



Aspiro Pharma Limited
Sy. No. 321, Biotech Park Phase – III,
Karkapatla(Village), Markook (Mandal),
Siddipet (District), Telangana (State)- –502281 India.

CERTIFICATE OF ANALYSIS
(Finished Product)

Name of the Product: Fosaprepitant			
Generic Name	Fosaprepitant Dimethylglumine for Injection 150 mg/vial	Stage	DURING PACKING
Batch No.	AS1240397B	A.R. No.	APLFP24003694
Batch Size	4503 Vials	Market	Makiz Pharma- Russia
Product Code	440838	Sampling Quantity	3 Vials
Mfg. Date	Nov-2024	Exp. Date	Oct-2026
Specification Id	DPRS180-00	STP No.	DPSTP049-00

S. No.	TEST	RESULT	SPECIFICATION
1	Appearance	Off white lyophilized cake	White to off white lyophilized cake or powder.
2	Identification Test		
2.1	By UV spectrum	The UV absorption spectrum of sample preparation exhibits maxima at the same wavelength as that of standard preparation.	The UV absorption spectrum of sample preparation should exhibit maxima at the same wavelength as that of standard preparation.
2.2	By HPLC	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.	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.
3	Completeness and clarity of the solution	(i)Constituted as directed on the label the solid dissolved completely, by leaving no undissolved matter. (ii)The constituted solution is not significantly less clear than an equal volume of the purified water contained in a similar vessel and examined similarly.	When constituted as directed on the label the solid dissolves completely, leaving no undissolved matter. The constituted solution is not significantly less clear than an equal volume of the diluent or of purified water contained in a similar vessel and examined similarly.
4	Color value (By UV-visible Spectrophotometer) (at 430 nm) (AU)	0.029 AU	NMT 0.2
5	Light Transmittance (%)	98.808 %	NLT 95
6	Reconstitution time (seconds)	45 Seconds	NMT 60
7	Uniformity of Dosage units (By mass variation) (%),	5.4 % m/m	Acceptance value should be less than or equal to L1 (15.0)

Checked By	Rajasekhara Rao.Gongada	Approved By	Sivakrishna Reddy.Bommareddy (Manager QC)
Checked On	13-12-2024 17:23	Approved On	13-12-2024 17:26
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CERTIFICATE OF ANALYSIS
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Name of the Product: Fosaprepitant			
Generic Name	Fosaprepitant Dimeglumine for Injection 150 mg/vial	Stage	DURING PACKING
Batch No.	AS1240397B	A.R. No.	APLFP24003694
Batch Size	4503 Vials	Market	Makiz Pharma- Russia
Product Code	440838	Sampling Quantity	3 Vials
Mfg. Date	Nov-2024	Exp. Date	Oct-2026
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	m/m)		
8	pH	8.19	Between 7.5 to 9.0
9	Water content (By KF) (%,m/m)	1.4 % m/m	NMT 5.0
10	Osmolality (mOsmol/kg)	626 mOsmol/kg	NLT 530 and NMT 670
11	Assay (By HPLC) (% , m/m) (Label claim as Fosaprepitant)	105.6 % m/m	NLT 90.0 and NMT 110.0
12	Related substances By HPLC (% m/m)		
12.1	Related Compound-01	0.74 % m/m	NMT 1.5
12.2	Related Compound-02	Less than LOQ	NMT 0.2
12.3	Related Compound-03	0.02 % m/m	NMT 0.2
12.4	Any individual unspecified Impurity	0.11 % m/m	NMT 0.2
12.5	Total Impurities	0.87 % m/m	NMT 1.5
13	Particulate matter		
13.1	Visible particles	Free from visible particles	Should be free from visible particles
13.2	Sub Visible particles (By Light obscuration particle count test)-Greater than or Equal to 10 µm - Particles/vial	34 Particles / Vial	NMT 6000
13.3	Greater than or Equal to 25 µm - Particles/vial	1 Particles / Vial	NMT 600
14	Bacterial Endotoxins Test	< 1.136 EU/mg of Fosaprepitant	NMT 2.3 EU/mg of Fosaprepitant
15	Sterility	Sterile	Should be Sterile

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Data transferred from A.R.No:APLFP24003596

Out Sourced Test(s): Appearance

By UV spectrum

By HPLC

Completeness and clarity of the solution

Color value (By UV-visible Spectrophotometer) (at 430 nm) (AU)

Light Transmittance (%)

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Reconstitution time (seconds)
Uniformity of Dosage units (By mass variation) (% , m/m)
pH
Water content (By KF) (% ,m/m)
Osmolality (mOsmol/kg)
Assay (By HPLC) (% , m/m) (Label claim as Fosaprepitant)
Visible particles
Sub Visible particles (By Light obscuration particle count test)-Greater than or Equal to 10 µm - Particles/vial
Greater than or Equal to 25 µm - Particles/vial
Bacterial Endotoxins Test
Sterility

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