

What is claimed is:

1. A form of rifaximin selected from one or more of Form Mu, Form Pi, Form Xi, Form Omicron, Form Xi or a salt, or hydrate form thereof.
2. The Form Mu of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at two or more of about 4.72, about 4.79, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 9.60, and about 12.54.
3. The Form Mu of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at two or more of about 4.72, about 4.79, about 6.29, about 6.94, about 7.44, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 8.88, about 9.60, about 10.15, about 10.32, about 10.88, about 11.02, about 11.20, about 12.09, about 12.54, about 12.79, about 12.96, about 13.42, about 13.63, about 13.86, about 14.54, about 14.90, about 15.25, about 15.50, about 16.00, about 16.30, about 16.62, about 16.78, about 16.97, about 17.27, about 17.47, about 17.57, about 17.84, about 18.20, about 18.57, about 18.97, about 19.42, about 19.88, about 20.78, about 21.76, about 22.18, about 22.52, about 22.83, about 23.27, about 23.70, about 24.17, about 24.47, about 24.67, about 25.26, about 25.81, about 26.53, about 26.98, about 27.55, about 28.23, about 28.50, about 28.87, and about 29.15.
4. The Form Mu of claim 1, comprising an X-ray powder diffraction substantially similar to one or more of Figures 1-3.
5. The Form Mu of claim 1, comprising an X-ray powder diffraction substantially similar to one or more of Figures 1-8 and one or more of Tables 1-9.
6. The Form Pi of claim 1, comprising an X-ray powder diffraction substantially similar to one or more of Figures 9 and 12-14.

7. The Form Pi of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at about 6.91 and about 7.16.
8. The Form Pi of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at about 7.05 and about 7.29.
9. The Form Pi of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at two or more of about 7.05, about 7.29, and about 9.33.
10. The Form Pi of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at about 6.91-7.05 and about 7.16-7.29.
11. The Form Pi of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at about 6.91-7.05, about 7.16-7.29, and about 9.15-9.33.
12. The Form Omicron of claim 1, comprising an X-ray powder diffraction substantially similar to Figure 11.
13. The Form Omicron of claim 1, comprising an X-ray powder diffraction comprising the peaks in Figure 11.
14. The Form Omicron of claim 1, comprising an XRPD substantially similar to one or more of Figures 32, 34, and 37.
15. The Form Omicron of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at two or more of about 5.87, about 6.99, and about 8.31.
16. The Form Omicron of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at two or more of about 5.87, about 6.99, about 8.31, about 9.13, about 13.27, about 13.69, and about 17.67.

17. The Form Omicron of claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at two or more of about 5.87, about 6.99, about 7.77, about 8.31, about 8.47, about 9.13, about 9.58, about 9.74, about 10.86, about 12.35, about 13.27, about 13.69, about 14.01, about 14.44, about 14.79, about 15.19, about 15.33, about 15.68, about 15.94, about 16.04, about 16.31, about 16.66, about 17.00, about 17.35, about 17.67, about 18.08, about 19.04, about 19.24, about 19.52, about 19.85, about 20.17, about 20.42, about 20.76, about 21.07, about 21.28, about 21.61, about 21.83, about 22.14, about 22.36, about 22.65, about 22.93, about 23.20, about 23.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, about 29.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, and about 29.46.
18. A Form of rifaximin according to any one of the preceding claims, wherein the rifaximin Form contains less than 5% by weight impurities.
19. A Form of rifaximin according to any one of the preceding claims, wherein one or more of the rifaximin forms is at least 50% pure, at least 75% pure, at least 80% pure, at least 90% pure, at least 95% pure, or at least 98% pure.
20. A Form of rifaximin according to any one of the preceding claims, wherein one or more of the rifaximin forms are formulated as coated or uncoated tablets, hard or soft gelatin capsules, sugar-coated pills, lozenges, wafer sheets, pellets, or powders in sealed packet.
21. A pharmaceutical composition comprising one or more forms of rifaximin selected from Form Mu, Form Pi, Form Omicron, or a salt, or hydrate form thereof, and a pharmaceutically acceptable carrier.

22. A method of treating, preventing, or alleviating a bowel related disorder, comprising administering to a subject in need thereof and effective amount of one or more forms of rifaximin selected from Form Mu, Form Pi, Form Omicron, or a salt, or hydrate form thereof, comprising one or more steps as disclosed herein.
23. A method of producing one or more of forms of rifaximin selected from Form Mu, Form Pi, Form Omicron, or a salt, or hydrate form thereof, comprising one or more steps as disclosed herein.
24. A method of producing rifaximin Form Eta, comprising:
dissolving a Form of rifaximin to form a first mixture;
cooling the first mixture to a seeding temperature;
adding a slurry of rifaximin Form Zeta to form a second mixture;
cooling the second mixture to sub-ambient temperature; and
filtering the second mixture to obtain Form Eta, which is optionally washed and dried.
25. The method of claim 24, wherein the Form of rifaximin comprises a solid form.
26. The method of any one of claims 24 and 25, wherein the Form of rifaximin is selected from Form Mu, Form Pi, Form Alpha, Form Beta, Form Xi, Form Nu, Form Theta, Form Gamma, Form Omicron, Form Zeta, or a salt, or mixtures thereof.
27. The method of any one of claims 24 to 26, wherein the Form of rifaximin is Form Zeta.
28. The method of any one of claims 24-27, wherein the first mixture comprises ethanol.
29. The method of any one of claim 24-28, wherein the water content of the first mixture is higher than approximately 3 wt %.

