



NATCO PHARMA LIMITED

Regd. Off: 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034,
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT (UNIT-9))

PRODUCT NAME:: Ledikast			
Generic Name:	Ledipasvir and Sofosbuvir Tablets, 90mg/400mg	Product Code:	GSL42AZ
Batch No.:	1903109	LIMS A.R. No.:	1900FPG22000250
Batch Size:	108904 Tablets	Sampled By:	Saiful
Sampling Date:	11/08/2022	Sampling Quantity:	28 Tablets
Date Of Release:	12/08/2022 11:10	Mfg. Date:	08/2022
Specification No:	FP/SPC/008-01	Exp. Date:	07/2025

S. No.	TEST	RESULT	SPECIFICATION
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		
2.1	By HPLC	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.	The retention time of the major peak in the chromatogram of the sample preparation should corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay.
2.2	By UV	The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths.	The UV absorption spectrum of the sample solution and standard solution should exhibit maxima at the same wavelengths.
3	Uniformity of dosage units (By content uniformity)	Sofosbuvir AV value: 3.07 Ledipasvir AV value: 2.85	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	Average Weight	1029.12 mg	1030.0 mg $\pm$ 5.0 %
5	Water content	2.39% w/w	Not more than 5.0% w/w
6	Dissolution (By HPLC)		
6.1	Sofosbuvir	Sofosbuvir Average: 99.5%	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Checked By	RUSTAM.ALAM	Checked On	12/08/2022 09:34
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Approved By:	Pandalaneni.Murali Mohan Rao	Approved On	12/08/2022 10:00
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Approved By:	Bidyut.Das	Approved On	12/08/2022 11:10
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Printed by: Bidyut.Das	Printed on: 12/08/2022 11:10
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		Sofosbuvir Minimum: 95.4% Sofosbuvir Maximum: 101.9%	minutes.
6.2	Ledipasvir	Ledipasvir Average: 99.4% Ledipasvir Minimum: 97.9% Ledipasvir Maximum: 100.2%	Not less than 80% (Q) of the labeled amount of Ledipasvir is dissolved in 45 minutes.
7	Assay (By HPLC)		
7.1	Each film coated tablet contains Ledipasvir 90 mg	102.1%	Not less than 95.0% and not more than 105.0% of the labeled amount of Ledipasvir.
7.2	Sofosbuvir 400 mg	102.7%	Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir.
8	Related impurities (% w/w, By HPLC)		
8.1	Sofosbuvir		
8.1.1	Any individual impurity	0.023% w/w	Not more than 0.30 % w/w
8.1.2	Total impurities	0.04% w/w	Not more than 1.0 % w/w
8.2	Ledipasvir		
8.2.1	Keto impurity	Below LOQ (Limit:0.048)	Not more than 0.8% w/w
8.2.2	Any individual unspecified impurity	0.021% w/w	Not more than 0.20% w/w
8.2.3	Total impurities	0.04% w/w	Not more than 1.2% w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

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Approved By:	Pandalaneni.Murali Mohan Rao	Approved On	12/08/2022 10:00
Approved By:	Bidyut.Das	Approved On	12/08/2022 11:10
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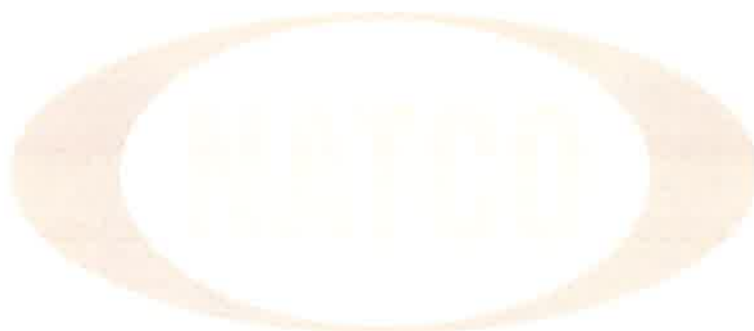
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