

SUPPLEMENTARY INFORMATION

ICP-MS: A tool for detection and quantitation of fosfomycin residues in cleaning samples of finished product by estimation of phosphorus load

Anirban Roy Chowdhury, ^{*a} Sujal Shah, ^a Rahul Y. Kapse, ^a Tushar Mehta^a and Amit Mukharya^a

^aAmneal Pharmaceuticals Pvt Ltd., Pharmez, Ahmedabad, Gujarat-382213, India.

Email id: anirban.rc16@gmail.com

ORCID: <https://orcid.org/0009-0001-8667-5265>

1) Equation S1 : Accuracy/precision stock solution preparation

$$\text{Accuracy stock solution (43.624 } \mu\text{g/mL of phosphorus)} = \frac{37.06}{100} \times \frac{30.974}{259.19} \times \frac{98.50}{100} \times 1000$$

..... (1)

Where,

30.974 = Molecular weight of phosphorus

259.19 = Molecular weight of fosfomycin tromethamine salt

98.5 = Potency of fosfomycin tromethamine salt

2) Equation S2: Calculation for critical limit level concentration (CLLC) of phosphorus

$$\text{Limit of fosfomycin (}\mu\text{g/mL)} = \frac{\text{MACO value (5 } \mu\text{g/Inch}^2\text{)}}{\text{Swab sample volume (10 mL)}} \times \text{Swab surface area (4 Inch}^2\text{)}$$

..... (2a)

$$\text{Subsequent limit of P (ng/mL)} = \text{Fosfomycin limit (2 } \mu\text{g/mL)} \times \frac{30.974}{138.06} \times 1000$$

..... (2b)

$$\text{Residue of Fosfomycin (} \frac{\mu\text{g}}{\text{Inch}^2}\text{)} = \frac{(CT - CSB)}{1000} \times \frac{138.06}{30.974} \times \frac{10}{SA}$$

..... (2c)

Where,

CT = Concentration of phosphorus element in sample solution (ng/mL)

CSB = Concentration of phosphorus element in swab blank solution (ng/mL)

138.06 = Molecular weight of fosfomycin

30.974 = Molecular weight of phosphorus

10 = Swab sample volume (mL)

SA = Swab surface area (Inch²)

3) Linearity and Range:

Table S1. Linearity data for concentration of phosphorus

Level	Linearity stock Solution (mL)	Internal standard solution (mL)	Volume made with diluent-2 (mL)	Concentration of phosphorus (ng/mL)
10%	0.1	1	50	44.92
25%	0.25	1	50	112.3
50%	0.5	1	50	224.6
100%	1.0	1	50	449.2
150%	1.5	1	50	673.8
200%	2.0	1	50	898.4

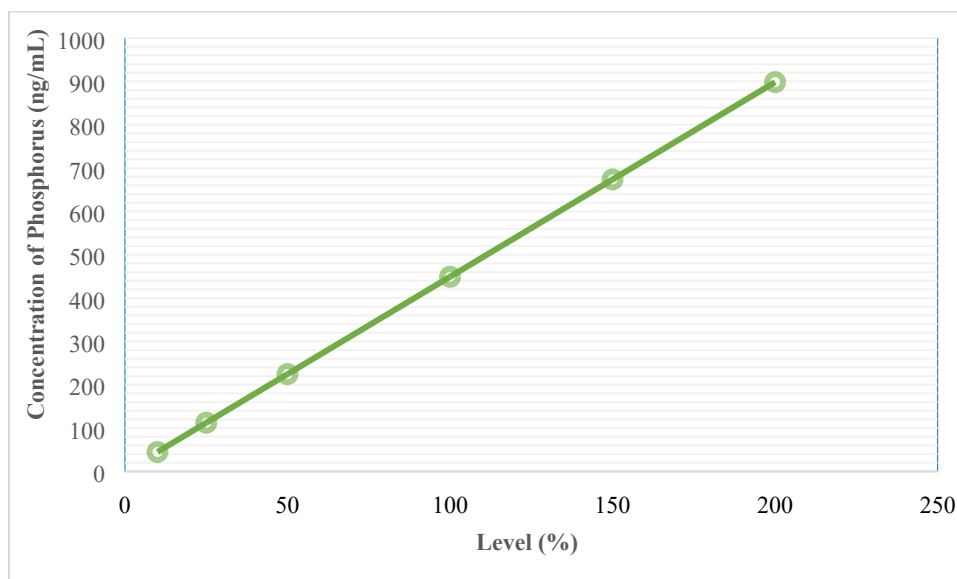


Figure S1. Linearity graph for developed method

4) Equation S3: Calculation of % drift and % bias

$$\% \text{ Bias} = \text{ABS} \left| \frac{[\text{Standard conc. of standard solution (150\% in ng/mL)} - [\text{Obtained conc. of standard solution (150\%) of drift check in ng/mL}]]}{[\text{Standard conc. of standard solution (150\% in ng/mL)}]} \right| \times 100$$

..... (3a)

$$\% \text{ Drift} = \text{ABS} \left| \frac{[\text{Standard solution (150\%) before sample solution aspiration (ng/mL)}] - [\text{Standard solution (150\%) after sample solution aspiration (ng/mL)}]}{[\text{Standard solution (150\%) before sample solution aspiration (ng/mL)}]} \right| \times 100$$

..... (3b)

Where, ABS represents to absolute

5) Table S2: Results of swab sample analysis of Fosfomycin

Sr. No.	Swab Sample Name	Result (µg/Inch² of Fosfomycin)
1	Equipment-1@, Location-A	Below LOD*
2	Equipment-1@, Location-B	Below LOD*
3	Equipment-1@, Location-C	Below LOD*
4	Equipment-2@, Location-A	Below LOD*
5	Equipment-2@, Location-B	Below LOD*
6	Equipment-2@, Location-C	Below LOD*
7	Equipment-2@, Location-D	Below LOD*
8	Equipment-3@, Location-A	Below LOD*
9	Equipment-3@, Location-B	Below LOD*
10	Equipment-3@, Location-C	Below LOD*
11	Equipment-3@, Location-D	Below LOD*

*LOD (Limit of detection) value: 0.25 µg/Inch²

@Actual equipment Id has been coded.