY  
PHARMA-GRADE

## **QUALITY, PURITY, SAFETY AND SUITABILITY FOR PHARMACEUTICAL MANUFACTURING**

### **ACE: A&C's EXCIPIENT PROGRAM**

Globalization of the pharmaceutical industry and the harmonization of international regulatory requirements have placed increasing demands on Pharmaceutical Manufacturers. A&C American Chemicals Ltd. has implemented the new *A&C Excipient Program* called ACE. All the chemicals within ACE are specially prepared for use as components in drug product manufacturing.

### **cGMP**

The excipients in the ACE program are manufactured with adherence to the GMP and Quality Control principles of:

<b>PQG</b>	Institute of Quality Assurance's Pharmaceutical Quality Group;
<b>IPEC</b>	International Pharmaceutical Excipients Council;
<b>WHO</b>	World Health Organization's GMP Guidelines for Excipients;
<b>ISO</b>	International Organization for Standardization.

GMP processes and documentation control begin with incoming inspection, identity and in-house testing. These records become an integral part of the documentation chain of traceability that is maintained until the final product reaches the customer. Product sampling, packaging and production take place in controlled environments with laminar flow HEPA-filtered air.

A&C personnel are competent, GMP aware and GMP trained.

### **CHANGE CONTROL**

Customers are notified of significant changes and pre-approval can be given.

Change controls govern:

- » raw materials
- » packaging and sources-material specifications
- » test methods
- » manufacturing and analytical equipment
- » production processes
- » manufacturing and packaging sites

### **CUSTOMER FOCUS IS PARAMOUNT**

A&C engages the customer in determining the excipient quality, labelling, specifications and delivery requirements before supply commences. Skilled A&C staff support the customer's documentation requirements by assembling all Quality documents including GMP certificates, certificates of origin, BSE/TSE and residual solvents statements and others into a standard dossier assuring completeness.

TO ENSURE THE EXCIPIENTS THAT YOU REQUIRE ARE PART OF THE ACE PROGRAM, CONTACT US.

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