ENCLOSED 4

PHARMACOPE CONFORMITY RESULT REPORT

IRON (II) SULPHATE HEPTA HYDRATE PHARMACOPE CONFORMITY ANALYSES

Report No: GOK0108LA

Report Version: 01

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Contracted Research Institution:	Yeditepe Health Services Inc. Co.

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1 Purpose

This report has been prepared to demonstrate the results of the Pharmacopie (USP, BP, EP) conformity tests conducted at the Yeditepe University, Pharmaceutical Faculty and Yeditepe University GLP Laboratory on the "iron (II) sulphate hepta hydrate" solid raw material synthesized by Gökay Mining at GOK0108LA coded study.

2 Scope

This report covers the results of the analyses of the "iron (II) sulphate hepta hydrate" solid raw material synthesized by Gökay Mining.

3 Summary

"Iron (II) sulphate hepta hydrate" solid raw material has been analyzed according to methods at the pharmacopies.

4 Working Conditions

4.1 Sample Processes

The samples taken from 2 different series of the "iron (II) sulfate hepta hydrate" solid raw material synthesized by Gökay Mining was preserved under suitable conditions and analyzed.

4.2 Performing Sample Analyses

At each control, 4 ea samples were prepared by taking 2 ea sample form 2 series and these samples were analyzed.

5 Results

Name	Limit	Obtained value	Conformity
Characteristic tests			√
Appearance	Bluish green crystal	Bluish green crystal	√
Solubility	Soluble in water, non-soluble in alcohol	Soluble in water, non-soluble in alcohol	√
Identification tests			
$FeSO_4.7H_2O$ (AAS)		% 101.9	√
Pb (AAS)		1 ppm	√
Cu (AAS)		< 0.5 ppm	√
Ferric ions	Max % 0.5	% 0.072	√

Sulphate reaction	White sediment	+	√
Mn	Max % 0.1	< 0.1 %	√
Zn	Max 500 ppm	< 500 ppm	√
Heavy Metals	Max 50 ppm	< 50 ppm	√
Cl ions	Max 300 ppm	< 300 ppm	√
Iron reaction	Non-dissolving blue sediment	+	√
As		< 0.1 ppb	√
Hg		< 0.1 ppb	√
Organic residual		none	√
pH		3.17 (5 gr/100ml)	√

6 Conclusion

As a result of the analyses made, the "iron (II) sulphate hepta hydrate" solid raw material synthesized by Gökay Mining was found to be conforming to all the pharmacopies.

7 Documentation

The analyses were recorded on to Laboratory notebook according to Standart Operating Procedure, SY-L-001 Performing a Study.