PURPOSE
The purpose of this study was to develop an IVIVC Apparatus 3 dissolution method for a highly soluble API in an extended release soft gelatin capsule.

INTRODUCTION
In-vitro in-vivo correlation (IVIVC) is defined in the USP as ‘the establishment of a rational relationship between a biological property, or a parameter derived from drug plasma concentrations produced by a dosage form, and a physicochemical property or characteristic of the same dosage form.’ If the active pharmaceutical ingredient (API) from a drug product in a bioequivalence clinical study. Once in-vivo, the results show an immediate release of API, while the RLD was controlled release. Figure 2 displays the mean plasma data from the clinical study.

EXPERIMENTAL METHODS
The dissolution testing is currently performed using a 2-stage approach, using an USP Apparatus 3 with an agitation rate of 30 rpm. The first stage medium consists of 250 mL of Fasted-state Simulated Gastric Fluid (FaSSGF). The second stage medium consists of 250 mL of Fasted-state Simulated Intestinal Fluid (FaSSIF). Samples were collected at 1, 2, 4, 8, and 12 hours. Quantitation of drug in the dissolution media was determined to represent the best fit for IVIVR dissolution method for this drug product. This poster presents the data supporting the development of an IVIVR Apparatus 3 dissolution method for a highly soluble API in an extended release soft gelatin capsule.

RESULTS
The initial ‘QC’ dissolution method was an Apparatus 3 using 250 ml of USP simulated gastric fluid without enzymes as the medium at 15 dpm. The results from the method showed that the API did not dissolve in the media. Once in-vitro, the results show an immediate release of API, while the RLD was controlled release. Figure 2 displays the mean plasma data from the clinical study.

The two new drug product formulations were evaluated in the clinic. The results of the new study showed ‘extended release’ behavior observed with both sets of formulations. Figure 6 displays the de-convoluted new target ‘dissolution profiles’ from both sets of clinical data. After deconvoluting the second set of clinical data, a new target IVIVR dissolution profile was generated. The goal was to develop a new IVIVR method that would predict, in-vitro, the behavior observed with both sets of formulations. Figure 6 displays the de-convoluted new target ‘dissolution profiles’.

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