containing ADCs. Similarly, there is a need for a method for detecting and quantifying duocarmycin linker-drug in a sample comprising duocarmycin-containing ADCs and duocarmycin linker-drug (if present).

SUMMARY

The present disclosure is based in part on the discovery that acetonitrile can aid in the separation of duocarmycin linker-drug in a non-conjugated form from a duocarmycin-containing ADC via filtration.

In one aspect, the present disclosure refers to a composition, comprising (a) a solvent system containing water and acetonitrile; (b) an acid; (c) an antibody-drug conjugate of formula **(I)**:

$$Ab\text{-}(L\text{-}D)_m \quad (\mathbf{I}),$$

wherein Ab is an antibody or an antigen-binding fragment thereof, L-D is a duocarmycin linker-drug and m represents an average DAR of from 1 to 12; and optionally (d) the duocarmycin linker-drug in non-conjugated form;

wherein said composition comprises 30% to 60% (v/v) of said acetonitrile, preferably 35% to 55% of said acetonitrile.

In another aspect, the present disclosure refers to a method, which comprises combining (i) an aqueous solution or a lyophilized product of an antibody-drug conjugate of formula **(I)**:

$$Ab\text{-}(L\text{-}D)_m \quad (\mathbf{I}),$$

wherein Ab is an antibody or an antigen-binding fragment thereof, L-D is a duocarmycin linker-drug and m represents an average DAR of from 1 to 12, and optionally further comprising the duocarmycin linker-drug in non-conjugated form, with (ii) a dilution medium that comprises water, acetonitrile, and acid to form a composition, wherein said composition comprises 30% to 60% (v/v), preferably 35% to 55%, of said acetonitrile.

In yet another aspect, the present disclosure refers to a method of releasing/approving an antibody-drug conjugate batch, which comprises:

1) Obtaining a sample from an antibody-drug conjugate batch, wherein said batch comprises an antibody conjugated with a duocarmycin linker-drug and optionally duocarmycin linker-drug in non-conjugated form;
2) Combining said sample with a dilution medium which comprises water, acetonitrile, and acid to form a filterable composition which comprises 30% to 60% (v/v), preferably 35% to 55%, of said acetonitrile;