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CERTIFICATE OF ANALYSIS

CALCIUM FOLINATE USP44

BATCH NUMBER	20221103	TEST DATE	Nov 08, 2022
BATCH SIZE	5.0kg	MANUFACTURE DATE	Nov 05, 2022
QUANTITY	5.0kg	RETEST DATE	Nov 04, 2024
TEST	SPECIFICATION	RESULT	
Appearance:	A white or light yellow powder; Microyellow crystalline or amorphous powder; No visible evidence of contamination by foreign matter.	conforms	
Identification:			
A	IR spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of the USP reference standard.	conforms	
B	It gives reaction of Calcium.	conforms	
C	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	conforms	
Water Content	Not More Than 17.0%	11.9%	
Residual Solvent			
1.Ethyl ether	≤ 1000ppm	0.2ppm	
2.Ethanol	≤ 5000ppm	1979ppm	
Assay:	95.0% to 105.0% of $C_{20}H_{21}CaN_7O_7$ Calculated on the anhydrous basis	99.3%	
Related substances			
1.5-Formyl-5,6,7,8-tetrahydropteroic acid	≤ 0.5%	0.007%	
2.4-Aminobenzoylglutamic acid	≤ 1.5%	0.06%	
3.10-Formyldihydrofolic acid	≤ 1.0%	0.05%	
4.5,10-Diformyltetrahydrofolic acid	≤ 1.5%	0.1%	
5.7,8-Dihydrofolic acid	≤ 0.5%	0.2%	
6.10-Formylfolic acid	≤ 0.5%	0.1%	
7.Folic acid	≤ 1.5%	0.02%	
8.Individual, unspecified impurities	≤ 0.3%	0.08%	
9.Total impurities	≤ 2.5%	0.7%	
Microbiological control:			
Total aerobic microbial count	NMT 1000cfu/g	conforms	
Molds and yeasts total count	NMT 100cfu/g	conforms	
Bacterial Endotoxins	NMT 0.5EU/mg	conforms	

