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Research Article

DISSOLUTION PERFORMANCE OF POORLY SOLUBLE DRUGS INFLUENCE BY DISSOLVED GAS

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ABSTRACT

Dissolved gases has a major impact on the dissolution performance present in the dissolution media have studied variously previous, few article has been published, related the effect of dissolved gases on dissolution media. There are various methods available to control the level of dissolved gases in dissolution media. The aim of this study was established a study for impact of dissolved gases on dissolution performance.

Keywords: Dissolution testing, poorly soluble drugs, High performance liquid chromatography.

INTRODUCTION

Dissolution Medium contained Dissolved gases, which influence drug dissolving performance in dissolution experiments. The dissolved gases can affect performance of the dissolution medium by changing pH during test ,forming bubbles on basket (USP Type I)if used or on the used formulation or by affect the interaction of the medium and the active of dosage form . Hence a suitable techniques should be expertise for the removal of dissolved gases.

According to USP water from aqueous media which include a combination of heating and vacuum filtration followed by stirring under vacuum has mention.

EXPERIMENTAL

Material and method

As present study dealing with poorly soluble drugs hence two poorly soluble drugs dosage form selected Acitretin capsules and Gliclazide MR Tablets got as a gift sample from Ranbaxy laboratories also both working standard received. Other reagents were AR or HPLC grade as Acetonitrile (spectrochem).ethanol (Merck), Diminiralized water, Sodium hydroxide (Rankem), orthophosphoric acid(Merck),Triethylamine(Rankem)etc, used for experimental study.

Instrumentation

Dissolution apparatus Electrolab, Distek make were used whereas HPLC Agilent, water alliance 2695 with Empower software was used. Perkin Elmer Shimadzu UV-Spectrometer used for measurement of dissolution aliquots.

Instrumental parameters

Dissolution parameter for Acitretin capsules selected as 100 RPM,900 mL of pH 10+3%SLS(as per USP) while for Gliclazid MR tablets dissolution parameter were 900 mL of pH 7.4phosphate buffer and 100 RPM with basket also selected same. Sample aliquot withdrawn separately at the time interval of 10, 20, 30, 45 minutes.

While for Gliclazide MR tablets Time points selected 2hour, 6 hour and 16 hours.

RESULTS AND DISCUSSION

Table 1: Acitretin capsules dissolution without removal of dissolved gases

Dosage unit	Drug Dissolved in Minutes			
	10 min.	20 min	30 min	45 min
1	70	79	90	97
2	75	83	92	98
3	69	78	91	97
4	70	79	94	99
5	72	78	93	98
6	71	77	92	97
Mean	71	79	92	98

Table 2: Acitretin capsules Dissolution with removal of dissolved gases by USP method

Dosage unit	Drug Dissolved in Minutes			
	10 min.	20 min	30 min	45 min
1	70	78	91	98
2	74	84	92	99
3	73	82	91	98
4	72	80	93	99
5	70	77	95	99
6	71	77	92	98
Mean	72	80	92	100

Table 3: Gliclazide Modified Release Tablets Dissolution without removal of dissolved Gases

Dosage Unit	Drug dissolved in Hour		
	2 Hr.	6 Hr	16 Hr
1	12	43	80
2	14	45	81
3	15	46	82
4	14	41	83
5	12	47	85
6	15	48	82
Mean	14	45	82

Table 4: Gliclazide Modified Release Tablets dissolution with removal of dissolved gases (USP method)

Dosage Unit	Drug dissolved in Hour		
	2 Hr.	6 Hr	16 Hr
1	18	47	97
2	19	48	98
3	17	45	99
4	20	48	96
5	20	50	99
6	19	52	97
Mean	19	48	98

CONCLUSIONS

Above study focused on dissolution rate affecting by dissolved gases however it was observed in some immediate release dosage forms even poorly soluble drugs ,solubility is not significantly affected by dissolved gases media while treated or not (ideal practice should be deaeration to be required) but in long term running dissolution test which may be for extended release dosage form or modified release dosage form dissolved gas create a significant impact on drug release even results may be out of specification .so that during method development it is recommendation to identify the influence study with the dissolved gases for different product and choose a suitable practice or technique to avoid its affect.

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