

# Chem-Impex International, Inc.

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Manufacturing site:

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## Certificate of Analysis

<b>Catalogue Number</b>	32484
<b>Product</b>	<b>Irinotecan hydrochloride trihydrate</b>
<b>Lot Number</b>	002942-190902 CPT-11 trihydrate
<b>CAS Number</b>	136572-09-3
<b>Molecular Formula</b>	C <sub>33</sub> H <sub>38</sub> N <sub>4</sub> O <sub>6</sub> •HCl•3H <sub>2</sub> O
<b>Molecular Weight</b>	677.19

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<b>Appearance</b>	Yellowish or almost yellow crystalline powder
<b>Solubility</b>	Slightly soluble in water, ethanol and chloroform, practically insoluble in acetone.
<b>Odor</b>	Odorless
<b>Heavy Metals</b>	< 10 ppm
<b>Water Content (Karl Fisher)</b>	8.2%
<b>Mould and Yeast</b>	< 10 cfu/g
<b>Infrared Spectrum</b>	Conforms to structure
<b>Residual Solvents</b>	Ethanol : Not detected Dichloromethane : Not detected Acetone : Not detected
<b>Microbial Count</b>	< 100 cfu/g (TAMC)
<b>Related Substances</b>	Limit of Irinotecan Hydrochloride Enantiomer : 0.06% Irinotecan related compound A : 0.02% Irinotecan related compound B : 0.05% Irinotecan related compound C, D, E, F, G : 0.0% Any unspecified impurity : 0.02% Total impurities : 0.21%
<b>Residue On Ignition</b>	0.06%
<b>Purity by HPLC</b>	99.7% (Anhydrous basis)
<b>Grade</b>	USP
<b>Storage</b>	Store at 2 - 8 °C

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**Additional Information**

Identification for Chloride : Positive reaction

**Remarks**

See material safety data sheet for additional information

For laboratory use only

**The foregoing is a copy of the Certificate of Analysis as provided by our supplier**



**Bala Kumar**  
**Quality Control Manager**