

**CHEMICAL PRODUCT:**

*Four Alpha Digits*

Example:

TRIS = Tromethamine (Tris)

**PACKAGING  
CONFIGURATION:**

*Two Numerical Digits*

Example: -25 = 25 kg

TRIS-3220-01

**COMPLIANCE LEVEL:**

*One Numerical Digit*

- 2 = Active Grade
- 3 = Excipient Grade
- 4 = Pharma GMP Grade
- 5 = Ultra non-GMP Grade
- 7 = Customer Specific
- 8 = Development Material
- 9 = Research Material

**PHASE:**

*One Numerical Digit*

- 1 = Liquid
- 2 = Solid
- 3 = Blend Batch

**VARIANT OF PRODUCT  
GRADE SPECS OR  
OTHER SPECIAL  
REQUIREMENTS:**

*Two Numerical Digits*

01-99 = Quality Specifications  
Example: 50 = Low Bioburden,  
Low Endotoxin (LBLE)

The first four digits are alpha digits which indicate the **Chemical Product** manufactured, where TRIS represents Tris (Tromethamine). The fifth digit is numeric which represents the **Compliance Level** of the product (\*see definitions below). The sixth digit is also numeric which indicates the **Phase** of the finished good product. The seventh and eight numeric digits reflect the **Variant of Product Grade Specifications or Special Requirements**. The ninth and tenth digits are specific to the **Packaging Configuration**.

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## **COMPLIANCE LEVEL DEFINITIONS**

- 2** = GMP API Grade compliance level according to ICH-Q7 guidelines and USFDA requirements – referred to by BSI as “Active Grade”
- 3** = GMP Excipient Grade compliance level according to ICH-Q7 guidelines – referred to by BSI as “Excipient Grade”
- 4** = GMP Pharmaceutical Process Chemical compliance level according to IPEC guidelines – referred to by BSI as “Pharma GMP Grade”
- 5** = non-GMP Reagent Grade compliance level, various compendial and non-compendial guidelines – referred to by BSI as “Ultra non-GMP Grade”
- 7** = Contract manufactured material meeting specific customer demands, generally but not always GMP – referred to by BSI as “Customer Specific”
- 8** = Developmental material, made under GMP but prior to validation of the final manufacturing process for that specific product – referred to by BSI as “Development Material”
- 9** = Research material, made in our development labs and prior to scale development work – referred to by BSI as “Research Material”