

WRS  
M36-1

# ACME FORMULATION PVT. LTD.

Ropar Road, Nalagarh, Distt. Solan (H.P.)

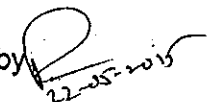
## WORKING STANDARD CERTIFICATE OF ANALYSIS

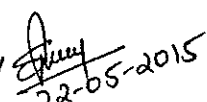
Product	Mifepristone IH	Prepared on	22/05/2015
Working Standard No.	AF/HQ/WS/005/15-16	Effective Date	22/05/2015
Batch No.	XI-140718	Valid Up to	21/05/2016

### RESULT OF ANALYSIS

Sr. No.	Test performed	Specification	Observation
1.	Description	Light yellow to yellow crystalline powder.	Light yellow crystalline powder.
2.	Identification		
	A) By IR	The infrared absorption spectrum should be concordant with the spectrum of Mifepristone reference standard.	Complies.
	B) By HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation obtained as directed in the assay.	Complies.
3.	LOD/ Water	Not more than 0.5% w/w	0.28% w/w
4.	Related Substances (By HPLC)		
	Single Impurity	Not more than 0.5%	0.184%
	Total Impurities	Not more than 1.0%	0.234%
5.	Assay (as such basis)		99.26 % w/w
	Assay (dried basis)	Not less than 99.0 % and not more than 102.0 % w/w.	99.54 %w/w

Remarks: The above material is qualified for working standard.

Prepared by   
Date 22-05-2015

Checked by   
Date 22-05-2015

