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 Dimeglumine for Injection 150 mg/vial	**Stage**	DURING PACKING
Batch No.	AS1240442A	**A.R. No.**	APLFP25000127
Batch Size	3050 Vials	**Market**	Makiz Pharma- Russia
Product Code	440838	**Sampling Quantity**	104 Vials
Mfg. Date	Dec-2024	**Exp. Date**	Nov-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**	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 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)**	0.032 AU	NMT 0.2
5	**Light Transmittance (%)**	99.173 %	NLT 95
6	**Reconstitution time (seconds)**	45 Seconds	NMT 60
7	**Uniformity of Dosage units**	3.4 % m/m	Acceptance value should be less than

Checked By	DASAM.SUBRAHMANYAM	Approved By	Sivakrishna Reddy.Bommareddy (Manager QC)
Checked On	12-01-2025 15:04	Approved On	12-01-2025 15:19
Printed by: Sivakrishna Reddy.Bommareddy		**Printed on: 12-01-2025 15:21**	
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	(By mass variation) (%, m/m)		or equal to L1 (15.0)
8	**pH**	7.78	Between 7.5 to 9.0
9	**Water content (By KF) (%,m/m)**	1.4 % m/m	NMT 5.0
10	**Osmolality (mOsmol/kg)**	593 mOsmol/kg	NLT 530 and NMT 670
11	**Assay (By HPLC) (%, m/m) (Label claim as Fosaprepitant)**	104.2 % m/m	NLT 90.0 and NMT 110.0
12	**Related substances By HPLC (% m/m)**		
12.1	**Related Compound-01**	0.64 %m/m	NMT 1.5
12.2	**Related Compound-02**	0.05 %m/m	NMT 0.2
12.3	**Related Compound-03**	0.01 %m/m	NMT 0.2
12.4	**Any individual unspecified Impurity**	0.13 %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**	143 Particles / Vial	NMT 6000
13.3	**Greater than or Equal to 25 µm - Particles/vial**	3 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): Results taken from A.R.No.: APLFP24003951

Out Sourced Test(s): By UV spectrum
By HPLC
Completeness and clarity of the solution

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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
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Bacterial Endotoxins Test
Sterility

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