30. The method of any one of claim 24-29, wherein the water content of the first mixture ranges from about 3 wt % to about 10 wt %.

What is claimed is:

1. A rifaximin polymorph Form Mu or a salt, or hydrate form thereof, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at

two or more of about 4.72, about 4.79, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 9.60, and about 12.54; or

two or more of about 4.72, about 4.79, about 6.29, about 6.94, about 7.44, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 8.88, about 9.60, about 10.15, about 10.32, about 10.88, about 11.02, about 11.20, about 12.09, about 12.54, about 12.79, about 12.96, about 13.42, about 13.63, about 13.86, about 14.54, about 14.90, about 15.25, about 15.50, about 16.00, about 16.30, about 16.62, about 16.78, about 16.97, about 17.27, about 17.47, about 17.57, about 17.84, about 18.20, about 18.57, about 18.97, about 19.42, about 19.88, about 20.78, about 21.76, about 22.18, about 22.52, about 22.83, about 23.27, about 23.70, about 24.17, about 24.47, about 24.67, about 25.26, about 25.81, about 26.53, about 26.98, about 27.55, about 28.23, about 28.50, about 28.87, and about 29.15.

2. A rifaximin polymorph Form Pi, or a salt, or hydrate form thereof, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at

about 6.91 and about 7.16; or

about 7.05 and about 7.29; or

two or more of about 7.05, about 7.29, and about 9.33; or

about 6.91-7.05 and about 7.16-7.29; or

about 6.91-7.05, about 7.16-7.29, and about 9.15-9.33.

3. A rifaximin polymorph Form Omicron, or a salt, or hydrate form thereof, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at

two or more of about 5.87, about 6.99, and about 8.31; or

two or more of about 5.87, about 6.99, about 8.31, about 9.13, about 13.27, about 13.69, and about 17.67; or

two or more of about 5.87, about 6.99, about 7.77, about 8.31, about 8.47, about 9.13, about 9.58, about 9.74, about 10.86, about 12.35, about 13.27, about 13.69, about 14.01, about

14.44, about 14.79, about 15.19, about 15.33, about 15.68, about 15.94, about 16.04, about 16.31, about 16.66, about 17.00, about 17.35, about 17.67, about 18.08, about 19.04, about 19.24, about 19.52, about 19.85, about 20.17, about 20.42, about 20.76, about 21.07, about 21.28, about 21.61, about 21.83, about 22.14, about 22.36, about 22.65, about 22.93, about 23.20, about 23.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, about 29.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, and about 29.46.

4. The Form Mu of rifaximin according to claim 1, wherein the rifaximin Form contains less than 5% by weight impurities.

5. The Form Mu of rifaximin according to claim 1, wherein the rifaximin Form is at least 50% pure, at least 75% pure, at least 80% pure, at least 90% pure, at least 95% pure, or at least 98% pure.

6. A pharmaceutical composition comprising the polymorph Form Mu of rifaximin according to claim 1, the polymorph Form Pi of claim 2, or the polymorph Form Omicron of claim 3, or a salt or hydrate thereof and a pharmaceutically acceptable carrier.

7. A method of producing rifaximin Form Eta, comprising:
dissolving a Form of rifaximin selected from Form Mu, Form Pi, Form Alpha, Form Beta, Form Xi, Form Nu, Form Theta, Form Gamma, Form Omicron, Form Zeta, or a salt, or mixtures thereof to form a first mixture;
cooling the first mixture to a seeding temperature;
adding a slurry of rifaximin Form Zeta to form a second mixture;
cooling the second mixture to sub-ambient temperature; and
filtering the second mixture to obtain Form Eta, which is optionally washed and dried.

