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STABILITY REPORT

PREDNISOLONE/SUSPENDRX ANHYD SWEETENED FORMULATION STABILITY STUDY

SP# 1151968
Revision 03
Effective Date: 30 Nov 2020

PURPOSE

The purpose of this study is to assess the chemical stability of Prednisolone formulation at 20mg/ml concentration per dose in SuspendRx Anhydrous, Sweetened (unflavored).

STUDY SPONSOR(S)

API: Spectrum Pharmacy Products, 777Jersey Ave, New Brunswick, NJ 08901

FORMULATION

SpecializedRx, Prednisolone (20mg/ml)_50ml: SRx Procedure P2565, Revision R1.

REPORT RESULTS

Sample Condition: Ambient (25 ± 2°C):

Time Points	Value
Appearance (Day 0)	White opaque homogeneous liquid, 18 May 2020
Appearance (Day 180)	White opaque homogeneous liquid, 14 Nov 2020

Samples Condition: Ambient (25 ± 2°C):

Time Points	Value	Baseline	% Label Claim	Status
Assay 20mg/ml (Day 180)	90-110%	N/A	**107.6%**	**Pass**

Sample Condition: Accelerated (45 ± 2°C):

Time Points	Value
Appearance (Day 0)	White opaque homogeneous liquid, 18 May 2020
Appearance (Day 45RT) 180 Day (6M)	White opaque homogeneous liquid, 02 Jul 2020

Samples Condition: Accelerated (45 ± 2°C):

Time Points	Value	Baseline	% Label Claim	Status
Assay 20mg/ml (Day 45RT) 180 Day (6M)	90-110%	N/A	**105.3%**	**Pass**

For further study details, contact SpecializedRx.