



Manufacturers & Exporters of Pharmaceuticals
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**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

(Under Drugs & Cosmetics Act 1940 & Rules made there-under)

| | | | |
|----------------------------|-------------------------------------|---------------------------|-------------|
| Product Name : | Delgra 100 mg Chewable | | |
| Generic Name : | Sildenafil Citrate Chewable Tablets | | |
| Mfg. Lic. No. : | 10/UA/2004 | | |
| Batch No. : | QRAP02 | A.R. No. : | F2012120708 |
| Mfg. Date : | Nov. 2012 | Pack Size : | 1X10 TAB |
| Exp. Date : | Oct. 2014 | Pack Type : | Blister |
| Batch Size : | 100000 TAB | Sampled On : | 07/12/12 |
| Product Code : | 40008980 | Sample Qty.: | 80 TAB |
| Specification No. : | STS/FP/40008980-00 | Sampled By : | ARUN |
| Ref. STP No. : | STP/FP/40008980-00 | Analyzed By : | ROBINDRA |
| Manufactured For : | Delta Enterprises | Date of Analysis : | 07/12/12 |
| Manufactured By : | Akums Drugs (Plant-1) | Completion Date : | 11/12/12 |

| S.No. | TEST | ACCEPTANCE CRITERIA | RESULTS |
|-------|--|---|---|
| 1 | Description | White, diamond shape, biconvex & '100' engraved on one side uncoated chewable tablet. 10 tablets packed in a blister of clear PVC film & printed aluminum foil. | White, diamond shape, biconvex & "100" engraved on one side uncoated chewable tablet. 10 tablets packed in a blister of clear PVC film & printed aluminum foil. |
| 2 | Identification | In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution . | Complies |
| 3 | Dimension | As below | As below |
| 3.a | Length | 14.4 mm \pm 0.2 mm | 14.47 mm |
| 3.b | Width | 10.4 mm \pm 0.2 mm | 10.33 mm |
| 3.c | Thickness | 4.9 mm \pm 0.3 mm | 4.79 mm |
| 4 | Average weight | 481.0 mg \pm 5.0% | 480.30 mg |
| 5 | Uniformity of weight | Within \pm 5.0 % of Average weight | -2.4% to +2.2% |
| 6 | Hardness | Not less than 3.5 kg/cm ² | 4.60 kg/cm ² |
| 7 | Friability | Not more than 1.0 % w/w | 0.01 % w/w |
| 8 | Assay - Each Chewable tablet contains: | Shelf Life Limit | Release Limit |
| | | | Found/Tab. Stated/Tab. |



Prepared By *[Signature]*
(Sign & Date) 11/12/12

Checked By *[Signature]*
QC Executive
(Sign & Date) 11/12/12

Approved By *[Signature]*
Head QC
(Sign & Date) 11/12/12