8. The method of claim 7, wherein the Form of rifaximin comprises a solid form.

9. The method of claim 7, wherein the Form of rifaximin is Form Zeta.
10. The method of claim 7, wherein the first mixture comprises ethanol.
11. The method of claim 10, wherein the water content of the first mixture is higher than approximately 3 wt %.
12. The method of claim 11, wherein the water content of the first mixture ranges from about 3 wt % to about 10 wt %.
13. The Form Pi of rifaximin according to claim 2, wherein the rifaximin Form contains less than 5% by weight impurities.
14. The Form Pi of rifaximin according to claim 2, wherein the rifaximin Form is at least 50% pure, or at least 75% pure, or at least 80% pure, or at least 90% pure, or at least 95% pure, or at least 98% pure.
15. The Form Omicron of rifaximin according to claim 3, wherein the rifaximin Form contains less than 5% by weight impurities.
16. The Form Omicron of rifaximin according to claim 3, wherein the rifaximin Form is at least 50% pure, or at least 75% pure, or at least 80% pure, or at least 90% pure, or at least 95% pure, or at least 98% pure.
17. The pharmaceutical composition according to claim 6, wherein one or more of the rifaximin forms are formulated as coated or uncoated tablets, hard or soft gelatin capsules, sugar-coated pills, lozenges, wafer sheets, pellets, or powders in sealed packet.
18. The Form Mu according to claim 1, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at:

three or more of about 4.72, about 4.79, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 9.60, and about 12.54; or

three or more of about 4.72, about 4.79, about 6.29, about 6.94, about 7.44, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 8.88, about 9.60, about 10.15, about 10.32, about 10.88, about 11.02, about 11.20, about 12.09, about 12.54, about 12.79, about 12.96, about 13.42, about 13.63, about 13.86, about 14.54, about 14.90, about 15.25, about 15.50, about 16.00, about 16.30, about 16.62, about 16.78, about 16.97, about 17.27, about 17.47, about 17.57, about 17.84, about 18.20, about 18.57, about 18.97, about 19.42, about 19.88, about 20.78, about 21.76, about 22.18, about 22.52, about 22.83, about 23.27, about 23.70, about 24.17, about 24.47, about 24.67, about 25.26, about 25.81, about 26.53, about 26.98, about 27.55, about 28.23, about 28.50, about 28.87, and about 29.15.

19. The Form Mu according to claim 18, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at:

four or more of about 4.72, about 4.79, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 9.60, and about 12.54; or

four or more of about 4.72, about 4.79, about 6.29, about 6.94, about 7.44, about 7.84, about 8.11, about 8.36, about 8.55, about 8.70, about 8.88, about 9.60, about 10.15, about 10.32, about 10.88, about 11.02, about 11.20, about 12.09, about 12.54, about 12.79, about 12.96, about 13.42, about 13.63, about 13.86, about 14.54, about 14.90, about 15.25, about 15.50, about 16.00, about 16.30, about 16.62, about 16.78, about 16.97, about 17.27, about 17.47, about 17.57, about 17.84, about 18.20, about 18.57, about 18.97, about 19.42, about 19.88, about 20.78, about 21.76, about 22.18, about 22.52, about 22.83, about 23.27, about 23.70, about 24.17, about 24.47, about 24.67, about 25.26, about 25.81, about 26.53, about 26.98, about 27.55, about 28.23, about 28.50, about 28.87, and about 29.15.

20. The Form Pi according to claim 2, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at

about 7.05 and about 9.33; or

about 7.29 and about 9.33.

21. The Form Omicron according to claim 3, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at

three or more of about 5.87, about 6.99, about 8.31, about 9.13, about 13.27, about 13.69, and about 17.67; or

three or more of about 5.87, about 6.99, about 7.77, about 8.31, about 8.47, about 9.13, about 9.58, about 9.74, about 10.86, about 12.35, about 13.27, about 13.69, about 14.01, about 14.44, about 14.79, about 15.19, about 15.33, about 15.68, about 15.94, about 16.04, about 16.31, about 16.66, about 17.00, about 17.35, about 17.67, about 18.08, about 19.04, about 19.24, about 19.52, about 19.85, about 20.17, about 20.42, about 20.76, about 21.07, about 21.28, about 21.61, about 21.83, about 22.14, about 22.36, about 22.65, about 22.93, about 23.20, about 23.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, about 29.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, and about 29.46.

22. The Form Omicron according to claim 21, having an X-ray powder diffraction comprising peaks, in terms of 2θ , at

four or more of about 5.87, about 6.99, about 8.31, about 9.13, about 13.27, about 13.69, and about 17.67; or

four or more of about 5.87, about 6.99, about 7.77, about 8.31, about 8.47, about 9.13, about 9.58, about 9.74, about 10.86, about 12.35, about 13.27, about 13.69, about 14.01, about 14.44, about 14.79, about 15.19, about 15.33, about 15.68, about 15.94, about 16.04, about 16.31, about 16.66, about 17.00, about 17.35, about 17.67, about 18.08, about 19.04, about 19.24, about 19.52, about 19.85, about 20.17, about 20.42, about 20.76, about 21.07, about 21.28, about 21.61, about 21.83, about 22.14, about 22.36, about 22.65, about 22.93, about 23.20, about 23.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, about 29.46, about 23.71, about 24.15, about 24.35, about 24.67, about 25.07, about 25.40, about 25.80, about 26.22, about 26.54, about 26.76, about 27.17, about 27.78, about 28.69, about 28.88, about 29.21, and about 29.46.