

M7-3

MA-3



SYNOKEM PHARMACEUTICALS LIMITED,  
PLOT NO -35,36; SEC-6(A) IIE,SIDCUL,RANIPUR,BHEL,HARIDWAR-249403

### CERTIFICATE OF ANALYSIS

Name of material	MISOPROSTOL BP AS MISOPROSTOL 1 % HPMC DISPERSION
WRS No.	QC/WS/G/M01/18
Batch No.	B18739
Q.C. Reference No.	GSPR-0406/18-19
Manufacturing Date	02/2018
Expiry Date	02/2023
Manufactured by	PIRAMAL HEALTHCARE
Use before Date	29/07/2019
Effective Date	30/07/2018

Test Carried out	Result	Specification
Description	A off white powder.	A off white powder.
Identification (By HPLC)	The retention time of principal peak in the chromatogram of test solution corresponds to that in the chromatogram of the standard solution	The retention time of principal peak in the chromatogram of test solution corresponds to that in the chromatogram of the standard solution
Water	1.32% w/w	NMT 2.0 %w/w
Assay	0.989% ( as such basis ) 1.002% ( on anhydrous basis )	0.95 – 1.05% (On anhydrous basis.)
RSD.(Relative standard deviation)	0.34%	NMT 1.00%(for multiple Assay)

Remarks: The Assay is the average value of multiple analysis.



Prepared by:

Date

*Signature*  
30/07/18

Checked by:

Date

*Signature*  
30/07/18