

NQCL-WRS - I 27-1

I 27-1



**Quality control department
Working standard Certificate of Analysis**

PRODUCT NAME	IRINOTECAN	STANDARDIZED DATE	14/10/2016
BATCH NUMBER	4000P16F2003	W.S. NO.	WS-027-16
W.S. RETEST DATE	Oct 2016	W.S. USE BEFORE	13/09/2017
MANUFACTURED BY	VMG Pharmaceuticals Pvt. Ltd.	PRIMARY LOT. NO./TRACEABILITY	R022P0/ USP

TESTS	SPECIFICATIONS	RESULTS
Description	A pale yellow to yellow crystalline powder.	A pale yellow crystalline powder.
Solubility	Soluble in water	Complies
Identification		
A) By IR	Infrared spectrum of the sample should match with that of the standard spectrum.	Infrared spectrum of the sample should match with that of the standard spectrum.
B) By HPLC	In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution.	In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution.
C) Chlorides	A white curdy precipitate is formed.	A white curdy precipitate is formed.
Residue on Ignition	NMT 0.1 %	0.08%
Heavy Metals	NMT 10 ppm	8 ppm
Limit of Irinotecan Hydrochloride enantiomer	R-enantiomer 0.15%	Not Detected
Organic Impurities		
Irinotecan Related	NMT 0.15 %	BDL*
Compound B		
Irinoteca Related	NMT 0.10%	BDL*
Compound C		
Any unspecified impurity	NMT 0.10%	0.05
Total Impurities	NMT 0.5%	0.07
Microbial Enumeration Tests:		
a) Total aerobic microbial count	NMT 1000 cfu per gram	610 cfu per gram
b) Total yeast and mold count	NMT 100 cfu per gram	12 cfu per gram
Water (% W/W By KF)	7.0 % to 9.0 %	7.19 % w/w
Assay By HPLC (As Irinotecan On anhydrous basis)	Not less than 98% and Not More than 102.0% calculated on anhydrous basis	99.8 % (Irinotecan OAB)

BDL* Below Detection Limit

REMARKS: The above working standard complies with USP specifications.

Analyzed By: Deepshikha
Designation: QC Chemist
Date: 14/10/2016



Approved By: Nishu Panigrahi
Designation: QA Manager
Date: 14/10/2016

VMG Pharmaceuticals Pvt. Ltd.