# HETERO LABS LIMITED (UNIT-II)

## (Formulations Division)

## CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| Product Name | LEDIFOS (Ledipasvir 90mg and Sofosbuvir 400mg Tablets) | | |
| Product Code | 4013077 | A.R.No. | H5FP15006521 |
| Batch No. | 3115858 | Batch Size | 0.5 Lac |
| Mfg.Date | Dec-2015 | Pack size/Type | Container |
| Exp.Date | Nov-2017 | Specification No. | FPSAS3007107-1-02 |



| S.No | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1.0 | Description | Brown coloured, capsule shaped, bevel biconvex film coated tablets debossed with 'H' on one side and 'L18' on other side. | Brown coloured, capsule shaped, bevel biconvex film coated tablets debossed with 'H' on one side and 'L18' on other side. |
| 2.0 | Identification By HPLC | The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the assay. | The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the assay. |
| 3.0 | Average weight | 1025.00mg ± 3.0% (994.25mg to 1055.75mg) | 1027.15 mg |
| 4.0 | Uniformity of weight | ± 5.0% of average weight | -0.63 % to 0.30 % |
| 5.0 | Water content (By KF) | Not more than 5.0% w/w | 2.77 % w/w |
| 6.0 | Uniformity of Content (By HPLC) | Not less than 85.0% and Not more than 115.0% of average content. | Min: 98.4 % Max: 101.0 % |
| 6.1 | Content of Ledipasvir | | Average: 100.2 % |
| 7.0 | Dissolution (By HPLC) | | |
| 7.1 | Ledipasvir | Not less than 75 % (D) of labeled amount of Ledipasvir should dissolve in 30 minutes. | Tablet 1 : 100.5 %<br>Tablet 2 : 100.3 %<br>Tablet 3 : 96.6 %<br>Tablet 4 : 99.1 %<br>Tablet 5 : 100.6 %<br>Tablet 6 : 97.9 %<br>Average: 99.2 % |
| 7.2 | Sofosbuvir | Not less than 75 % (D) of labeled amount of Sofosbuvir should dissolve in 30 minutes. | Tablet 1 : 101.2 %<br>Tablet 2 : 101.5 %<br>Tablet 3 : 97.7 %<br>Tablet 4 : 100.9 %<br>Tablet 5 : 102.7 %<br>Tablet 6 : 99.5 %<br>Average: 100.8 % |
| 8.0 | Related Substances (By HPLC) | | |
| 8.1 | Sofosbuvir Related compound -01 | Not more than 0.50% | 0.01 % |
| 8.2 | Ledipasvir Related compound -04 | Not more than 1.0% | 0.20 % |







| | Prepared by | Checked by | Approved by |
|---|---|---|---|
| Name | Dimple Raj | J.Sudhakar Reddy | D.S.N. Reddy |
| Designation | Executive – Q.C. | Asst.Manager – Q.C. | Manager - Q.C. |
| Sign | Dimp | JS | CVR |
| Date | 21-12-2015 | 21-12-2015 | 21-12-2015 |



*Office :* 7-2-A/2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad-18, INDIA. Tel : 040-23704923/24/25, Fax : 040-23704926
*Factory :* Village : Kalyanpur, Chakkan Road, BADDI, Tehsil : Baddi, Distt. Solan, H.P. - 173 205 INDIA.

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## (Formulations Division)

## CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| Product Name | LEDIFOS (Ledipasvir 90mg and Sofosbuvir 400mg Tablets) | | |
| Product Code | 401377 | A.R.No. | HFBR1500531 |
| Batch No. | 3115858 | Batch Size | 0.5 Lac. |
| Mfg.Date | Dec-2015 | Pack size/Type | Container |
| Exp.Date | Nov-2017 | Specification No. | FPS/B-3007107-1-02 |



| S.No | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 8.3 | Max. single Unknown Impurity | Not more than 0.50% | 0.08 % |
| 8.4 | Total Impurities | Not more than 2.0% | 0.35 % |
| 9.0 | Assay (By HPLC) Each film coated tablet contains: | | |
| 9.1 | Ledipasvir ($C_{49}H_{54}F_2N_8O_6$), in mg | Not less than 85.5mg and Not more than 94.5mg | 92.21 mg |
| 9.2 | (%) Labeled amount | Not less than 95.0% and Not more than 105.0% | 102.5 % |
| 9.3 | Sofosbuvir ($C_{22}H_{29}FN_5O_9P$), in mg | Not less than 380.0mg and Not more than 420.0mg | 402.83 mg |
| 9.4 | (%) Labeled amount | Not less than 95.0% and Not more than 105.0% | 100.7 % |





Remark: The product Complies as per above specification.

| | Prepared by | Checked by | Approved by |
|---|---|---|---|
| Name | Dimple Raj | J.Sudhakar Reddy | D.S.N. Reddy |
| Designation | Executive – Q.C. | Asst.Manager – Q.C. | Manager - Q.C. |
| Sign | Dimple | J | |
| Date | 21-12-2015 | 21-12-2015 | 21-12-2015 |



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