

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1207921

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 04/10/2023

Sample Class: Normal Everyday Sample **Sample Origin:** Domestic/Import **Sample Basis:** Surveillance
Sample Flag: **Sample Type:** Official **Collecting District:** ORA-HFB
Home District: **Orig C/R and Records To:** ORA-HFB **Collection PACs:** 63001A

Product Name: Vitamin, Mineral, Proteins and Unconventional Dietary Specialities For Humans and Animals, N.E.C.; H

Product Description: AK Forte - Dietary Supplement; 100 Tablets; 400mg/tablet

Collection Reason: For ID/semi-quantitation of dexamethasone, methocarbamol, and diclofenac or other NSAIDs

Lab: SJNLMP **Split Num:** 0 **Date Received:** 02/02/2023

Date Out of Lab: 04/07/2023

District Conclusion: **District Conclusion Made By:**

District Conclusion Date:

Disposition Reason: **Disposition Authorized By:**

Disposition Authorized Date:

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SJNLMP	63001A		DRT		3 - Adverse Findings	Completed

Lab Conclusion

LCMS analysis shows that the sample contains an estimated amount of the following chemical compounds: 51 md/dose of Diclofenac, 0.6mg/dose of Dexamethasone and 0.004mg/dose of Methocarbamol. These compound were identified and the amount was determined using USP Reference Standards.

Lab Conclusion Date **Lab Conclusion Made By**

04/07/2023

Espinet,Hector