



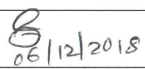
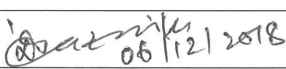
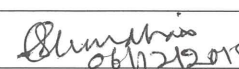
Natco Pharma Limited

Regd. Off : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel : +91 40 23547532, Fax : +91 40 23548243

Email: info@natcopharma.co.in
CERTIFICATE OF ANALYSIS

| | |
|--|---------------------------|
| Product Name: Ledikast | B.No. : 1901059 |
| Generic Name : Ledipasvir and Sofosbuvir Tablets | Product Code : GSL42AZ |
| Batch size: 108318 Tablets | Sampling Date: 04/12/2018 |
| Qty. Sampled: 01 Container | Mfg. Date: 11/2018 |
| Analysis Date: 04/12/2018 | Exp. Date: 10/2020 |
| Reporting Date: 06/12/2018 | A.R. No.: FP/AR/374/18 |

| S.No | TEST | SPECIFICATION | RESULT |
|------|---|---|--|
| 1. | Description | Green colored, oval shaped, film-coated tablets debossed with 'SL' on one side and plain on other side. | Green colored, oval shaped, film-coated tablets debossed with 'SL' on one side and plain on other side |
| 2. | Identification a) By HPLC b) By UV | <p>The retention time of the major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the Assay.</p> <p>The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.</p> | <p>The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay.</p> <p>The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths.</p> |
| 3. | Uniformity of dosage units (By content uniformity) | The acceptance value of the first 10 dosage units is less than or equal to L1 (L1 is 15.0 and L2 is 25.0) | 4.57 (Sofosbuvir) 5.31 (Ledipasvir) |

| | PREPARED BY | CHECKED BY | APPROVED BY |
|-------------|---|--|---|
| Sign |  |  |  |
| Name | Jayanta Sarma | Dipankar Hazenke | Sangay S. Chandra |
| Designation | Asst. officer | Executive | Sr manager |

Format No.: QCS/004/F04-02

Page No: 1 of 3



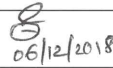
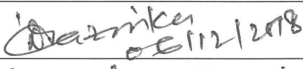
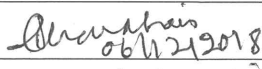
Natco Pharma Limited

Regd. Off : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel : +91 40 23547532, Fax : +91 40 23548243

Email: info@natcopharma.co.in
CERTIFICATE OF ANALYSIS

| | |
|--|----------------------------|
| Product Name: Ledikast | B.No. : 1901059 |
| Generic Name : Ledipasvir and Sofosbuvir Tablets | Product Code : GSL42AZ |
| Batch size: 108318 Tablets | Sampling Date: 04/12/2018 |
| Qty. Sampled: 01 Container | Mfg. Date: 11/2018 |
| Sampled by: Bikumani | Analysis Date: 04/12/2018 |
| | Exp. Date: 10/2020 |
| | Reporting Date: 06/12/2018 |
| | A.R. No.: FP/AR/374/18 |

| S.No | TEST | SPECIFICATION | RESULT |
|------|---|---|---|
| 4. | Average weight per tablet | 1030.0 mg \pm 5.0 % | 1032.64 mg |
| 5. | Water content (by KF) | Not more than 5.0% w/w | 2.74 %w/w |
| 6. | Dissolution (By HPLC) | Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45 minutes. | Minimum : 96.5 % Maximum : 102.3 % Average : 98.3 % |
| | Dissolution (By HPLC) | Not less than 80% (Q) of the labeled amount of Ledipasvir is dissolved in 45 minutes. | Minimum : 95.2 % Maximum : 99.5 % Average : 96.8 % |
| 7. | Assay (By HPLC) Each film coated tablet contains Ledipasvir 90 mg | Not less than 95.0% and not more than 105.0% of the labeled amount of Ledipasvir. | 100.4 % |
| | Sofosbuvir 400 mg | Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir. | 99.2 % |

| | PREPARED BY | CHECKED BY | APPROVED BY |
|-------------|---|--|---|
| Sign |  06/12/2018 |  06/12/2018 |  06/12/2018 |
| Name | Jayanta Sarma | Dipankar Hazarika | Sangram S. Chandra |
| Designation | Asst. Officer | Executive | Sr manager-ac |

Format No.: QCS/004/F04-02

Page No: 2 of 3



Natco Pharma Limited

Regd. Off : 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel : +91 40 23547532, Fax : +91 40 23548243

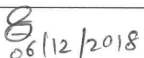
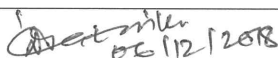
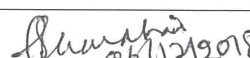
Email: info@natcopharma.co.in
CERTIFICATE OF ANALYSIS

| | |
|--|---------------------------|
| Product Name: Ledikast | B.No. : 1901059 |
| Generic Name : Ledipasvir and Sofosbuvir Tablets | Product Code : GSL42AZ |
| Batch size: 108318 Tablets | Sampling Date: 04/12/2018 |
| Qty. Sampled: 01 Container | Mfg. Date: 11/2018 |
| Analysis Date: 04/12/2018 | Exp. Date: 10/2020 |
| Reporting Date: 06/12/2018 | A.R. No.: FP/AR/374/18 |

| S.No | TEST | SPECIFICATION | RESULT |
|------|-------------------------------------|----------------------|--------------------|
| 8. | Related impurities (% w/w, By HPLC) | | |
| | a) Sofosbuvir | | |
| | Any individual impurity | Not more than 0.30 % | 0.08 % |
| | Total impurities | Not more than 1.0 % | 0.12 % |
| | b) Ledipasvir | | |
| | Keto impurity | Not more than 0.8% | Below LOQ* (0.048) |
| | Any individual unspecified impurity | Not more than 0.20 % | 0.05 % |
| | Total impurities | Not more than 1.2 % | 0.06 % |

*LOQ = Limit of Quantification

Remarks: The product complies as per Specification No. : FP/SPC/008-00

| | PREPARED BY | CHECKED BY | APPROVED BY |
|-------------|---|--|---|
| Sign |  06/12/2018 |  06/12/2018 |  06/12/2018 |
| Name | Jayanta Sarma | Dipankar Hazarika | Sangam S. Chandra |
| Designation | Asst. officer | Executive | Sr manager |

Format No.: QCS/004/F04-02

Page No: 3 of 3