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CERTIFICATE OF ANALYSIS

Product : N-[[P(S),2'R]-2'-Deoxy-2'-fluoro-2'-methyl-P-phenyl-5'-uridylyl]-L-alanine 1-methylethyl ester (**Sofosbuvir**)
CAS NO. : 1190307-88-0 Manufacturing Date : Apr.09, 2015
Quantity : 130kg Retest Date : Apr.08, 2016
Batch NO. : 201504003 Report Date : Apr.09, 2015
Analysis NO. : 15027

| Tests | Specifications | Results |
|---------------------------------|---|--------------|
| Appearance | Off-white to white powder | White powder |
| Identification | A.IR: Similar to Reference Substance | Complies |
| | B. Retention Time :Similar to Reference Substance | |
| Melting Range | 95~100℃ | 95~97℃ |
| Polymorphic Identity | XRD | Form I |
| Water | ≤0.5% | 0.04% |
| Heavy metals | ≤0.002% | Complies |
| Isomers | SFBD1≤0.15% | Undetected |
| | SFBD2≤0.15% | Undetected |
| | SFBE≤0.15% | Undetected |
| Related substances | SFBA-1≤0.15% | 0.05% |
| | SFBMA≤0.15% | Undetected |
| | Chloro-SFB≤0.15% | 0.01% |
| | DiSFBMA-SFB≤0.15% | 0.02% |
| | Methyl-SFB≤0.15% | Undetected |
| | Pentafluoro-phenol≤0.15% | Undetected |
| | Amino-SFB≤0.15% | Undetected |
| | Any unknown impurity≤0.10% | 0.04% |
| | Total impurities≤1.0% | 0.20% |
| Residue solvents | Methanol≤3000ppm | Undetected |
| | Isopropyl alcohol≤5000ppm | 19ppm |
| | Dichloromethane≤600ppm | Undetected |
| | Tetrahydrofuran≤720ppm | Undetected |
| | Isopropyl acetate≤5000ppm | Undetected |
| | Acetic acid≤5000ppm | Undetected |
| | Toluene≤890ppm | Undetected |
| | Chlorobenzene≤360ppm | Undetected |
| Methyl tert-butyl ether≤5000ppm | 29ppm | |
| Assay | ≥99.0% | 99.8% |

The results above meet all requirements under **Sofosbuvir** in **In-House Standard**

Analysed by:

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Checked by:

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