



Sharon
BIO-MEDICINE LTD.

SHARON BIO-MEDICINE LTD., DEHRADUN
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product	Famotidina 40 mg			Page 1 of 2
Label claim :	Each film coated tablet contains : Famotidine USP : 40 mg Excipients : qs			
Batch No.	AF6018A	A. R. No.	FPI60956	
Pack Style	36 x 50 x 10's	Release Date	08/10/16	
Batch Size	12,50,000 tabs	Ref. Spec. No.	FPS/AFK	
Mfg. Date	09/2016	Exp. Date	09/2018	

Sr. No.	Test	Specification	Observation / Result
1.	Description	White coloured round shaped, biconvex, coated tablet with plain surface on both side.	White coloured round shaped, biconvex, coated tablet with plain surface on both side.
2.	Identification A) By TLC B) By HPLC	A) The principle spot from the test solution corresponds in appearance and R_f value to that of the standard solution. B) The retention time of the major peak in the sample solution corresponds to that in the standard solution, as obtained in the assay.	Complies Complies
3.	Average weight	205.00 mg $\pm$ 2%	204.09 mg
4.	Uniformity of weight	$\pm$ 7.5 % of average weight of a tablet	-1.6% to +1.5%
5.	Dissolution (By UV)	Not less than 80% (Q) of the labeled amount of Famotidine ($C_8H_{15}N_7O_2S_3$) is dissolve in 30 minutes.	98%, 99%, 99%, 100%, 98%, 99% Average : 99%
6.	Related substances (By HPLC) A) Famotidine Sulfoxide ^a B) Famotidine Propionic Acid (Famotidine related Compound F) ^b C) Famotidine Sulfamoyl Propanamide (Famotidine related Compound C) ^c D) Famotidine Propanamide (Famotidine related Compound D) ^d E) Total impurity	A) Not more than 1.0 % B) Not more than 0.5 % C) Not more than 0.5% D) Not more than 0.5% E) Not more than 1.5%	A) Not detected B) Not detected C) Not detected D) 0.05% E) 0.07%
7.	Content Uniformity	Complies USP requirements (The acceptance value (AV) of 10 dosage unit $\leq$ 15)	3.0

Prepared By:	Reviewed By:	Approved By:
Name: Rohit Pandey	Name: Swati Kunal	Name: Bipin Singh
Designation: Sr. Executive	Designation: Sr. Executive	Designation: Sr. Manager
Sign/Date: 08/10/16	Sign/Date: 08/10/16	Sign/Date: 08/10/16

Format No. 202.001.03/03

FAMOTIDINA 40 MG X 500 COMP (BE) PO 4414 LC NO: 82707900001909 Dated 06.10.2016

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08/10/16



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CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product	Famotidina 40 mg			Page 2 of 2
Label claim :	Each film coated tablet contains : Famotidine USP : 40 mg Excipients : qs			
Batch No.	AF6018A	A. R. No.	FP160956	
Pack Style	36 x 50 x 10's	Release Date	08/10/16	
Batch Size	12,50,000 tabs	Ref. Spec. No.	FPS/AFK	
Mfg. Date	09/2016	Exp. Date	09/2018	

8.	Assay : (By HPLC) Each film coated tablet contain: Famotidine USP 40 mg	36mg to 44mg (90% to 110% of the labeled amount of Famotidine ($C_8H_{15}N_7O_2S_3$)).	39.6 mg/tab 98.9%
Remarks: The above sample Complies /Does not comply with respect to above specification.			
Storage: Preserve in well closed, light-resistant containers. Store at controlled room temperature.			

Prepared By:	Reviewed By:	Approved By:
Name: Rohit Pandey	Name: Shweta Kumar	Name: Bipin Singh
Designation: Sr. Executive	Designation: Sr. Executive	Designation: Sr. Manager
Sign/Date: 08/10/16	Sign/Date: 08/10/16	Sign/Date: 08/10/16

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