WRS A53-2



BAFNA PHARMACEUTICALS LIMITED 147,MADHAVARAM REDHILLS HIGH ROAD,GRANTLYON VILLAGE, VADAKARAI POST,CHENNAI-52

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product : S-Amlodipine Besilate (Working Standard) : Bafna Pharmaceuticals Ltd Manufacturer API Batch No. : MK30314042 Exp Date : JUNE 2019 : JULY 2014 Mfg Date Date of Report : 02.10.2015 : 200mg Quantity : WS/15/S-AMLO/02 W.S. No A.R.No : BRD151021 Page NO : 1 of 1 Valid upto : Sep - 2016

Compared Against

| Name | : S-Amlodipine Besilate CRS | Supplier | : Praveen Laboratories Pvt Ltd., |
|------|-----------------------------|----------|----------------------------------|
| | | Assay | : 99.0 %w/w |

| S.No. | TEST | RESULTS | LIMITS |
|-------|---|--|--|
| 1. | Description | Pale yellow powder. | A White to pale yellow powder. |
| 2. | Solubility | Freely soluble in methanol, practically insoluble in water. | Freely soluble in methanol, practically insoluble in water. |
| 3. | Identification: | | |
| | By IR | IR spectrum of the sample should be concordant with IR spectrum of S-Amlodipine Besilate standard. | IR spectrum of the sample should be concordant with IR spectrum of S-Amlodipine Besilate standard. |
| 4. | Water content | 6.0%w/w | Not more than 8.0 %w/w |
| 5. | Assay (By HPLC) (On anhydrous basis) | 99.0%w/w | Between 98.0% to 102.0%w/w as C ₂₆ H ₃₁ O ₈ N ₂ ClS |

Remarks: The above sample is tested traceable to 'S-Amlodipine CRS / batch No: SL-017-033' reference standard from SimSon Pharma ltd., and can be used as working standard.

CHECKED BY
MANAGER – Q.C
(N.R RAVICHANDRAN)

