SLN Pharmachem®

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : WARFARIN SODIUM USP
(WARFARIN SODIUM CRYSTALLINE CLATHRATE USP 38)
BATCH NO. : WS/OL/17/01
DATE OF MFG. : APRIL 2017
DATE OF EXP. : MARCH 2022

RESULTS OF ANALYSIS:

SR. No	SPECIFICATION	LIMITS	RESULT
1.	APPEARANCE	White Crystalline Powder	White Crystalline Powder
2.	SOLUBILITY	Very Soluble In Water, Freely Soluble In Alcohol, Moderately Soluble In Chloroform And Ether.	Complies
3	IDENTIFICATION	A) By IR Absorption B) Retention time of the major peak of sample solution corresponds to that of the standard solution as obtained in the Assay. C) Sodium: should meet the requirement of flame test	Complies Complies Complies
4.	PH	Between 7.2 and 8.3, in solution (10 mg/ml)	7.83
5.	WATER BY KF	NMT 0.3 %	0.25 %
6.	ABSORBANCE IN ALKALINE SOLUTION	NMT 0.10	0.0686
7.	ISOPROPYL ALCOHOL CONTENT	NLT 8.0% And NMT 8.5%	8.41 %
8.	ASSAY BY HPLC (ON ANHYDROUS BASIS, AS PER USP 38) IPA FREE BASIS	NLT 97.0% and NMT 102.0%	99.87 %
9.	CHROMATOGRAPHIC PURITY	NLT 99%	99.79 %
10.	IMPURITIES	1) Heavy Metals : NMT 10 ppm 2) Organic Impurity a) Individual Impurity: NMT 0.3% b) Total Impurities: NMT 1%	Complies 0.15% 0.21%
11.	PARTICLE SIZE	10 microns to 30 microns.	15 microns.

REMARK: THE ABOVE MATARIAL CONFORMS TO SPECIFICATION OF WARFARIN SODIUM USP 38.

STORAGE CONDITION: PACKAGES SHOULD BE SEALED WHEN NOT IN USE AND MUST BE KEPT AIR TIGHT. KEEP SEALED PACKAGES IN COOL AND DRY ATMOSPHERE.

Analysed By-
(Chemist)
Date: 22.04.2017

Approved By-
(Q. C. In charge)

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