MICROSOLV
TECHNOLOGY CORPORATION

White Paper

Equivalency Study of MicroSolv Brand Syringe filters

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Filter Compatibility

Any filters used in the dissolution should not affect the concentration of the active ingredient. Filter compatibility was performed by testing the Final Standard Solution for 25mg potency and the 24mg tablet dissolution sample with the following types of filters

Titan2™ Reg. Cellulose 0.45µm
Titan2™ PVDF 0.45µm
Titan2™ No Prefilter Nylon 0.45µm
Titan2™ Nylon 0.45µm
MicroSolv™ Nylon 0.45µm
MicroSolv™ Reg. Cellulose 0.45µm
Gelman Acrodisc™ 1.2µm Supor membrane, non pyrogenic Gelman Acrodisc™ PVDF 0.45µm
Gelman Acrodisc™ Nylon 0.45µm Gelman GHP Acrodisc™ GF 0.45µm

1. PreparationofStandardSolutions:

Stock Standard Solution:
About 56.8mg of Ondansteron HCL standard was transferred into a 250ml volumetric flask, added about 100ml of Deionized water, sonicated for 10 minutes. Brought to volume with Deionized water and mixed well.

Final Standard: for 24mg tablets (0.047mg/ml)
Pipetted 6ml of the Stock Standard Solution into a 25ml volumetric flask, brouht to volume with Deionized water and mixed well, discarding the first 3.0ml of filtrate.

2. One tablet (Ondansetron 24mg F/C Tablet
WWCN: 064D68 B#68,R&D 0428) was weighed out and dissolution was run as a finished product (see Section E). Dissolution solution aliquot was taken at 60 minutes.

3. FilteringProcedure
For each filter, the 1st ml, 3rd ml, 5th ml, 7th ml and 9th ml filtrates of the final standard solutions and the dissolution sample solution were collected. Each filtrate solution was injected twice on an HPLC system at the wavelength of 216nm.

4. Centrifuged solutions were used as reference standards

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5. Results

24mg Tablet Dissolution Sample

Filter Type	1st ml	3rd ml	5th ml	7th ml	9th ml
Titan2™ Reg Cellulose 0.45µm	19.771	56.506	77.038	95.444	101.398
	19.782	56.558	77.137	95.490	101.296
Titan2™ PVDF 0.45µm	51.565	83.649	98.444	104.109	102.141
	52.331	83.701	98.433	104.139	102.223
Titan2™ No Prefilter Nylon 0.45µm	84.431	91.261	94.011	97.129	98.929
	84.377	91.260	94.064	97.121	98.926
Titan2™ Nylon 0.45µm	41.816	71.745	100.625	105.747	106.723
	41.965	71.847	100.676	105.956	106.797
MicroSolv™ Nylon 0.45µm	92.757	99.299	99.989	100.590	101.015
	92.789	99.235	99.893	100.513	100.914
MicroSolv™ Reg Cellulose 0.45µm	15.324	83.903	94.923	99.319	101.010
	15.315	83.781	94.932	99.068	100.820
Gelman Acrodisc™ 1.2µm Supor	92.318	99.906	100.819	100.875	101.429
Membrane, non pyrogenic	92.369	99.991	100.739	101.012	101.364
Gelman Acrodisc™ PVDF 0.45µm	79.005	94.780	95.296	96.869	98.044
	79.157	94.789	95.170	96.636	97.147
Gelman Acrodisc™ Nylon 0.45µm	90.146	95.805	97.868	100.427	100.942
	90.118	95.691	97.742	100.377	100.748
Gelman GHP Acrodisc™ GF 0.45µm	56.855	87.442	100.540	103.251	101.992
	56.892	87.296	100.520	103.428	102.173

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5. Results

24mg Final Standard

Filter Type	1st ml	3rd ml	5th ml	7th ml	9th ml
Titan2™ Reg Cellulose 0.45µm	10.077	57.506	82.608	91.523	99.516
	10.456	57.639	82.825	91.589	99.627
Titan2™ PVDF 0.45µm	54.641	78.850	84.778	100.742	102.961
	54.596	78.633	94.743	100.635	103.075
Titan2™ No Prefilter Nylon 0.45µm	88.189	94.203	96.189	98.263	98.750
	88.279	94.440	96.345	98.444	98.707
Titan2™ Nylon 0.45µm	43.303	80.067	98.836	103.927	102.365
	43.477	80.009	98.862	103.976	102.570
MicroSolv™ Nylon 0.45µm	86.582	100.447	100.420	101.309	101.209
	86.984	100.644	100.422	101.322	101.306
MicroSolv™ Reg Cellulose 0.45µm	13.105	80.676	92.271	99.635	102.268
	13.177	80.952	92.447	99.766	102.176
Gelman Acrodisc™ 1.2µm Supor	96.601	101.308	101.383	101.833	101.608
Membrane, non pyrogenic	96.815	101.518	101.487	101.916	101.521
Gelman Acrodisc™ PVDF 0.45µm	80.044	94.248	97.392	97.942	98.474
	80.351	94.452	97.383	97.887	98.483
Gelman Acrodisc™ Nylon 0.45µm	94.076	97.659	99.660	99.705	100.633
	94.047	97.556	99.441	99.891	100.646
Gelman GHP Acrodisc™ GF 0.45µm	40.504	51.733	98.622	104.325	102.632
	40.555	51.783	98.528	104.256	102.733

Reference: JZ 1768/22-27, 1768/28-32
Limit: 98.0%-102.0%

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6. Conclusion:

For Sample Solution

Based on the studies done, it was found out that MicroSolv Nylon 0.45µm filter (discarding the first 2mls) and the Gelman Acrodisc™ Nylon 0.45µm filter (discarding the first 4mls) are suitable for final dissolution standard.

For Sample Solution

MicroSolv Nylon 0.45µm Filters (discarding the first 2mls) and Gelman Acrodisc™ 1.2µm Supor membrane, non pyrogenic filters (discarding the first 2mls) are suitable for dissolution solution.

SELECTIVITY

1. Preparation of Placebo
   The placebo formulation was prepared by mixing all the inert ingredients for Ondansetron HLC tablets 24mg in the same ration as per Finished Product Formulation

Ingredients	Control No.	Mg/Tab	Actual Wt (mg)
Pregelatinized Starch, NF (starch 1500)	R5833	70.0	3,502.0
Microcrystalline Cellulose NF (Avicel PH 101)	R5815	50.0	2,501.5
Colloidal Dioxide NF (Cab-o-sil)	R5862	2.0	100.8
Anhydrous Lactose, NF (direct Tablet Grade)	R5824	124.0	6,201.1
Microcrystalline Cellulose, NF (Avicell PH 102)	R5821	120.0	6,000.9
Magnesium Stearate, NF	R5778	4.0	201.9
Total		370.0	18,508.2

Reference: CJ 1808/53

2. 371.0mg of placebo mix (equivalent to the amount of inactive ingredients in one tablet weight) was weighed out and dissolution procedure as a finished product was carried out as per section E.

3. Result:
   No interference of Ondansetron HCL was found from the placebo mix (reference HN 1850/100).

4. Conclusion:
   Ondansteron HCL was not detected from the placebo mix.

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