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Quality-by-Design based Formulation and in-vitro Evaluation of Liquisolid compacts of Axitinib

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Abstract: Axitinib, a BCS Class 2 drug was formulated into Liquisolid Compacts with an objective of to enhance solubility profile related to oral bioavailability. Liquisolid systems are free flowing, dry looking, and readily compressible powdered forms of liquid drug medications. Neusilin® US2 was used as carrier as well as coat due to its high specific surface area, porosity and oil absorption capacity. Polyethylene Glycol 400 was selected as nonvolatile solvent via solubility analysis. Quality-by-Design approach was applied by using Central Composite Design on Design Expert ® 12.0 software. Independent variables were selected viz. Concentration of the nonvolatile solvent (W %) and Carrier: Coat Ratio (R). Dependent factors were Drug release (%), Angle of Repose and Tablet Hardness (kg/cm^3). LS-9 was suggested as optimized batch by ANOVA having 99.6 % drug release, 28.1° angle of repose and 2.4 kg/cm_3 tablet hardness. LS-9 dissolution profile was compared with DCT (59 %) profile which demonstrated a high D_r (Drug Dissolution Rate) of LS-9 as compared to DCT. It was attributed to enhanced wetting property due to LS exposing a large surface area of AXITINIB available for dissolution. LS-9 was subjected to ageing studies at 40°C ±2°C temperature and 75 ±5% R.H. for 3 months upon which LS-9 demonstrated no major deviation in its attributes. Thus, authors concluded that Liquisolid technology serves a useful application in solubility which ultimately enhances bioavailability.

Key Words: Liquisolid Technology, Neusilin® US2, Quality-by-Design, ANOVA, In-vitro release study.

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