

UNIMED
 TECHNOLOGIES LTD.

CERTIFICATE OF ANALYSIS
WORKING STANDARD

Material	Nepafenac (Micronized & Sterile)	A.R. No.	431RIH0027		
Evaluated against	RS16057	Lot No.	NFC-ST3		
Mfg. Date for Material	07/11/2014	Exp. date for Material	07/11/2019		
Reference	Spec no. BD0301O0DA ,Rev-3.0	WS No.	WS17005		
Effective Date	02/02/2017	Valid up to	01/02/2018		
Quantity prepared	16.9 gm	No. of bottle Prepared	24		
Intended Use	For Qualitative and Quantitative analysis	Direction for Use	As such		
TEST	RESULTS	SPECIFICATION			
➤ Description	Yellow powder	Yellow powder.			
➤ Identification By IR	Meets the requirements	IR absorption spectrum of the sample as potassium bromide dispersion is concordant with similarly recorded spectrum of Nepafenac RS.			
➤ Identification By HPLC	Meets the requirements	Retention time of major peak in the chromatogram of test solution corresponds to the retention time of major peak in the chromatogram of identification solution as obtained in the test for related substances.			
➤ Loss on drying	0.25%	Not more than 0.5 %			
➤ Assay by titrimetry	99.2 % as is basis 99.4 % ODB	Between 99.0 % and 101.0 on dried basis.			
➤ Related substances (by HPLC)	Known Impurity Impurity I : BQL Impurity-II : BQL Unknown impurities- Any unspecified impurity : 0.049 % Total impurities : 0.092 %	Not more than 0.15 % Not more than 0.15 % Not more than 0.10 % Not more than 0.50 %			
Remarks : The substance complies against the standard and qualifies for usage as a working standard.					
Storage : Preserve in tight, light resistant containers at temperature below 25° C					
Template No.	RMT/0063/2017, Hard book No. QC/RG/K16/699 Page No. 96 , Hard book No. QC/RG/K17/179 Page No.20				
Analyzed by / Date	Checked by / Date	Approved by / Date			

F/QC-S-011/012/00

